COMPILED COMMENTS ON CLH CONSULTATION

Comments provided during consultation are made available in the table below as submitted through the web form. Please note that the comments displayed below may have been accompanied by attachments which are listed in this table and included in a zip file if non-confidential. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

ECHA accepts no responsibility or liability for the content of this table.

Last data extracted on 25.01.2021

Substance name: Silver
CAS number: 7440-22-4
EC number: 231-131-3
Dossier submitter: Sweden

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Carl Weishaupt	Company-Manufacturer	1
Comment received				
Ladies and Gentlemen, My family has been appointed by the court to manuacture silverware since 1692 in Munich and are following up to now. All countries worldwide ever respected the high cultural value of works in silver. Silver did proove to be the most human friendly material within several thousand years of experiment, we cannot accept to ignore the fact silver being a most helpful material to mankind in history. Your concern with Ag+ ions in suspension, if it could have an effect used in different products, is a totally different issue, and cannot be presented in conjunction with solid silver. It would be dangerous to create a wrong public perception without any reason. The manufacuring process of silverware eleminates automatically Ag+ ions together with copper in the suface. Their dissolution in a medium would anyhow be impossible in normal use. The presence of these ions has no effect to health anyhow, if not used in a very high dosis. If under this condition any recommendation from your side would be appropriate, is beyond our knowledge. However it has to be separated from the term silver, but in case clearly related to the relative product only, which you might have in mind. Life is toxic, silver ranges among the less toxic materials ever, and is the most wonderful one. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver Metal letter.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	<confidential>	Company-Manufacturer	2
Comment received				
Dear Sir/Madam, We have attached our comment, on the Proposal for Harmonised Classification and Labelling				

of Silver, in a Word document.

Best regards

<confidential>

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment <confidential>.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	Test and Measurement Coalition	Industry or trade association	3

Comment received

Test & Measurement Coalition members use silver solder is used as an electrical conductor on printed circuit boards. Silver is also used in finishes, plating (for connectors or conductive epoxy), as conductive ink, or as filling in epoxy or in components. The choice to use Tin-silver-copper (SnAgCu, also known as SAC) solders was made after extensive reliability evaluations over the past decade. No alternatives are currently available that are RoHS-compliant and meet these reliability needs. Substitution of silver in these applications is not currently possible without introducing reliability concerns or having performance implications. Any restriction on the use of silver in electronics would necessitate changes to virtually every component in the global supply chain in addition to product redesign and re-qualification that would involve Billions of Euros globally and take more than a decade to achieve.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Input silver CLH - TMC - 18.12.2020.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France	RECHARGE	Industry or trade association	4

Comment received

see attachement

ECHA note – An attachment was submitted with the comment above. Refer to public attachment RECHARGE Silver classificationPublic Consultation.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	AURUBIS AG	Company-Manufacturer	5

Comment received

We support the scientific comments submitted by the European Precious Metals Federation (EPMF).
More information is provided in the attached document.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Aurubis comments to Silver CLH proposal 2020-12-18.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	AZUR SPACE Solar Power GmbH	Company-Downstream user	6
Comment received				
We would like to comment on the proposal for silver harmonized classification: We manufacture solar cells for space satellite applications. Our uses of silver are a) to coat product surfaces with a massive silver layer for electrical contacts and b) massiv silver alloy stripes to form electrical contact bars from them as part of the products. All residual silver is recycled. No silver is released to environment. These uses can not be substituted by other metals without loosing the functionality.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	7
Comment received				
On behalf of the <confidential> I would like to inform that in our 254 years history we never found nor observed hazardous influence of silver on life and health of our employees and environment. We deal with silver everyday on a mass scale when produce numismatic coins, tokens, bars, national distinctions and other products. Every year we produce few millions of these products and use few tones of silver. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Austria	Wirtschaftskammer Österreich		8
Comment received				
see attachment ECHA note – An attachment was submitted with the comment above. Refer to public attachment su_309_StN öK Silber CLH.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	WirtschaftsVereinigung Metalle	Industry or trade association	9
Comment received				
• Silver is as an indispensable material for many branches downstream the WVMetalle members. Silver is used in a very wide range of essential uses like in electrical applica-tions and electronic parts, in energy generation and transmission, in solar panels and wind turbines, in solders and brazing sticks, in medical equipment and healthcare prod-ucts etc. A lot of further examples and detailed technical aspects for the non-substitutable nature of silver will be delivered during this consultation by a brought range of European and national federations as well as by individual companies. There-fore, we have serious concerns about the potentially far-reaching consequences of the proposed classification. • WVMetalle support the scientific comments submitted by the European Precious Metals Federation (EPMF). We especially agree with EPMF that a read-across from silver salts to metallic silver is not scientifically justified as bioavailability is an intrinsic property which				

needs to be considered when assessing the hazards of metals.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020-12-18_WVMetalle Comment on CLH Proposal for Silver.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	10

Comment received

The following comments on the Proposal for Harmonized Classification and Labelling for Silver (CAS 7440-22-4) are submitted on behalf of the Network NanoSilber. The network consists of various partners from industry and academia. For us, the unbiased investigation of the opportunities and risks of nanosilver and elemental silver over the entire product life cycle is very important. We are particularly committed to the responsible planning of R&D projects and our goal is to develop products that offer an additional benefit for the customer while ensuring high product safety.

We appreciate the opportunity to comment on this publication at this stage of the CLH process and we recognize the efforts of the authors to investigate the toxicological assessment of silver using the cited data. However, we have detected several serious deficiencies:

The CLH proposal covers only a brief list of important uses of silver (p. 18). In fact, silver has many more uses critical to everyday life. The high technical potential of silver stems from its excellent antimicrobial properties, its thermal and electrical conductivity as well as its special optical properties. This opens up important application fields, ranging from flexible displays to antimicrobial equipment for hospital textiles, wound dressings, wall panels and water preservation. Silver is also an important substance to achieve the goals of the EU regarding climate protection and controlling the growing danger of multi-resistant germs.

The network NanoSilber and its partner use silver and nanosilver for medical applications, functional coatings (including antimicrobial, antiviral, dissipative, and antistatic coatings), as well as for water treatment. Silver is also used to replace human toxic compounds like isothiazolinones. Restricting the use of silver will force users to apply hazard chemicals. The network further cooperates with various authorities and several medical facilities to develop safe silver containing coatings to fight germ transmission as well as antimicrobial resistance. Almost all industry projects in the network are based on the use of silver.

- GBneuhaus GmbH uses silver and nanosilver not only as antimicrobial additive but also for electrical conductive, antistatic and dissipative coatings based on sol-gel technology. The patented technology is applied in various industries, including automotive, building, and electronics.

- The economic importance of silver, nanosilver and, above all, the technologies associated with them in all fields of application is essential for the Fraunhofer Institute for Chemical Technology (ICT) and for the associated industrial partners.

- RAS AG has been developing technologies based on silver and nanosilver for more than 20 years. Silver is used because of its high electrical conductivity as well as its unique antimicrobial properties, enabling applications, which are used among other reasons to meet the goals of the EU with regard to climate protection and growing danger of multi-

resistant germs.

- The start-up Silvertex aqua GmbH is active in the drinking and industrial water segment, preserving high amounts of water with a globally patented 3D spacer fabric consisting of silver yarns and polyester. In Germany alone, over 80.000 mobile drinking water canister in caravans and boats are suited with this technology, protecting against legionella, e coli- and pseudomonas. Silver is also used in air humidifiers as well as in cooling towers and in warm water circulation systems in hospitals. Due to its unique character silver is the only metal applicable for this kind of use that requires neither additional energy nor the use of additional chemicals.

Silver is also of high value to other sectors and networks:

- printed electronics as key topic of the network nanoInk, a cooperation network for industrial inkjet printing including various partner from industry and academia. Silver and nanosilver is highly relevant for the development of printed electronics (e.g. photovoltaics, integrated sensors). Silver is used because of its high conductivity and stability against oxidation and corrosion. Currently, the network coordinates more than eight industry projects based on the technical use of nanosilver.

- electromobility as key topic of the network Nano4eMob, a cooperation network for electro mobility including various partner from industry and academia. Silver and nanosilver is used for the development of batteries, renewable energy technologies, fuel cells, and electronics because of its high electrical and thermal conductivity.

Our main comments on the proposal for harmonised classification and labelling (CLH) for silver are as follows (see also public attachment):

ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United Kingdom	<confidential>	Company-Manufacturer	11

Comment received

The following comments are submitted in response to the Proposal for Harmonized Classification and Labelling for Silver (CAS 7440-22-4).
Our company is a manufacturer of silver and silver products which go into numerous sectors and applications. The figure attached provides a very high level summary of these markets/applications.
There is no single substance that is an ideal alternative to the silver compounds in these applications, and in fact, for the more specialised uses such as in certain electronic circuitry applications, currently no technically equivalents alternatives are available to replace silver. Higher-end applications (e.g. in automotive applications) where there is a need for high levels of reliability and longer lifespans of products, potential silver alternatives such as copper are not viable.

We support, and actively contributed to the preparation of, the scientific comments submitted by the European Precious Metals Federation (EPMF). Rather than reiterating all of these comments we would like to draw particular attention to / supplement the following key messages and arguments which are addressed in more detail in the EPMF's comments:

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver products.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	12
Comment received				
As the <confidential>, we have been using Silver in our operations with no evidence of any hazardous situation. Silver is a fundamental material for a substancial number of our operations.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United Kingdom	Ames Goldsmith UK Ltd	Company-Manufacturer	13
Comment received				
Ames Goldsmith is a global producer of chemically produced silver products. We use silver to produce silver chemicals (silver nitrate and silver oxide) and to produce high performance silver powders. Metallic silver is all round us in our everyday lives and is essential to communication technologies and in renewable energy supply. Our plant in the UK reflects the largest historic use of silver for photography since it is a former Kodak plant. As Ames Goldsmith this site has worked with customers and our chemicals are now used to form silver in many applications – electrical contacts, Mirrors (including solar mirrors), catalysts, and batteries. Globally our plants produce silver powders which are used in electronics, touch screens and solar (PV) panels. We will always work to safety and environmental best practise, but believe that the science supporting those regulation should be done thoroughly and correctly.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	14
Comment received				
The attachment describes our process regarding the production of silver coins and the protective measures adopted. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Bio-Gate AG	Company-Manufacturer	15
Comment received				
Dear Sir/Madam, These comments are submitted on behalf of Bio-Gate AG, Germany. We would like to comment on the Proposal for Harmonized Classification and Labelling for Silver (CAS 7440-				

22-4).
Bio-Gate uses metallic/elemental silver in a lot of applications and due to its special properties it is indispensable and cannot be replaced by other substances.

Metallic silver has a lot of unique properties which are combined in one single substance like:
• skin conditioner
• antimicrobial
• antiviral
• anti-inflammatory (limited)
• skin and microbiome friendly
• is not able to penetrate the skin and mucosa tissue

There is no other known natural ingredients that offers this range of positive effects.

Bio-Gate manufactures its silver MicroSilver BG from pure metallic/elemental silver with medical grade.
There are three different grades available:
- MicroSilver BG for cosmetic applications
o This grade is also certified for natural cosmetics because metallic silver is a natural ingredient
- MicroSilver BG Med for medical devices
- MicroSilver BG Tec for industrial/consumer and biocidal applications

Bio-Gate's use metallic/elemental silver includes the following applications:
• wound care products
• derma cosmetic products
• coating of implants
• surface treatments
• other medical devices like catheters and bone cement

We have more than 200 customers who have more than 500 different cosmetic products on the market.
A lot of these products are used for therapy-accompanying care of e.g. atopic dermatitis.

Regarding the Proposed Classification of silver:

Bio-Gate disagrees with the proposed classification for silver metal according to the Harmonised Classification and Labelling (CLH) as the scientific methodology used for all endpoints (listed below) in the proposed Harmonised Classification and Labelling (CLH) classification for silver metal is not fully based on evidence.
In particular the endpoint for the proposed classification of silver metal as a Category 1B Reproductive Toxicant (Repr. 1B) under the Biocidal Products Regulation (BPR). This data and conclusion is not based on metallic/elemental silver. Bio-Gate would prefer for the OECD Test Guideline (TG443)-compliant Extended One-Generation Reproductive Toxicity Study (EOGRTS) to be first concluded or even the same is performed with metallic/elemental silver before any classification decision is made.
Until there is evidence Bio-Gate believes it is both prudent and pragmatic not to prematurely classify silver metal until all the scientific data is available.

Bio-Gate agrees with the comments on the silver metal endpoint classification of the EPMF and extends them by further points:

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Bio-Gate Safety Studies.zip
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Bio-Gate Microsilver BG Confidential Safety Studies.zip

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	I&P Europe - Imaging and Printing Association e.V.	Industry or trade association	16

Comment received

see attached document

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments to the silver metal CLH public consultation.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	17

Comment received

The CLH report refers to a very limited list of uses of silver in industry (section 5, p.18). The report should have given a comprehensive overview of the diversity of use in order to reflect the importance of silver in a wide range of manufacturing processes.
We would like to highlight the essential need of silver in the electrical equipment domain, in particular for the manufacturing of electricity transmission and distribution grid equipment. The use of silver in electricity transmission and distribution equipment shows specific and outstanding characteristics like its electrical conductivity, hardness, melting point, corrosion and friction properties. Such advantageous property combination is not found anywhere else on the periodic table of elements. Silver allows the electricity grid network to be energy efficient, safe and reliable.
For a detailed overview of the use of silver in electricity transmission and distribution, please refer to the additional public document provided in this consultation.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	Eurometaux	Industry or trade association	18

Comment received

It is exceptional that Eurometaux submits direct comments on the CLP public consultations for RAC examination of single substances, whereby Eurometaux' s main attention and interest focusses on the correct and full application of the REACH and CLP guidance. As such the present case on the environmental classification of Silver metal warrants an intervention for the Public Consultation, given the upcoming review touches upon several important aspects of the CLP guidance for data rich substances and metals in particular.

ECHA note – An attachment was submitted with the comment above. Refer to public

attachment Enclosure 2 - Overview of metal environmental classification entries including some history.zip

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France		MemberState	19

Comment received

Please RMS specify if the particle size distribution of each compound tested (Silver powder, Nanosilver) is number based or volume based?

The purity of the test items used to perform all physicochemical properties tests should be reported.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	ZVEI - German Electrical and Electronic Manufacturers' Association	Industry or trade association	20

Comment received

We would like to comment on the Proposal for Harmonized Classification and Labelling for Silver (CAS 7440-22-4).
Particularly, we want to emphasize the importance of silver as a material for our industry and express our serious concerns about the potentially far-reaching indirect consequences of the current classification proposal for our industry.

Comment 1:
Chapter 5, p. 18: Identified Uses of the CLH report :
The current description is insufficient and does not reflect properly the different uses of silver metals.
Silver is technically essential for numerous applications throughout the whole electrical and electronics industry (see table in the attachement with the most important, basic applications). It is also of utmost relevance to fulfil the goals of the Green Deal by the European Commission. Metallic silver is applied for example in wires, pins, contacts, solders, brazing, sintering, adhesives, fuses, lead frames, printed circuit boards, semiconductors and LEDs (non-exhaustive list). These components are utilized in switchgear and apparatus for electric energy generation by conservative power plants and e.g. solar panels and wind farms, electric energy transmission on high voltage level and distribution on medium and low voltage level, consumer/industrial electric equipment (phones, computers, white goods, domestic installation, low voltage switchgear, etc), electric equipment for transportation (trains, aircrafts and cars/e-mobility) and electric medical equipment.
The wide use of silver is caused by its outranging technical functionalities, such as electrical conductivity, power dissipation, hardness, melting point, corrosion and friction properties, contact wear, reflectivity, whisker protection and thermal conductivity.
The overall functionality of silver cannot generally be replaced by other materials without a negative impact on the appliances it is used in.
Neither copper nor gold are suitable substitutes for the wide range of silver applications from a technical point of view. Moreover, gold is also a conflict raw material. There are ongoing huge efforts to reduce the quantity of silver used in electrical and electronic applications for cost reasons for decades. This has led in most cases already to a minimum use of silver and silver compounds in the EEE applications.

Due to the high volumes of silver (roughly one third of the global demand of silver can be assigned to the EEE industry) used in the EEE sector we fear the possible indirect consequences of silver being classified as a CMR substance (Reprotox 1B) under the CLP regulation. This could lead to further regulatory measures under the REACH Regulation (EC No 1907/2006), such as inclusion in the REACH candidate list with significant information duties under art. 33 (1) REACH and according to the requirements of the SCIP database, authorisation (Annex XIV) and possible restrictions (Annex XVII).
In addition, the listing in Annex II of the RoHS Directive 2011/65/EU (Restriction of Hazardous Substances in Electrical and Electronic Equipment) could be a consequence of the planned reclassification of silver. It should be mentioned here, that silver was already the alternative for lead that had to be laboriously substituted as a result of the introduction of the ELV and RoHS directives at the beginning of the millennium, and that those efforts so far have not reached completion. While achieving this substitution, all soldering processes had to be converted to higher bath temperatures, extended heating phases and application/qualification of new electronic components that were able to withstand these conditions. Silver and/or copper served to increase the melting temperature, mechanical strength and structural stability.
The handling of silver containing materials within the EEE sector requires special know-how, the workers are trained for. Workers are obliged to wear gloves and/or other protection in order to prevent damaging the parts during manufacturing of the respective electronic products/parts (their functionality), e.g. through fingerprints. General public is not exposed to silver by EEE products. The silver components used in EEE products are in general not accessible to public and evaporation or release of silver powder or silver salts does not occur. Exposure to operator and maintenance personnel of EEE products is negligible. As another example silver plating on contact surfaces during manufacturing is mostly done by galvanization. Health of employees is taken care of by using the appropriate protective equipment. Low voltage contacts may e.g. be manufactured by sintering silver and metal oxide powder within automated processes. Exposure to workers is prevented by closed production lines additionally to health and safety measures. Where there are water condensation or strong environmental influences, the device is usually protected against these, so no leakage into the environment or contact with silver or silver salts is to be expected (protection goal of the Low Voltage Directive).

Comment 2:
We support the scientific comments submitted by the European Precious Metals Federation (EPMF).

Comment 3:
In June 2019, the European Chemicals Agency (ECHA) accepted the EPMF's proposal for an EOGRTS. As far as we are informed, this assessment is currently underway alongside an assessment of toxicokinetics, to allow robust read-across from silver acetate to different silver substances. Unfortunately, from the current perspective, the obtained results will be available too late to be fed into the adopted RAC opinion for the CLH proposal for silver metal. In view of the possible consequences for our industry, we find this very regrettable and do not perceive why the consultation and decision making has not been postponed until these for this matter very relevant studies are completed. In addition, we doubt that a read-across from silver salts to metallic silver can be justified at all from a scientific point of view. We support the statement made by EPMF in its statement to this consultation that bioavailability is an intrinsic property of substances.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201218 ZVEI Silver Applications in EEE and Comments Ag CLH Consultation.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	C.HAFNER GmbH + Co. KG	Company-Manufacturer	21

Comment received

Comments of the Company C. HAFNER GmbH + Co. KG on the Public Consultation of the Silver CLH Proposal

C.HAFNER is one of Europe's leading companies in the field of precious metal technology. We recover precious metals especially gold and silver from secondary material, which we process into different materials for a wide sector of use.
We use massive silver to produce silver containing alloys for semi-finished products for the use in jewelry, for dental and industrial applications.
We produce µ-sized silver powder as well in completely separated manufacturing process. It is used to produce semi-finished products and brazing pastes for the jewelry industry as well as conduct parts for industrial applications.
When looking for alternatives for silver it becomes evident that these have not the unique properties of silver (e.g. ductility, conductivity) at the same available quantities and with comparable costs. Silver was replaced by other metals wherever it was technically and economically feasible.
The proposed classification will have severe influence on the future use of silver. Therefore, we require environmental classification according ECHA Guidelines – different classification of Ag massive and powder – and that other proposed classifications are based on hard and comprehensible scientific facts. Silver in a massive form should not be classified. C.HAFNER is a member of the European Precious Metals Federation (EPMF) and a joined registrant of silver under the REACh legislation. Hence C.HAFNER supports the scientific comments submitted by the EPMF.

We would be pleased if you could consider our comments in the further process.

Please do not hesitate to contact us if you have any further questions.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	<confidential>	Company-Manufacturer	22

Comment received

I would like to refer to the document under "Public Attachment"

ECHA note – An attachment was submitted with the comment above. Refer to public attachment <confidential>_Public Cons. Ag CLH Proposal.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Belgium	European Precious Metals Federation (EPMF)	Industry or trade association	23

Comment received

Comments on uses (CLH report section 'identified uses' - p.18):
The section on identified uses of silver in the CLH report is very short and mainly focuses on the biocidal use of silver. We would like to highlight that silver has many more uses critical to everyday life: silver is used in electronics and electrical equipment used in consumer applications, industrial applications, automotive uses, green energy (including solar and

wind) and brazing and soldering applications and is also used in medical devices and in vitro diagnostic (IVD) medical devices. Furthermore, silver is used in jewellery and in tableware/silverware. Other uses include use of silver in aeroplanes, satellites and defence applications, in personal care products, in photographic films, papers and emulsions and in a variety of industrial applications not accounted for in the list above, in diamond tools, as investments, or in the manufacture of other chemical substances, mirrors and surface treatment.
In this respect, we also refer to the individual comments submitted by several silver downstream users, further describing the uses and criticality of silver.

Summary of comments on read-across (CLH report section 'data sources' - p.18-22):
• In the absence of substance specific data, it is not justified to perform read-across from any silver containing substance with silver content ranging from 2.5 to 75%, for which conclusive silver ion release data are not available, for which the overall composition is in many cases unknown and for which other constituents contribute (or even be responsible) for observed effects.
• In vitro bioelution data cannot be used on their own to reliably predict silver bioavailability, as silver behaviour and speciation in in vitro assays is driven by bioelution media composition (like presence of chlorides) rather than test item characteristics. Also, behaviour and speciation in vivo are complex and are influenced by a variety of chemical and biochemical processes, which influence the absorption characteristics of silver forms.
• To address this further, EPMF is currently conducting comparative in vivo toxicokinetic (TK) studies, covering ionic Ag forms, AgNP and massive/powdered forms of elemental Ag as test articles. Results of these studies have to be awaited since no alternative in vivo data on bioavailability of metallic Ag are available to investigate and potentially justify the read-across possibilities. The test data will be available H1 2021.
• The CLH report incorrectly states that bioavailability is not an intrinsic property.
For further details / justification, please refer to the attached document pages 7-10.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH Ag Comments FINAL_201217.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Netherlands		MemberState	24

Comment received

Specific comments
The dossier submitter justifies the use of data from silver nanoparticles and silver containing active substances (SCAS) to use in a read-across approach as there is no data available for massive silver. We agree with this approach but remark that this is only applicable to systemic endpoints. For local effects, it is important to justify if the effects observed are also expected after contact with massive silver or to propose a separate classification for different forms.
Effects with nanosilver are considered to represent an intrinsic property of the silver ion. This seems to be based on a single study only (van der Zande M, IIIB, page 20). The reliability of the van der Zande article is not stated in the summary table and text. Please reflect on the reliability as it seems to provide key information about silver forms toxicokinetics and bioavailability.
Taken together, data used for classification should preferably incorporate studies with silver salts with components that are not expected to influence toxicity as well as data on silver nanoparticles. The NL-CA agrees studies with these compounds provide adequate data for classification of silver.

The DS proposes to set the dermal uptake at an upper level of 5%. This may be a valid approach for setting a limit value when performing a risk assessment. However the relevance for this dossier is unclear and this approach is normally not appropriate for hazard based classification purposes.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Netherlands	<confidential>	Company-Manufacturer	25
Comment received				
Dear Madam/Sir, These comments are submitted on behalf of <confidential> (<confidential>). We manufacture and sell circulation and commemorative coins to 70 central banks worldwide. The use of silver is critical for our commemorative coins, our most important activity. Silver is unique in its appearance and value. Silver coins are a unique way to celebrate and give meaning to historical events or people of national importance. Silver coins can be sold in a price range different from gold and makes commemorative coins more accessible to the greater public. In addition, we use silver for our royal decorations and jewellery for the royal chancellory and other public institutions. Silver has unique properties in terms of appearance, enamel and coating. Making these products in other materials is not possible. Moreover, having 100.000s of customers, buying silver coins from us for centuries, we never received comments that there were hazardous risks of silver. People have been using silver cutlery, jewellery and other silver products for centuries. We do not believe that there are material hazards related to silver, never having received any indications of this kind. The hazards described in the Proposal for Harmonized Classification and Labelling for Silver (CAS 7440-22-4) are often not sufficiently substantiated. In short, silver is a crucial commodity for our business operation and our customers. The business will not disappear with European regulation. The result will be that non-European mints take over our activities.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	France	FRANCECLAT, BOCI and UFBJOP	Industry or trade association	26
Comment received				
Please find our general comments in the attached document. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments on CLH proposal for silver.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Fachvereinigung Edelmetalle e. V.	Industry or trade association	27
Comment received				
The precious metal silver has been used in various ways since ancient times. It has the lowest contact resistance and the highest electrical and thermal conductivity of all metals				

which makes it essential in many components of Green Technologies. Solar panels, rapid charging-stations, in-road applications and certain types of electrodes all require silver. It is used in switches, circuit boards and in some types of batteries when the required speed of conduction exceeds that of what copper can deliver. Silver is used in X-rays, other medical applications and equipment because of its natural antimicrobial properties. With the rapid rise of antibiotic-resistant strains of microbes researchers are focusing on silver as one of the keys to future defences to protect human health. It is used for water purification also.
The use of silver is sustainable, as unlimited recycling is possible and due to elemental characteristics, silver and silver alloys will be essential for future European Green Deal.
When looking on alternatives, it becomes evident that these have inferior properties (non-precious metals) or are much more costly, not thinking about required quantities (other pre-cious metals).
The proposed classification will have severe influence on the future use of silver. Therefore, we require environmental classification according ECHA Guidelines – different classification of Ag massive and powder – and that other proposed classifications are based on hard and comprehensible scientific facts. Silver in a massive form should not be classified.
Reduction or more precisely the minimization of Silver used in applications was major R&D focus over the last decade. A replacement of Silver was executed wherever technically possible mainly due to cost reasons. However, a vast amount of Silver is technically irreplaceable in electric industry sector due to the combination of high conductivity and low corrosion.
Silver has various areas of application
• Massive silver is used to produce investment bars and alloys containing silver for semi-finished products for the use in jewelry, for industrial and dental applications. The silver compounds potassium silver cyanide, silver cyanide and silver nitrate are used in electroplating baths.
• Pure silver powder and silver containing powder is mainly used in industrial applica-tions to produce semi-finished products like electrical contact industry and brazing pastes for the jewelry industry.
• In the electronics industry silver is an essential part for the production of contact materials, contact parts and functional surfaces, as they are used in e.g. electric contac-tors, relays, circuit breakers, inverters, electric connectors, EV batteries by our down-stream users. These semi-finished materials are manufactured via powder- and melt-ing-metallurgical methods.
Also due to its catalytic effect, silver cannot be replaced in its industrial application:
o Formaldehyde is one of the most important chemical raw materials (approx. 5-10 million tons p.a. worldwide). It is needed for the production of various resins (phenolic resins, melamine, etc.) and polymers. The synthesis is done indus-trially almost exclusively from methanol, either by dehydrogenation or partial oxidation. The most important manufacturing process, according to which ap-prox. 80% of the industrial plants operate, is the so-called silver contact pro-cess. In this process, fine silver is used as a catalyst to increase the yield with less energy consumption (temperature/pressure).
In the course of the process the silver catalyst ages and after 4-7 months of operation an increased production of formic acid occurs. This corrodes the plant and starts an unwanted polymerization of the product. The catalyst must therefore be replaced at regular intervals. Silver is therefore indispensable for this important process in the basic industry.
Furthermore, silver is not substitutable for the production of ethylene oxide. The large-scale production of ethylene oxide is carried out exclusively by the catalytic oxidation of ethene with oxygen.
Finely dispersed silver powder, which is applied to an inorganic, oxide-con-taining carrier (preferably aluminium oxide), is used as a catalyst.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment FVEM comments CLH silver.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Federal Associations of the German Jewellery and Silverware Industry	Industry or trade association	28

Comment received

The Federal Associations of the German Jewellery and Silverware Industry as a group was founded in 1952 with the aim of uniting all German organizations in the jewellery and silverware sector, from industry to crafts and trade. It represents a necessary platform on which all German representatives of the industry can exchange views on the issues that affect the entire industry, find common posi-tions on these issues and represent their interests on a national and international level. The main focus of the association is the representation of German interests in the World Jewellery Confeder-ation CIBJO for the benefit of the industry, the craft and the trade.
The following associations are members of the association:
- German Association of Jewelry, Watches, Silverware and Related Industries e.V.
- German Association of the Gemstone and Diamond Industry e. V.
- German Association of Jewelers, Jewelry and Watch Specialists e.V.
- German Association of Importers and Exporters of Gemstones and Pearls e.V.
- Association of the Gablonz Industry e.V.
- Precious Metals Association, Schwäbisch Gmünd
- Society for the Art of Goldsmithing, Hanau

Silver and silver compounds are used in the jewellery, watch and silverware sector in various com-ponents and products, where applications include the use of massive silver, silver plating and the use as a component in silver, gold and copper alloys. These are used within in a broad range of end products that are designed for everyday use, mid-tier products and luxury products. The key prop-erties of silver and silver compounds include its function as a reflective/ornamental and store of value, but also its natural antimicrobial properties.
As the combined group of representations of the German jewellery, watch and silverware industry sector we would like to indicate that it would not be possible to find an alternative to metallic silver for most of its uses in mid-tier and luxury products, since it is not possible to provide the same aes-thetic, economic and technical functionality. For products in everyday use, these can and have al-ready be substituted with other cheaper alternatives (e.g. stainless steel).
In response to the proposed Reprotox Cat. 1B classification of silver and silver compounds, the com-panies of our industry sector as downstream users of these compounds in the jewellery, watch and silverware sector will suffer greatly, not only because of the restrictions to silver products, but espe-cially because of the use of silver in almost any other precious metal alloy. Most companies will most likely at least try to continue operations. However, the future of our industry sector will be subject to both the affordability of future products, and how consumer demand changes after silver is clas-sified Repr. 1B, as it is possible consumers will demand jewellery, watch and silverware without the use of silver, which is near to impossible.
We would also like to point out that the costs of the proposed classification are unforeseeable for the mostly small and medium-sized enterprises in our industry sector. They range from costs of com-pliance (additional risk management measures, monitoring and data requirements, etc.) to the loss in value added due to stigma effects.
In contrast to costs, the benefit of the proposed classification from the reduced exposure of the af-fected population is unknown due to insufficient scientific evidence on the potential reproductive toxicity of the silver and silver compounds (including whether there are any

risks). Therefore, the Federal Associations of the German Jewellery and Silverware Industry strongly support the scientific comments submitted by the European Precious Metals Federation (EPMF).

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201216-comments-vbv-clh-silver.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Austria	<confidential>	Company-Manufacturer	29

Comment received

It has been known since ancient times that silver has an antibiotic effect. It has been known for over 3,000 years that water in silver vessels stays fresh longer. In the past, you put a silver coin in milk to keep it fresh longer.
In the 19th and early 20th centuries, silver was of great medical importance. At the end of the 19th century, silver nitrate was dripped into the eyes of newborn babies to prevent the then widespread eye tripper. Then in 1928 penicillin was discovered and the antibiotic effect of silver was forgotten. The Rennaissance experienced silver in the form of colloidal silver in the late 1990s, as the increasingly antibiotic-resistant strains of bacteria develop.

In many relectrotechnical products silver is used for plating contacts, as well as in fuse-links (melting strip) and electronics. It has perfect features for these applications. Without silver it is not possible to reach such a low power loss (e.g. melting strip of a fuse-link) and constant electrical conductivity of contact systems. We use silver in the switchgear we are producing. Without silver it would not be possible to produce sustainable and environmentally friendly devices with less power loss!

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	European Committee for Surface Treatment aisbl	Industry or trade association	30

Comment received

CETS is gratefully taking the opportunity to comment the proposal. Please consider our comments summarized in the attached file.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment CETS-comments Silver labelling CAS 7440-22-4 201217.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany		Individual	31

Comment received

As a citizen of Europe I have to express that the approach of classifying Silver metal as harmful seems to be weird. Silver metal has been used for jewelry for thousands of years, in long-term skin contact. If there were any significant adverse effects it would have been major concerns in the public - which are not! Therefore a classification of Silver metal in general appears to be irrational.
If there should be any concerns about specific appearance of Silver like dust or nano form, Eu-Commission should first implement clear definition of the specific forms. The the

classification has to be restricted to the form of concern. If CLP does not give this opportunity, the classification of Silver in the proposed way has to be rejected necessarily. Please consider my deep concern about the usage of tax money by EU Commission and Agencies. Personally I do not agree spending it to such questionable topics.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Zentralverband Oberflächentechnik e.V.	Industry or trade association	32

Comment received

Zentralverband Oberflächentechnik e.V. is grateful for the opportunity to comment on the proposed new classification and labelling of Silver metal. Please consider the comments summarized in the document attached.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020-12-11 comment public consultation Ag ZVO.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Austria	<confidential>	Industry or trade association	33

Comment received

Silberlegierungen werden zur Erzeugung von Schmuck und Hartloten verwendet.
Darüberhinaus wird die Rückseite von Kristallen mit einer Silberschicht chemisch verspiegelt (nasschemisches Sprühverfahren auf Silbernitratbasis). Ebenso wird Silber bei der nasschemischen Verspiegelung von Flachglas (Automotive, Sicherheit, Möbel, Bad, etc) benötigt. Im Bereich TableWare kommt Silber bei Tafelgeschirr und Besteck zum Einsatz. Neben den technischen Eigenschaften von Silber spielt vor allem das hohe Reflexionsvermögen und der Weiß-Grad eine wesentliche Rolle.
Silber hat eine antiseptische Wirkung. Es sind uns keine gesundheitsbedenklichen Fälle in der Anwendung und/oder Verarbeitung bekannt. Es liegen uns auch keine Indizien für Hautirritationen vor. Aus diesem Grund können wir zu den nachstehenden "Comments on the open Hazard classes" nichts beitragen, da die dort angeführten Eigenschaften/Klassifizierungen nach unserem Wissensstand nicht gegeben sind.
Bei der Herstellung von Schmuck und Tafelgeschirr wird Silber üblicherweise in kompakter Form verarbeitet. Dabei kann es zu Abrieben kommen. Allfällige Schädigungen der Gesundheit und der Umwelt sind uns dabei nicht bekannt bzw. werden diese durch Einhaltung der bereits bestehenden gesetzlichen Vorschriften (Arbeitnehmerschutz) auf ein Minimum reduziert.
Uns ist vor allem bei der Schmuckerzeugung und Verspiegelung kein alternatives Produkt zu Silber bekannt, welches dieselben Eigenschaften und Qualitätsanforderungen hätte.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Czech Republic	SAFINA, a.s.	Company-Manufacturer	34

Comment received

Please see the attached file.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment SAFINA_CLH public consultation_silver metal - completed.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Norway	<confidential>	Company-Manufacturer	35

Comment received

Precious metals are not at the heart of our process and represent small volumes. Nevertheless, and as described further in the attached document, their production, including silver production, is critical for ourproduction process. Indeed, one of the conditions to continue in a sustainable way our main productions of nickel, copper and cobalt, is to be able to recover as much as possible of the other elements contained in the raw material. Please see the attached document.
Beyond the criticality of the silver production within our production process as a whole, we support the scientific comments submitted by the European Precious Metals Federation (EPMF) that are specified below in the comments on the open hazard classes.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments CLH Ag -17.12.20.pdf
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Comments CLH Ag - <confidential> - 17.12.20 - confidential info.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Spain	CAPIEL	Industry or trade association	36

Comment received

Dear colleagues,
Please find enclosed the comments prepared by CAPIEL on the dossier proposing harmonised classification and labelling for Silver

ECHA note – An attachment was submitted with the comment above. Refer to public attachment CAPIEL Comments.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Heimerle + Meule GmbH	Company-Manufacturer	37

Comment received

The precious metal silver has been used in various ways since ancient times. It has the lowest contact resistance and the highest electrical and thermal conductivity of all metals which makes it essential in many components of Green Technologies. Solar panels, rapid charging-stations, in-road applications and certain types of electrodes all require silver. It is used in switches, circuit boards and in some types of batteries when the required speed of conduction exceeds that of what copper can deliver. Silver is used in X-rays, other medical applications and equipment because of its natural antimicrobial properties. With the rapid rise of antibiotic-resistant strains of microbes researchers are focusing on silver as one of the keys to future defences to protect human health. It is used for water purification also.
The use of silver is sustainable, as unlimited recycling is possible and due to elemental characteristics, silver and silver alloys will be essential for future European Green Deal.
When looking on alternatives, it becomes evident that these have inferior properties (non-precious metals) or are much more costly, not thinking about required quantities (other precious metals).
The proposed classification will have severe influence on the future use of silver. Therefore, we require environmental classification according ECHA Guidelines – different classification

of Ag massive and powder – and that other proposed classifications are based on hard and comprehensible scientific facts. Silver in a massive form should not be classified.
Reduction or more precisely the minimization of silver used in applications was a major R&D focus over the last decade. A replacement of silver was executed wherever technically possible mainly due to cost reasons. However, a vast amount of silver is technically irreplaceable in electric industry sector due to the combination of high conductivity and low corrosion.
Silver has various areas of application in which Heimerle+Meule products are used:
• Massive silver is used to produce investment bars and alloys containing silver for semi-finished products for the use in jewellery, for industrial and dental applications. Silver compounds such as potassium silver cyanide, silver cyanide and silver nitrate are used in electroplating baths.
• In the electronics industry silver is an essential part for the production of contact materials, contact parts and functional surfaces, since those are used in e.g. electric contactors, relays, circuit breakers, inverters, electric connectors, EV batteries by our down-stream users. These semi-finished materials are manufactured via powder- and melting-metallurgical methods.
There are also a lot of other applications in which silver is used:
• Pure silver powder and silver containing powder is mainly used in industrial applications to produce semi-finished products like electrical contact industry and brazing pastes for the jewellery industry.
• Due to its catalytic effect, silver cannot be replaced in different industrial applications.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment H+M comments CLH silver.pdf

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Belgium	ACEA	Company-Manufacturer	38

Comment received

The automotive industry is following the new proposal for the classification of silver and its salts with concern. A classification of silver and its salts as reprotoxic 1B and Skin Sens. 1 can endanger current and future developments in the automotive industry.
Silver is used in particular in many areas of the automotive industry due to its diverse physical and chemical properties. Because of its properties resulting in the highest electrical and thermal conductivity of all metals, a good corrosion resistance, a low melting point, a temperature resistance and pressure tightness, silver is used in products such as solders, adhesives, paints, polymeric materials, semiconductors, ceramics and many more. Without the use of silver, the resulting components such as pins, cables, screws, electrical circuits, light emitting diodes (LEDs), printed circuit boards (PCBs), housings, electrical tubes, heating units, security systems, airbag systems, displays, multimedia interface systems, instrument panels, lamps, etc would no longer be able to fulfill the high quality standards of the automotive industries on durability, safety and environment. The excellent light reflection properties of silver can also be found in components such as mirrors as well as in lighting applications in the automotive industry. Finally also the development of alternative drive technologies would be endangered in case of stricter classifications.
In general terms, especially because of the high market price of silver, it is only used in very limited cases where it is technically required and were a substitution by less expensive substances is technically impossible. Since silver has such a wide range of uses, a general substitution either is not possible at all or would at least have a high economic impact on our sector because the production of automobiles in their current form would simply no longer be possible any longer.
We therefore call for a distinction between the classification of solid silver and silver in

powder form.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Austria	FEEI - Fachverband der Elektro- und Elektronikindustrie	Industry or trade association	39

Comment received

Sehr geehrte Damen und Herren,
der Fachverband der Elektro- und Elektronikindustrie vertritt in Österreich rund 300 Unternehmen und möchte zum vorliegenden Vorschlag für eine harmonisierte Klassifizierung und Kennzeichnung von Silber (CAS 7440-22-4) wie folgt Stellung nehmen:

Im Bereich der Sicherungen und Schaltgeräte verwenden die Hersteller Silber in einem Großteil ihrer Produkte als Kontaktmaterial. Nahezu in allen Komponenten – außer in Verteiler-Schränken – ist Silber enthalten: Fehlerstromschutzschalter, Leitungsschutzschalter, Leistungsschalter, offene Air Circuit Breaker, Hilfskontakte, Zubehörgeräte, Trennschalter, elektrische Steckverbinder, etc.
Durch langwierige und kostenintensive Forschungsarbeit hat sich Silber als das am besten geeignetste Schmelzleitermaterial für den Kurzschlussschutz im Niederspannungsbereich für Halbleiter sowie im Mittelspannungsbereich für Transformatoren, Kondensatoren und Motoren herausgestellt.
Auch bei elektronischen Schutz- u. Leittechnikgeräten für das Steuern und Schützen von Umspannwerken, Übertragungsnetzen und Großtransformatoren für Energieversorgungsunternehmen oder bei der Herstellung von elektronischen passiven Bauelementen (Widerstände), die in leistungselektronischen/-elektrischen Systemen eingesetzt werden, wird Silber in Loten verwendet. Bei letzterem auch in Kontaktierungen, galvanischen Beschichtungen und im Silbersinterprozess.
Silber wird außerdem in kritischen elektrischen Kontaktelementen verwendet, welche thermisch bedingten Relativbewegungen ausgesetzt sind. Alternative Beschichtungen führen in derartigen Anwendungen zu Ausfällen.
Aufgrund der erhöhten elektrischen, chemischen und mechanischen Eigenschaften (u.a. hohe elektrische Leitfähigkeit, konstant niedrig bleibende Übergangswiderstände im Betrieb, gute Verbindung mit Kupfer, Viskosität, Korrosionsschutz, etc.) oder auch als Ersatz für Blei, gibt es keine Alternative zu Silber. Insbesondere hitzeempfindliche Bauteile benötigen ein Lot mit höherem Silberanteil.
Um in elektrischen Anlagen einen optimalen Schutz bieten zu können, ist Silber ebenfalls ein unerlässliches Material. Ohne Silber wird eine Strom-Verteilung, wie wir sie heute kennen, nicht mehr möglich sein, da Zuleitungen für Geschoße (auch schon in Einfamilien-Häusern) und jede Industrie-Anwendung ohne Silber nicht mehr geschaltet werden kann.
Eine einwandfreie Lötqualität ist auch für elektronische Produkte, welche in der kritischen Infrastruktur eingesetzt werden, unumgänglich. Mit einem Verbot von Silber würde daher der sichere Schutz der elektrischen Netze (kritische Infrastruktur) in Gefahr gebracht.
Daneben verursachen Alternativen zu Silber überwiegend auch mehr Verlustleistung und würden daher Bemühungen zu Energie-Einsparungen entgegenwirken.
Abschließend möchte ich darauf hinweisen, dass Silber während des Be- und Verarbeitungsprozesses schon jetzt sehr streng kontrolliert und sowohl bei der Be- als auch Verarbeitung sowie Nutzung des Endprodukts kein Silber in Pulverform freigesetzt wird. Normalerweise sind die silber-hältigen Anwendungen verkapselt und kommen nicht mit der Umwelt in Berührung (Ausnahme Galvanische Oberflächenbeschichtungen). Darüber hinaus gibt es gerade für Elektro-Altgeräte wohl definierte Prozesse zum Recycling von Rohstoffen.
Nachdem Silber einen teuren Rohstoff darstellt, wird ein besonderes Augenmerk darauf

gelegt, dass dieser umfassend wiederverwendet wird und nicht in die Umwelt gelangt.

Auf Grund der von uns vorgebrachten Argumente sind wir der Ansicht, dass eine harmonisierte Einstufung von Silber als Skin.Sens. 1, Muta. 2 und Repr. 1B nicht gerechtfertigt ist. Selbiges gilt auch für die harmonisierten Einstufung von Silber in massiver Form hinsichtlich von Umweltgefahr.

Ich ersuche um Berücksichtigung unserer Argumente und stehe bei Fragen gerne unter <confidential> bzw. <confidential> zur Verfügung.
Freundliche Grüße,

<confidential>
Senior Consultant

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 201214_Stellungnahme_FEEI_CAS_7440-22-4_Upload.pdf

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Siemens AG	Company-Manufacturer	40

Comment received

Chapter 5, p. 18: Identified Uses of the CLH report: The current description is insufficient and does not reflect properly the different uses of silver metals. On the other hand, the European Chemicals Agency (ECHA) did accept in June 2019 a proposal by the European Precious Metals Foundation (EPMF) for an Extended One-Generation Reproductive Toxicity Study (EOGRTS). This TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts) study is designed to fill the identified data gaps for this endpoint and will allow a conclusive judgement for this endpoint. In view of the possible consequences for our company, we find this very regrettable and urge to postpone the decision making until these for this matter very relevant studies are completed.
Silver is technically essential for numerous applications throughout our electrical and electronics products and solutions, which are furthermore of very high importance to fulfil the requirements of the EcoDesign Directive supporting the goals of the Green Deal set by the European Commission. Metallic silver is applied for example in wires, pins, contacts, solders, brazing, sintering, adhesives, fuses, lead frames, printed circuit boards, semiconductors and LEDs (non-exhaustive list). These components are utilized in switchgear and apparatus for energy-efficient automatization and drive technologies, as well as electricity distribution and transmission on high voltage level and distribution on medium and low voltage level and electric equipment for transportation (trains, commercial vehicles). The wide use of silver is due to its physical properties leading to the necessary technical functionalities for efficient operations, such as high electrical conductivity, power dissipation, hardness, melting point, corrosion and friction properties, contact wear, reflectivity, whisker protection and thermal conductivity.
The overall functionality of silver hinders a general replacement by other materials without a negative impact on the appliances where it is used in, possibly even leading to the shut-down of such applications. Neither copper nor gold are suitable substitutes for the wide range of silver applications from a technical point of view, rendering the whole system of electricity distribution and protection dependent on silver. Moreover, gold is also a critical raw material with high environmental impacts associated during e.g. mining, as well as a known conflict raw material.

Date	Country	Organisation	Type of Organisation	Comment

				number
16.12.2020	Germany	<confidential>	Industry or trade association	41
Comment received				

<confidential> was founded in Pforzheim in 1947. As a lobby group for over 170 predominantly medium-sized member companies, <confidential> represents the interests of its members at a national, European and inter-national level. <confidential> is a member of the Federation of German Industries (BDI). It is responsible for coordinating the federal associations of the German jewellery and silverware industry. In this capaci-ty it is also integrated in global efforts of the World Jewellery Confederation, CIBJO. <confidential> represents the interests of the German watch and clock industry at a European level as a member of the Europe-an watchmaking associations EUROTempus and CPHE. <confidential> is also a member of the Responsible Jewellery Council (RJC).

Silver and silver compounds are used in the jewellery, watch and silverware sector in various compo-nents and products, where applications include the use of massive silver, silver plating and the use as a component in silver, gold and copper alloys. These are used within in a broad range of end prod-ucts that are designed for everyday use, mid-tier products and luxury products. The key properties of silver and silver compounds include its function as a reflective/ornamental and store of value, but also its natural antimicrobial properties.

As a representation of the jewellery, watch and silverware industry sector we would like to indicate that it would not be possible to find an alternative to metallic silver for most of its uses in mid-tier and luxury products, since it is not possible to provide the same aesthetic, economic and technical functionality. For products in everyday use, these can and have already be substituted with other cheaper alternatives (e.g. stainless steel).

- Page 2 of 3 -

In response to the proposed Reprotox Cat. 1B classification of silver and silver compounds, the com-panies of our industry sector as downstream users of these compounds in the jewellery, watch and silverware sector will suffer greatly, not only because of the restrictions to silver products, but espe-cially because of the use of silver in almost any other precious metal alloy. Most companies will most likely at least try to continue operations. However, the future of our industry sector will be subject to both the affordability of future products, and how consumer demand changes after silver is classified Repr. 1B, as it is possible consumers will demand jewellery, watch and silverware without the use of silver, which is near to impossible.

We would also like to point out that the costs of the proposed classification are unforeseeable for the mostly small and medium-sized enterprises in our industry sector. They range from costs of compli-ance (additional risk management measures, monitoring and data requirements, etc.) to the loss in value added due to stigma effects.

In contrast to costs, the benefit of the proposed classification from the reduced exposure of the af-fected population is unknown due to insufficient scientific evidence on the potential reproductive toxicity of the silver and silver compounds (including whether there are any risks). Therefore, the <confidential> strongly supports the scientific comments submitted by the European Precious Metals Federation (EPMF).

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201214-<confidential>-clh-silver-comments.pdf

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Finland	<confidential>	Company-Manufacturer	42
Comment received				
Type of organization - Only representative on non-EU manufacturer				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany		MemberState	43
Comment received				
The DE CA agrees that read-across from uncoated nanosilver to massive silver is generally acceptable for the purpose of classification for health hazards, since it will not underestimate the hazard. To our knowledge, nanosilver is usually coated and nanosilver without modifications is rather uncommon. Coating may influence physicochemical, toxicokinetic and toxicological properties of the nanomaterial. This should be reflected in the classification decision. Regarding the testing of silver in nano size we would like to stress that it is not clear to us if the entry in Annex VI of the CLP Regulation as proposed in table 7 of the report is for coated or uncoated particles or for both. This needs to be clarified and, if necessary, the read-across concept should be presented. Next to this, the given EC number in table 7 seems to be not correct. As far as we understand, a coated form of nanosilver was used in T/D studies. As mentioned in the report (section 11.3.1) it is not unambiguously shown that the coated nano silver was dissolved to Ag+ ions. It is stated that there are indications "that a major part of the conventional dissolved silver was in particulate/colloidal form." It is not clear to us how this was taken into account when assessing nano-silver particles. Therefore, it is not clear whether Ag+ or other forms of silver induce the measured effects. Are only Ag-ions in the solution due to the ultrafiltration? Also the report states: "With regards to the test material it is not known to what extent the type of surface coating present influenced the dissolution of silver. It is stated in the report that much of the coating was removed in the cleaning steps." Does this mean that more or less uncoated silver was used in the tests? Indeed, we are wondering what influence the coating on the solubility of the particles has. Is one coating sufficient to draw a conclusion for all silver nanoparticles coated or uncoated? Moreover, we generally question the appropriateness of the CLH proposal to split the CLP Annex VI entry in „Silver - with the exception of other forms of silver metal specified elsewhere in this Annex" and „Silver, nano [1-100 nm] as defined by (2011/696/EU)". If a split entry should indeed be considered, reference to the solubility and not to the form of silver would be more appropriate in our opinion. Finally, we do not support the read-across from silver-zinc-zeolite to nanosilver and massive silver because of the possible confounding effects of the zinc ion. In the conclusions on classification, clear differentiation should be made between "classification not possible" resulting from inconclusive or lacking data and "no classification" based on evidence for inactivity (e.g. page 59, 120, and 237).				

Date	Country	Organisation	Type of Organisation	Comment

				number
16.12.2020	Switzerland	Federation of the Swiss Watch Industry FH	Industry or trade association	44
Comment received				
To conclude, the FH therefore wishes to emphasize the following points: - For the CLP classification of metallic silver it is essential to consider nano-, powder and massive forms separately. - Despite a huge experience accumulated by regular exposure of a large majority of the population during very long periods, the prevalence of allergies to massive silver or silver containing alloys is extremely low. The classification of massive silver as a skin sensitizer is therefore not justified. - It is essential to wait for the publication of the results of the EPMF study before taking a decision on the elemental silver reprotoxic classification. More generally, we fully support the scientific comments submitted by the EPMF in their position letter. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 4388_001.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	France	FEC Federation of European manufacturers of Cookware and cutlery	Industry or trade association	45
Comment received				
FEC comments on the proposed harmonized classification and labeling of silver are in the attached document. ECHA note – An attachment was submitted with the comment above. Refer to public attachment FEC response to Public consultation_Silver classification proposal.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	46
Comment received				
Heraeus Deutschland GmbH & Co KG, GBU Heraeus Medical Components is a Global Business Unit of the Heraeus Group – a market leading device outsourcing partner to medical device OEMs. Silver in form of metal or in alloys is used in several components, e.g. wires, sensors, implantable pulse generators, X-ray tubes, which are used in production of medical devices. o Medical devices – refer to "products, services or solutions that prevent, diagnose, monitor, treat and care for human beings by physical means". o In-vitro diagnostic (IVD) medical devices – refer to "non-invasive tests used on biological samples (for example blood, urine or tissues) to determine the status of one's health". Technical function of silver-based components might be: o electrical conductor in cardiac rhythm management (CRM) or neuro modulation leads o mechanical joint for brazing of vacuum-tight connections in implantable pulse generators				

(IPGs) and X-ray tubes
o X-ray radiation filter for mammography to detect breast cancer
o electrochemical sensor for continuous glucose monitoring (CGM), electrocardiography (ECG), electroencephalography (EEG), transcutaneous electrical nerve stimulation (TENS)
o antimicrobial function in wound healing.
For CGM applications, about 100 Mio. sensors were produced in 2020 and with the estimated trend in diabetes patients worldwide, there is an annual growth of more than 25% in application of these sensors to monitor and treat this disease.

We support the scientific comments submitted by the European Precious Metals Federation (EPMF).

The use of silver in medical devices provides huge advantages within medical investigations and medical treatments. Substitution of substances for medical devices have several restrictions in terms of biocompatibility or risks connected with failed devices when substitute substances have negative effects on lifetime or other critical quality features. For applications like CGM sensors there is no known substitute to silver based electrodes. As world leading supplier of components for medical devices, we fear that proposed classification Skin Sens. Cat 1 H317, Muta 2 H 341 and Reprotox. H360FD will imply legal barriers for use of silver in medical devices and additionally, it may generate psychological barriers at physicians and patients.
In any case, if the decision for the mentioned classification is made, the decision should be made on clear and founded scientific studies.

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	47

Comment received

The purpose of our answer to this consultation is not to debate around silver toxicity as it's not under our competencies, but to give some key elements on the usages, the controlled exposure risks and the technico-economic impacts, in order to help ECHA to evaluate the most appropriate regulatory option if needed in a second step, according to the conclusions of the toxicity studies. More detailed information are given in the confidential attachement section.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	48

Comment received

see comment_CLH_silver_RAS_AG.pdf attached

ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Switzerland	Argor-Heraeus SA	Company-Manufacturer	49

Comment received

Argor-Heraeus S.A. is the largest global provider of services in the precious metal industry. The business includes:
o refining gold, silver, platinum, palladium
o Ingots for banks, traders and products for the electronic and chemical industry
o Semi-finished products and solutions for watchmaking and luxury jewelry
o Services for the physical trading of precious metals
Silver, on its own or as component of alloys is one of our key materials.

We support the scientific comments submitted by the European Precious Metals Federation (EPMF).

The proposed classification of silver as Reprotox. Cat 1 and Aquatic Acute 1 and Aquatic Chronic 1 for silver massive, might trigger restrictions/substitution for silver in future.
The proposed classification will have severe influence on the future use of silver. Therefore, we require environmental classification according ECHA Guidelines – different classification of Ag massive and powder – and that other proposed classifications are based on hard and comprehensible scientific facts. Silver massive should not be classified.

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Belgium	Umicore	Company-Manufacturer	50

Comment received

Dear Sir or Madame,
We as the Umicore group for several legal entities in different Member States would like to comment on the Proposal for Harmonized Classification and Labelling for Silver (CAS 7440-22-4).
Please find the description of our uses, the impact and the scientific comments in attached pfd.
thank you for taking these into consideration
best regards <confidential>

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Umicore public consultation_final 20201215.pdf

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	United Kingdom	AeroSpace and Defence (ASD) Industries Association of Europe	Industry or trade association	51

Comment received

These comments are submitted on behalf of the AeroSpace and Defence (ASD) Industries Association of Europe. We would like to comment on the Proposal for Harmonized Classification and Labelling for Silver (CAS 7440-22-4) since it is a relatively ubiquitous substance within our sector with few or no known alternatives affording similar and reliable (i.e. suitably tested and verified for aerospace & defence (A&D) applications) physiochemical properties.

To summarise, the use of silver in the A&D and space sector include:-

o Ag in A&D conductive coatings, pastes, resins, glues, epoxies & inks. Ag may also be added as silver flake. Thermal pastes are used to conduct heat away from integrated circuits (ICs) in A&D electronics
o Silver loaded conductive electromagnetic compatibility (EMC) gaskets are used in A&D applications to get an electrical connection and provide a complete screen
o Silver coatings on glass for A&D mirrors and optics
o Ag metal in A&D piezoceramic manufacture & other sector applications
o Certain A&D batteries
o Ingredient in Pb solder wire & paste (including braze paste) for A&D applications
o Ingredient in Pb-free solder wire & paste (including braze paste) for A&D applications
o In A&D electronic assemblies within metalisation of parts/components, e.g. fasteners, diodes, resistors, sensors, bushes, connectors, RF connectors, pins etc

Concerning the criticality of Ag metal in the our sector, ASD would like to highlight that there are no universal alternatives to Ag metal affording the same suitability for a wide variety of critical properties associated with silver such as corrosion resistance, electrical conductivity, high oxidisation potential, temperature resistance, self-lubrication and anti-galling properties.
A&D end products affected include aeroplanes, rotorcraft vehicles (including drones and helicopters), satellites and specific defence applications.
Non-exhaustive examples of silver use and criticality are provided below:-

o Silver is used in sintering pastes as an alloying addition to join components at temperatures typically between 217 - 221°C. The sector primarily use tin-silver-copper, or 'SAC', alloys (SnAgCu) with different concentrations of silver (Ag) and copper (Cu). These Ag-based alloys are used so as to provide better wetting, improved joint reliability and afford a wider processing window and due to lead (Pb) being restricted for certain electronic applications under the RoHS Directive. This has led the sector to favour using SAC alloys in the short-medium term. Solder pastes are also used outside our sector in generic electronic applications. ASD politely requests that when the CLH process is finalised once the correct scientific methodologies for all endpoints have been fully agreed, any restriction/prohibition of silver resulting from a reclassification should take the criticality of Ag metal for our sector into account due to the safety-critical requirements of articles operating in extreme environments.

o Silver is used in brazing pastes to join components at temperatures above 600°C. The primary use of brazing in our sector is for use with electronic applications. This includes silver as an alloying addition in solder wire and paste (including brazing paste) since silver provides improved strength and conductivity.
Silver pastes are used to create conductive tracks on ceramic substrates such as alumina. These are used in current high temperature and high powered electronic applications and will become more important in the future due to the higher voltage and current requirements due to increased demand for electric vehicle technologies.

o Busbars are copper bars that carry the high current around the aircraft, which are coated with silver to ensure good electrical conductivity with the flight computer systems. Similarly satellites also contain significant amount of electronics, in the form of electronic circuitry, computers, LEDs, solar cells etc.

o Silver is used for its light sensitivity and used to help test the aeroplanes/rotorcrafts (and their components).

o Silver-zinc batteries and silver chloride-magnesium batteries are used in the aerospace and defence sector. The benefits of silver zinc-batteries are: (i) they have the highest output of any battery chemistries, which is important for certain applications; and (ii) silver batteries can also be left for longer periods of time without the need for maintenance (i.e. they are also more reliable than alternative battery technologies). Where alterative battery chemistries exist, i.e, with lithium-ion batteries, such chemistries afford shorter lifespans of battery products. Compared to silver-zinc batteries, lithium-ion batteries need to be recharged and undergo maintenance within shorter timeframes than their silver-based counterparts.

o Waveguides are used to send and receive electromagnetic waves (e.g. mobile calls and internet traffic) – the primary role of communications satellites and are made from aluminium which is coated in silver. Satellites use silver-plating as it has the longest working lifespan of the metals being used. This is especially important as satellites aren't accessible after launch and the technology needs to be reliable and resistant to degradation (e.g. from extreme fluctuation of temperatures in space). This is also why multiple waveguides are installed on satellites, so that if one part of the satellite stops working (for example it is hit by debris), then the rest of the satellite can still function. Replacing silver would require a redesign of the waveguides which may not be effective in the transmission of specific wavelength transmission.

o Silver plating of fasteners (e.g. springs, screws and screw inserts) or mechanical parts (e.g. bearings) for anti-galling or anti-voltaic corrosion purposes to allow the components to survive elevated temperatures without welding together. Ag users within our sector have indicated that this is a very important use, where silver-plated fasteners are the only known type to be able to withstand extreme temperatures and can be removed after flight for servicing of the parts (e.g. engines). Other components that are plated include aeroplane wheel and brake applications, as well as electroplating of aircraft ground products and facilities (e.g. test rigs, simulators & test equipment), related oil pumps and electronic components (e.g. sensors). Finally, as a very good conductor of electricity, silver plated components are also used in areas of the aeroplane/rotorcraft to help dissipate electrical lightning strikes.

o For combat torpedoes no alternative to silver has been identified given the long-term requirements for storage without maintenance and need for reliability.

Other metal alternatives do not possess the same thermal (or electrical) conductivity as silver since many are softer than silver or have lower melting temperatures than silver. Where silver metal alternatives do exist for certain applications, the alternative in question may include gold, platinum, nickel and tin, each of which have their downsides, such as higher cost (for the precious metals) or a reduction in functionality.

Proposed Classification of silver:-

ASD understand there is currently disagreement in relation to the scientific methodology used for all endpoints in the proposed Harmonised Classification and Labelling (CLH) classification for silver metal.
In relation one particular endpoint, i.e. the proposed intention to classify silver metal as a Category 1B Reproductive Toxicant (Repr. 1B) under the Biocidal Products Regulation (BPR), ASD would prefer for the OECD Test Guideline (TG443)-compliant Extended One-Generation Reproductive Toxicity Study (EOGRTS) to be first concluded before any

classification decision is made.
Until there is a consensus on the scientific methodologies used to classify silver metal concerning the comments put forward by the European Precious Metals Federation (EPMF) regarding all endpoint classification criteria, ASD believe it is both prudent and pragmatic not to prematurely classify silver metal until all the scientific data is available.

Date	Country	Organisation	Type of Organisation	Comment number
14.12.2020	Germany	Heraeus Metals Germany GmbH & Co. KG	Company-Importer	52
Comment received				
I would like to refer to the document under "Public Attachment'' ECHA note – An attachment was submitted with the comment above. Refer to public attachment AG_HMG_FM.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
14.12.2020	France	<confidential>	Company-Manufacturer	53
Comment received				
<confidential> uses silver as a constituent of impregnated activated carbon. The silver is strongly attached to the surface of the activated carbon. Activated carbon is used as a versatile sorbent and the silver changes the properties by enhancing the removal efficiency for contaminants in air or water which otherwise cannot be removed. The use of silver in our products ensures the proper functionality and for some products is required by international standards. This especially is the case for same activated carbon grades manufactured for the protection of humans against toxic industrial chemicals and warfare gases. In other cases, the presence of silver is necessary to maintain the safety of the treatment device, such that it does not age or itself become deleterious to human health.				

Date	Country	Organisation	Type of Organisation	Comment number
12.12.2020	Netherlands	Vereniging ION	Industry or trade association	54
Comment received				
See our letter in the appendix. ECHA note – An attachment was submitted with the comment above. Refer to public attachment ECHA Silver 20201212.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
11.12.2020	Romania	Heraeus Romania SRL	Company-Manufacturer	55
Comment received				
I would like to refer to the document under "Public Attachment" ECHA note – An attachment was submitted with the comment above. Refer to public attachment Heraeus Romania SRL_Public Cons. Ag CLH Proposal_11.12.2020_signed.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
11.12.2020	Germany	<confidential>	Company-Manufacturer	56
Comment received				
"<confidential> is a world leading company, providing, materials solutions for the packaging and component industry. These types of materials are used in electronics for consumer applications, industrial applications, automotive, aerospace, solar and wind energy. Due to high conductivity, stability and comparable low price, silver and silver alloys are base materials within the industry. We support the scientific comments submitted by the European Precious Metals Federation (EPMF). The proposed classification of silver as Reprotox. Cat 1 and Aquatic Acute 1 and Aquatic Chronic 1 for silver massive, might trigger restrictions/substitution for silver in future. Silver is a base material in electric and electronic equipment. It provides high conductivity, a good corrosion resistance. Therefore, silver guarantees low energy consumption and a longer life cycle of devices. When looking on alternatives, it becomes evident that these have inferior properties (non-precious metals) or are much more costly, not thinking about required quantities (other precious metals). The proposed classification will have severe influence on the future use of silver. Therefore, we require environmental classification according ECHA Guidelines – different classification of Ag massive and powder – and that other proposed classifications are based on hard and comprehensible scientific facts."				

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	France	ERCUIS	Company-Manufacturer	57
Comment received				
Dear Madam/Sir, We would like to comment on the Proposal for Harmonized Classification and Labelling for Silver (CAS 7440-22-4). We are FCM manufacturer and, alongside our products, we have several silverplated items, such as cutlery and holloware. Including silver and its compound in the REACH candidate list would heavily affect our business, since it is impossible to substitute silver with any other precious metal: sterling silver and silverplated items are used in cutlery and tableware since the beginning of time. Due to this impossible substitution, keeping the silverplated objects in our offer will result in a drastic increase of production costs to insure the food contact and safety compliance for both product and process. Costs increase are due to: - Labelling requirements - Migration tests - Risk assessment for health and safety - Worker's extra training - Worker relocation But the worst consequence will be the stigma effects, resulting from silver association with health hazards. We support the scientific comments submitted by the European Precious Metals Federation (EPMF). Key messages and arguments addressed in EPMF's comments: ECHA note – An attachment was submitted with the comment above. Refer to public attachment Consultation européenne sur l'argent ERCUIS_12-2020.pdf				

Date	Country	Organisation	Type of Organisation	Comment

				number
10.12.2020	Germany	SAXONIA Technical Materials GmbH	Company-Manufacturer	58
Comment received				
SAXONIA Technical Materials GmbH operating in Hanau (Germany) is a manufacturer of silver-based semi-finished materials with approx. 250 employees. These semi-finished materials are silver-based contact materials and brazing alloys, as they are used in e.g. electric contactors, relays, circuit breakers, automotive inverters (HEV, EV), electric motors and generators (wind power), vacuum interrupters, x-ray tubes by our downstream users. These semi-finished materials are manufactured via powder- and melting-metallurgical methods. Reduction or more precisely the minimization of silver used in above applications was major R&D focus over the last decade. A replacement of silver was executed wherever technically possible mainly due to cost reasons. However, a vast amount of silver is technically irreplaceable in electric industry sector due to the combination of high conductivity and low corrosion.				

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	59
Comment received				
I would like to refer to the document under "Public Attachment" ECHA note – An attachment was submitted with the comment above. Refer to public attachment HPM_RC_Public Cons. Ag CLH Proposal.docx				

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	Netherlands	Holland Water B.V.	Company-Downstream user	60
Comment received				
reference is made to attached le ECHA note – An attachment was submitted with the comment above. Refer to public attachment 201208_Public_Consultation_HW_comments_final.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	Germany	Doduco	Company-Manufacturer	61
Comment received				
DODUCO is operating following production sites with approx. 600 employees in Europe: Pforzheim (GER), Sinsheim (GER), Madrid (ESP), and Sibiu (ROU) DODUCO focuses on refining of precious metals (majority Silver) and – using refined materials as basis – the production of new value added semi-finished materials for use in electrical industry sector. These are Silver-based contact materials, contact parts and functional surfaces, as they are used in e.g. electric contactors, relays, circuit breakers, inverters, electric connectors, EV batteries by our downstream users. These semi-finished materials are manufactured via powder- and melting-metallurgical methods. Reduction or more precisely the minimization of Silver used in above applications was major R&D focus over the last decade. A replacement of Silver was executed wherever technically				

possible mainly due to cost reasons. However, a vast amount of Silver is technically irreplaceable in electric industry sector due to the combination of high conductivity and low corrosion.

Date	Country	Organisation	Type of Organisation	Comment number
09.12.2020	France	Comité Colbert	Industry or trade association	62

Comment received

Founded in 1954, the Comité Colbert is the French luxury association which gathers 85 French luxury houses, 16 cultural institutions and 6 European members.
Registered in the EU Transparency Register (62379572263-63), we are keen to participate in the EU decision making process and therefore provide input on EU consultations.

We represent 14 different sectors of activities, many of which use silver in their products (i.e. jewelry, silverware, cosmetics, etc.), and we are therefore happy to contribute to the public consultation on the silver metal CLH proposal.

In this context, the Comité Colbert wishes to state its full support to the comments of the European Precious Metals Federation (EPMF). We also wish to stress our concern that the classification proposals are often based on a low number of reliable information and are therefore lacking conclusive criteria.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment LT_Comité_Colbert_ECHA.pdf

Date	Country	Organisation	Type of Organisation	Comment number
08.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	63

Comment received

Heraeus Photovoltaic is the global market leader in the metallization paste business to metallize front and back sides of solar cells. Metallization with silver is the key process of todays and future green energy harvesting of solar cells. As silver being the metal with highest conductivity, it guarantees highest yield of energy. We support the scientific comments submitted by the European Precious Metals Federation (EPMF).
Generally, we would like to mention, that a classification according the CLH proposal, will provide a negative touch to all uses of silver, even if capsuled. People becoming aware, may refuse to buy or use articles containing silver. In case of photovoltaic industry there is a huge risk that this will lead to a drawback of the European Green Dial.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment HPT_Public Cons. Ag CLH Proposal_AH.pdf

Date	Country	Organisation	Type of Organisation	Comment number
03.12.2020	France		Individual	64

Comment received

Good Afternoon,
I do not hunderstand very well the differnts signification of the analyse for silver.

We do not know the level maxi of the classes.
It"s about 50 years I work the silver, I had never any problem with silver. I am 74 years and I have the best health.
Tank you to answere.
<confidential>

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	65

Comment received

Dear Madam/Sir,

These comments are submitted on behalf of company Metalor Technologies Electrotechnics (France) S.A.S.

We would like to comment on the Proposal for Harmonized Classification and Labelling for Silver (CAS
7440-22-4).

We use silver for the following activities:
• Refining of silver scrap which meets EU circular economy objectives
• Manufacturing of silver products:
o Silver bars for investment purposes
o Silver electrical contacts for several uses: automotive, medical, energy (silver panels),…
o Silver powders for technical applications
o Silver for jewelry
o Manufacturing of silver salts as silver nitrate, silver chloride,…

Regarding all our uses of silver and the quantities at more than 100 tonnes / year, silver is critical for our business and the different businesses of our customers.

Best regards,

<confidential>
Regulatory Affairs Cousel
<confidential>
Phone: <confidential>

CARCINOGENICITY

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Netherlands		MemberState	66

Comment received

The NL-CA agrees classification for carcinogenicity is not warranted because of inconclusive data. There are no studies with decent quality that assess the carcinogenic potency of silver compounds.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	67

Comment received
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachment in the questionnarie.docx

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France	MONNAIE DE PARIS	Company-Downstream user	68
Comment received				
Solid (massive) silver presents no carcinogenicity risks, as far as we know, and there is no scientific evidence showing the contrary. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 18 ECHA MdP 2020 survey CLH for Silver_VDEF.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
09.12.2020	France	Comité Colbert	Industry or trade association	69
Comment received				
We support the conclusions on page 120. ECHA note – An attachment was submitted with the comment above. Refer to public attachment LT_Comité_Colbert_ECHA.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	70
Comment received				
Carcinogenicity - never found nor observed in the <confidential>. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	71
Comment received				
-				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	72
Comment received				
none				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	73
Comment received				
We are not aware of any hazard originated my metalic silver and we have been using silver for a very long time.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	74
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany		MemberState	75
Comment received				
pages 111-120 We agree that data on silver and nanosilver are insufficient for classification, because of the low reliability of the respective animal studies. Read-across from silver-zinc-zeolite is not applicable. Therefore, classification is not possible.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	76
Comment received				
no comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	77
Comment received				
N/A				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC	Company-Manufacturer	78

		INDUSTRIES SAS		
Comment received				
No comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	79
Comment received				
see comment_CLH_silver_RAS_AG.pdf attached ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip				

MUTAGENICITY

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	WirtschaftsVereinigung Metalle	Industry or trade association	80
Comment received				
We think that the criteria for classifying silver as a germ cell mutagen have not been conclusively met as there is no direct human evidence that elemental silver (or ionic sil-ver) is able to induce heritable genetic mutations and the weight of evidence from a se-ries of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint. The proposed classification is based on low-reliability studies which are inadequate for classification purposes. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020-12-18_WVMetalle Comment on CLH Proposal for Silver.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	81
Comment received				
The criteria for classifying silver as a germ cell mutagen have not been conclusively met. Silver and nanosilver has been used for centuries and there is no direct evidence that silver induces heritable genetic mutations in humans. The CLH report refers to a number of low-reliability studies that did not conform to recognised test guideline. A number of studies with higher reliability do not support a classification of silver as a germ cell mutagen (see public attachment). ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United Kingdom	<confidential>	Company-Manufacturer	82
Comment received				
The criteria for classifying silver as a mutagen have not been conclusively met: • There appears to be rather a selective choice of data included in the CLH report that does not reflect the full dataset. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver products.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	83
Comment received				
To the best of our knwoledge the criteria for classifying silver as a germ cell mutagen have not been conclusively met: o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	aap Implantate AG	Company-Manufacturer	84
Comment received				
The criteria for classification as cell mutagen cannot be confirmed. ECHA note – An attachment was submitted with the comment above. Refer to public attachment aap Implantate AG_CLH_public_consultation_non-confidential_CAS 7440-22-4.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment aap Implantate AG_CLH_public_consultation_confidential_CAS 7440-22-4.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United Kingdom	Ames Goldsmith UK Ltd	Company-Manufacturer	85
Comment received				
• Germ cell mutagenicity - the criteria for classifying silver as a germ cell mutagen have not been conclusively met: o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and				

o the weight of evidence from a series of reliable studies – including in vivo models which cover
multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to
the proposed classification based on a number of low-reliability studies)

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	86
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland		Individual	87
Comment received				
• Germ cell mutagenicity - the criteria for classifying silver as a germ cell mutagen have not been conclusively met: ☐ there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and ☐ the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies) ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Bio-Gate AG	Company-Manufacturer	88
Comment received				
- the criteria for classifying silver as a germ cell mutagen have not been conclusively met: - there is no direct human evidence that elemental silver is able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and - the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies) - to use silver nitrate as a surrogate for metallic/elemental silver cannot be justified as silver nitrate and other silver types have a very different silver ion release profile than elemental silver, which as a precious metal releases a low amount silver ions. Please see attached a human study on bone cement with metallic/elemental silver where silver ions only have an effect in the viscinity of the bone cement. The elution profile and bioavailability of the generated silver ions is so low that it is not possible for the amount of silver ions to induce heritable genetic mutations.				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Bio-Gate Safety Studies.zip
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Bio-Gate Microsilver BG Confidential Safety Studies.zip

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	I&P Europe - Imaging and Printing Association e.V.	Industry or trade association	89
Comment received				
see attached document ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments to the silver metal CLH public consultation.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	90
Comment received				
no comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	<confidential>	Company-Manufacturer	91
Comment received				
o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France		MemberState	92
Comment received				
In agreement with the proposal of classification: Muta. 2, H341				

Date	Country	Organisation	Type of Organisation	Comment number

18.12.2020	Germany	ZVEI - German Electrical and Electronic Manufacturers' Association	Industry or trade association	93

Comment received

Germ cell mutagenicity - the criteria for classifying silver as a germ cell mutagen have not been conclusively met:
o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and
o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on several low-reliability studies)

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201218 ZVEI Silver Applications in EEE and Comments Ag CLH Consultation.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	C.HAFNER GmbH + Co. KG	Company-Manufacturer	94

Comment received

The criteria for classifying silver as a germ cell mutagen have not been conclusively met:
o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and
o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)
Please refer to the scientific comments submitted by the European Precious Metals Federation (EPMF).

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Belgium	European Precious Metals Federation (EPMF)	Industry or trade association	95

Comment received

Summary of comments on germ cell mutagenicity (CLH report p.72-111):
The criteria for classifying silver as a germ cell mutagen have not been conclusively met:
o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and
o the weight of evidence from a series of reliable studies - including in vivo models which cover multiple mutagenicity endpoints - support a non-classification for this endpoint (in contrast to the proposed classification based on a selective number of low-reliability studies).
For further details / justification, please refer to the attached document pages 20-33.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH Ag Comments FINAL_201217.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Netherlands		MemberState	96
Comment received				
The NL-CA supports classification for silver as mutagenic because there are numerous in vitro and in vivo mutagenicity studies that indicate genotoxicity after exposure to silver nanoparticles. Based on the studies and summaries in the section about germ cell mutagenicity, category 2 seems appropriate. However, it is noted that silver is able to reach the testis and cause adverse effects based on studies described in the sections about toxicokinetics and sexual function and fertility. In the latter section, there was also a study describing mutagenic effects in germ cells although this was after IV administration only. Please reflect if these studies together provide sufficient evidence for germ cell mutagenicity (category 1B).				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Netherlands	<confidential>	Company-Manufacturer	97
Comment received				
Germ cell mutagenicity - the criteria for classifying silver as a germ cell mutagen have not been conclusively met: * there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations. The same is true about useful data on somatic cell mutagenicity * the weight of evidence from a series of reliable studies support a non-classification for this endpoint				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	France	FRANCECLAT, BOCI and UFBJOP	Industry or trade association	98
Comment received				
Please find our comments on this specific hazard in the attached document. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments on CLH proposal for silver.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Fachvereinigung Edelmetalle e. V.	Industry or trade association	99
Comment received				
The criteria for classifying silver as a germ cell mutagen have not been conclusively met: o there is no direct human evidence that elemental silver, or ionic silver sub-stances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and o the weight of evidence from a series of reliable studies – including in vivo mod-els which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in				

contrast to the proposed classification based on a number of low-reliability studies)

ECHA note – An attachment was submitted with the comment above. Refer to public attachment FVEM comments CLH silver.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Federal Associations of the German Jewellery and Silverware Industry	Industry or trade association	100

Comment received

The criteria for classifying silver as a germ cell mutagen have not been conclusively met:
- there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and
- the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201216-comments-vbv-clh-silver.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	101

Comment received

no evidence

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachment in the questionnarie.docx

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	HAGER GROUP	Company-Downstream user	102

Comment received

Germ cell mutagenicity - the criteria for classifying silver as a germ cell mutagen have not been conclusively met:
o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and
o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)

ECHA note – An attachment was submitted with the comment above. Refer to public attachment CHL Ag- DU contribution- Hager group.docx

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Czech Republic	SAFINA, a.s.	Company-Manufacturer	103

Comment received
Please see the attached file. ECHA note – An attachment was submitted with the comment above. Refer to public attachment SAFINA_CLH public consultation_silver metal - completed.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Norway	<confidential>	Company-Manufacturer	104
Comment received				
The criteria for classifying silver as a germ cell mutagen have not been conclusively met: - there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity) - the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies) ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments CLH Ag -17.12.20.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Comments CLH Ag - <confidential> - 17.12.20 - confidential info.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Heimerle + Meule GmbH	Company-Manufacturer	105
Comment received				
The criteria for classifying silver as a germ cell mutagen have not been conclusively met: o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies) ECHA note – An attachment was submitted with the comment above. Refer to public attachment H+M comments CLH silver.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Siemens AG	Company-Manufacturer	106
Comment received				
Based on our assessment of the report and the discussion with industry experts, we think that the criteria for classifying silver as a germ cell mutagen have not been conclusively met, since there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity). Furthermore the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on several low-reliability studies).				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	<confidential>	Industry or trade association	107

Comment received

The criteria for classifying silver as a germ cell mutagen have not been conclusively met:
- there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and
- the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201214-<confidential>-clh-silver-comments.pdf

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Finland	<confidential>	Company-Manufacturer	108

Comment received

the criteria for classifying silver as a germ cell mutagen have not been conclusively met: there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations, and the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany		MemberState	109

Comment received

pages 72-111
There is a complex data situation with positive and negative results of in vitro and in vivo studies on nanosilver, silver salts, silver zinc (or copper) zeolite and Alphasan (silver sodium hydrogen zirconium phosphate). Assessing the data jointly results in an equivocal outcome. Thus, we agree that a WoE approach should be applied as the CLP guidance (2017) states: "In the case where there are also negative or equivocal data, a weight of evidence approach using expert judgement has to be applied."
The CLP guidance further states: "A complex data situation with positive and negative results might still lead to classification. This is because all tests detecting a certain type of mutation (e.g. point mutations) have been positive and all tests detecting chromosome mutations have been negative. Such circumstances clearly warrant classification although several tests have been negative which is plausible in this case. "
We suggests to apply a differentiated consideration of the individual silver species, nano particulate silver, ionic silver and silver in mixed materials (e.g. zeolites), as the toxicological results differ accordingly. In addition, we think that the read-across to the silver-containing biocidal active ingredients is not suitable, as they also contain other elements such as zinc or copper that may contribute to toxicity.

The individual consideration of silver species shows positive effects for in vitro MN, CA and comet assay, while reported negative outcomes were observed for surface modified silver nanoparticles. Silver in ionic form was reported predominantly with negative outcome.

In vivo studies show equivocal results with positive and negative reports.
In vivo CA tests were positive but some in vivo MN tests were negative. Moreover, some of the studies show deviations from OECD test guidelines.

Consequently, we conclude that the WoE justification in section 10.8.2. (Comparison with the CLP criteria) would justify the classification on Mutagenicity Cat. 2. However, it may be discussed whether some nanosilver species, e.g. those that are stably coated, and massive silver can be exempted.

Note: including the CLP guidance section on intraperitoneal application may be misleading, since there are oral studies, which were also considered for classification

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	110

Comment received

Germ cell mutagenicity - the criteria for classifying silver as a germ cell mutagen have not been conclusively met
o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity),
and
o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	111

Comment received

No comment

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	112

Comment received

see comment_CLH_silver_RAS_AG.pdf attached

ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Switzerland	Argor-Heraeus SA	Company-Manufacturer	113
Comment received				
Germ cell mutagenicity - the criteria for classifying silver as a germ cell mutagen have not been conclusively met o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Belgium	Umicore	Company-Manufacturer	114
Comment received				
Germ cell mutagenicity - the criteria for classifying silver as a germ cell mutagen have not been conclusively met: • there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and • the CLH proposal does not cite all relevant studies (in vivo / in vitro) • the majority of the genotoxicity studies are performed on AgNP (nanoparticles) and these studies often performed non-standardized testing. We are faced with the risk that non-reliable studies on AgNP will drive the full Ag mutagenicity profile. Moreover, there are certain read-across uncertainties between AgNP and more massive Ag forms, • the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies). ECHA note – An attachment was submitted with the comment above. Refer to public attachment Umicore public consultation_final 20201215.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	United Kingdom	AeroSpace and Defence (ASD) Industries Association of Europe	Industry or trade association	115
Comment received				
The criteria for classifying silver as a germ cell mutagen have not been conclusively met: • there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), • and the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint				

(in contrast to the proposed classification based on a number of low-reliability studies)

Date	Country	Organisation	Type of Organisation	Comment number
14.12.2020	France	<confidential>	Company-Manufacturer	116
Comment received				
The criteria for classifying silver as a germ cell mutagen have not been conclusively met: - there is no direct human evidence that ionic silver substances, or elemental silver, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and - a non-classification for this endpoint is supported by the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoint.				

Date	Country	Organisation	Type of Organisation	Comment number
11.12.2020	Germany	<confidential>	Company-Manufacturer	117
Comment received				
"Germ cell mutagenicity - the criteria for classifying silver as a germ cell mutagen have not been conclusively met o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)				

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	Germany	SAXONIA Technical Materials GmbH	Company-Manufacturer	118
Comment received				
elemental silver inducing heritable genetic mutations is not familiar to us, and the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)				

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	Germany	Doduco	Company-Manufacturer	119
Comment received				
no data showing direct human evidence that elemental silver is able to induce heritable genetic mutations is available				

Date	Country	Organisation	Type of Organisation	Comment number
09.12.2020	France	Comité Colbert	Industry or trade association	120
Comment received				

The criteria for classifying silver as a germ cell mutagen have not been conclusively met. There is currently no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations.
On the contrary, the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint.
Please refer to the EPMF full report for detailed analysis.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment LT_Comité_Colbert_ECHA.pdf

Date	Country	Organisation	Type of Organisation	Comment number
08.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	121

Comment received

Germ cell mutagenicity - the criteria for classifying silver as a germ cell mutagen have not been conclusively met
o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity),
and
o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)

ECHA note – An attachment was submitted with the comment above. Refer to public attachment HPT_Public Cons. Ag CLH Proposal_AH.pdf

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	122

Comment received

The criteria for classifying silver as a germ cell mutagen have not
been conclusively met:
o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and
o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	AURUBIS AG	Company-Manufacturer	123

Comment received

» Germ cell mutagenicity - the criteria for classifying silver as a germ cell mutagen have not been conclusively met:
- there is no direct human evidence that elemental silver, or ionic silver substances, are

able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and
- the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Aurubis comments to Silver CLH proposal 2020-12-18.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France	MONNAIE DE PARIS	Company-Downstream user	124
Comment received				
No evidence exists of direct human heritable genetic transformation or mutation. Studies even show no incidence. The classification under this risk would not be relevant to date. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 18 ECHA MdP 2020 survey CLH for Silver_VDEF.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United Kingdom	EU BPR Silver Task Force	Company-Downstream user	125
Comment received				
10.8 GERM CELL MUTAGENICITY (Sections 10.8.1 – 10.8.10 – CLH Report p.72-111 The proposed basis for the classification of silver as Muta. 2; H341 is dependent on conclusions from a number of low-reliability investigations of mammalian mutagenicity/genotoxicity for elemental and ionic silver forms. In addition, it does not properly take account of the weight of evidence from a series of reliable studies – including in vivo models that cover multiple mutagenicity endpoints – that have provided clear negative results. The classification proposal places undue emphasis on published studies on silver nano-materials. These investigations are of widely varying quality and they present contradictory results as to the genotoxicity potential of silver nano particles. Our view is that classification for mutagenicity cannot be assigned to metallic silver based on these nano silver data. For further information please refer to the attached document: Silver - STF comment on Muta 2 H341 - December 2020. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver - STF comment on Muta 2 H341 - December 2020.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	AZUR SPACE Solar Power GmbH	Company-Downstream user	126
Comment received				
The criteria for classifying silver as a mutagen have not been conclusively met: o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell				

mutagenicity), and
o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	127
Comment received				
Mutagenicity - never found nor observed in the Mint od Poland. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Austria	Wirtschaftskammer Österreich		128
Comment received				
see attachment ECHA note – An attachment was submitted with the comment above. Refer to public attachment su_309_StN öK Silber CLH.pdf				

TOXICITY TO REPRODUCTION

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	WirtschaftsVereinigung Metalle	Industry or trade association	129
Comment received				
We think that the criteria for classifying silver as a reproductive toxicant have not been conclusively met due to the very limited available human information that do not sup-port a classification. The key studies used in the read-across approach show several defi-ciencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. As-signment of a developmental toxicity classification for elemental silver is therefore premature. In agreement with the REACH regulation procedures and following the deci-sion at ECHA level in June 2019 EPMF is currently performing a TG443 compliant EOGRT study (including DIT and DNT cohorts) which is designed to fill the identified data gaps for this endpoint. The results of this study will allow a conclusive judgement for this end-point and should be waited for instead of starting a CLH discussion on silver now. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020-12-18_WVMetalle Comment on CLH Proposal for Silver.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	130
Comment received				
The criteria for classifying silver as a reproductive toxicant have not been conclusively met. The CLH report covers a very limited amount of data on reproductive toxicity in humans and				

does not support its classification for Cat. 1A. Additional reproductive toxicity investigations are needed to provide higher quality and information that is more robust.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United Kingdom	<confidential>	Company-Manufacturer	131
Comment received				
The criteria for classifying silver as a reproductive toxicant have not been conclusively met: • During ECHA's Testing Proposal Evaluation for reproductive toxicity endpoints (of the silver compounds REACH registrations) – which included consultation with MSCAs – it was decided that the Extended One Generation Reproductive Toxicity study (EOGRTs) was required to fill this datagap. This should be seen as a clear indication that this robust evaluation process determined insufficient reliable and relevant data were available to confirm classification or not. • Registrants have initiated work to meet the ECHA decision on the EOGRTs, which is a complex and expensive study to perform, with results to be provided by January 2022. • The evaluation of the proposed reproductive toxicity classification should preferably only be initiated once the data from this potentially definitive study, which to reiterate has been required following a regulatory decision under REACH, are available for consideration. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver products.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	132
Comment received				
To the best of our knwledge, the criteria for classifying silver as a reproductive toxicant have not been conclusively met: o the very limited available human data do not support a classification as reproductive toxicant, o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The Europea Precious Metals Federation (EPMF) is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	aap Implantate AG	Company-Manufacturer	133
Comment received				

The criteria for classification as toxic for reproduction cannot be confirmed.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment aap Implantate AG_CLH_public_consultation_non-confidential_CAS 7440-22-4.pdf
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment aap Implantate AG_CLH_public_consultation_confidential_CAS 7440-22-4.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United Kingdom	Ames Goldsmith UK Ltd	Company-Manufacturer	134

Comment received

• Reproductive toxicity - the criteria for classifying silver as a reproductive toxicant have not been conclusively met:
o the very limited available human data do not support a classification as reproductive toxicant,
o the strength of the evidence from animal studies do currently not provide clear evidence of
an adverse effect on sexual function/fertility, and
o the key studies used in a read-across approach show several deficiencies, uncertainties and
inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	135

Comment received

no evidence

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential>(003).docx

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland		Individual	136

Comment received

• Reproductive toxicity - the criteria for classifying silver as a reproductive toxicant have not been conclusively met:
☐ the very limited available human data do not support a classification as reproductive toxicant,
☐ the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and
☐ the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and

DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint.

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Bio-Gate AG	Company-Manufacturer	137

Comment received

- the criteria for classifying silver as a reproductive toxicant have not been conclusively met:
- the very limited available human data do not support a classification as reproductive toxicant,
- the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and
- the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint.
- when used in cosmetic applications metallic/elemental silver like MicroSilver BG it not able to penetrate the skin or mucosa tissue (please see attached studies on skin penetration), therefore an effect like reproductive toxicity is not possible
- to use silver nitrate as a surrogate for metallic/elemental silver cannot be justified as silver nitrate and other silver types have a very different silver ion release profile than elemental silver, which as a precious metal releases a low amount silver ions. Please see attached a human study on bone cement with metallic/elemental silver where silver ions only have an effect in the viscinity of the bone cement. The elution profile and bioavailability of the generated silver ions is so low that it is not possible for the amount of silver ions to induce reproductive toxicity.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Bio-Gate Safety Studies.zip
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Bio-Gate Microsilver BG Confidential Safety Studies.zip

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	I&P Europe - Imaging and Printing Association e.V.	Industry or trade association	138

Comment received

see attached document

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments to the silver metal CLH public consultation.pdf

Date	Country	Organisation	Type of Organisation	Comment number

18.12.2020	Belgium	T&D Europe	Industry or trade association	139
Comment received				
no comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Finland		MemberState	140
Comment received				
The dossier submitter proposes to classify silver Repr. 1B; H360F. We do not consider the data sufficient for Repr. 1B; H360F. Instead, it should be considered whether classification for Repr. 2; H361f is warranted for the substance. The proposal for Repr. 1B; 360F is primarily based on a few findings (reduced female fertility index, reduced number of implantations) in high dose animals of one one generation study with silver acetate (open literature publication). This study has major deficiencies. The two OECD guideline compliant two-generation studies with different silver containing active substances do not provide support for the findings of the one generation study. In our opinion, the justification for giving more weight on a few positive findings of the one-generation study and dismissing the negative findings of the two two-generation studies is insufficient. In the CLH-report the reproductive toxicity of the silver is assessed based on indirect information from studies performed with different silver containing active substances (SCAS) that release silver ions and studies on nanosilver. These include one-generation reproductive toxicity study with silver acetate (open literature publication, non GLP, according to FDA CFSAN Redbook, 2000), the two OECD TG 416 compliant two-generation studies performed with silver zinc zeolite and silver sodium zirconium hydrogenphosphate and open literature publications with nanosilver. In the CLH-report there is no reference for the publication of one generation study, but it appears to be Sprando RL et al. Silver acetate exposure: Effects on reproduction and post natal development. Food Chem Toxicol Aug; 106(PtA):547-557, 2017. We note that apparently before its publication the same data/study has been provided to EFSA for the Re-evaluation of silver (E 174) as food additive (EFSA Journal 2016;14(1):4364). Perhaps more detailed data than presented in the publication, could be available. The dossier submitter proposes to classify silver for Repr. 1B ;H360F on the basis of following findings: - The reduction of female fertility index (10%, not statistically analysed) and the statistically significant reduction of the number of implantations (22%, 11.3 compared to 14.4 in control) in high dose dams observed in the one generation study with silver acetate (IIIA 6.8.2-06). - Effects on spermatogenesis and number of spermatogenic cells and delay in onset of puberty in open literature studies with nanosilver. Female fertility index and the reduced number of implantations According to dossier submitter no statistical analyses has been performed on the female fertility index data and no individual animal data is available for the one-generation study with silver acetate. Moreover, several important parameters e.g. oestrus cyclicity, sperm parameters, histopathology of the reproductive organs (other than testes) have not been				

analysed in this study. It is therefore difficult to assess the toxicological significance of this result. The 10 % decrease in female fertility index is due to two dams which did not become pregnant i.e did not have implantation sites (two dams had total resorptions and did not produce litters). The difference in ability of males to produce litters between the control and the high dose group is small (16 high dose males produced litter vs. 17 control males). The data does not reveal the ability of high dose males to produce sperm that can fertilize egg (male fertility index) since implantations are not reported with respect to male data. According to publication testes weights were measured from all treatment groups and histopathology was analysed from 10 control and high dose individuals but there were no remarkable findings (it remains unclear whether testes were analysed histopathologically also from the pups). We note that this negative finding is not stated in the CLH-report.

No effects on fertily index or implantations are reported in the two-generation studies with silver sodium zirconium hydrogenphosphate and silver zinc zeolite. Only some findings of unknown significance are reported in these studies (e.g. changes in semen parameters, pre-coital interval of females, gestation length, the primordial follicle counts). The results of the two two generation studies therefore do not support the findings of the one generation study and classification for Repr. 1B; H360F.

The dossier submitter considers the two-generation studies most robust, but the classification proposal gives more weight for the one-generation study and the open literature studies with nanosilver. On pages 147- 148 of the CLH-report this is justified as follows: ”The data on silver zinc zeolite and silver sodium zirconium hydrogen phosphate are considered most robust but the substances also contain additional elements of possible toxicological significance and the amount of silver ions tested are limited by silver content and release. Therefore, data for a particular SCAS is not given precedence over another in this assessment, rather are positive findings noted for several SCAS given preference over negative results taking also into consideration silver content and release.”… “Although the estimated dose of silver ions tested actually was higher in the study with silver sodium hydrogen zirconium phosphate compared to the one-generation study with silver acetate, the latter was administered in drinking water and thus in ionic form compared to silver sodium hydrogen zirconium phosphate which was administered mixed in diet. Silver ions easily bind to thiol groups of proteins and the formation of different silver complexes with biomolecules may at least theoretically limit the availability of silver ions for absorption in the gastrointestinal tract.” We doubt whether this justification for dismissing the negative findings of two guideline compliant two-generation studies is appropriate. The justification seems to only be based on theoretical considerations, not on data on poorer bioavailability of silver ions in these studies. Therefore, the CLH-report seems to give preference for positive findings over negative findings without proper justification (e.g. reliability or relevance of the studies).

Effects on spermatogenesis and number of spermatogenic cells and delay in onset of puberty in open literature studies with nanosilver.
In the CLH report the results from several studies performed with nanosilver are considered to support an effect of silver ions on germ cells as they show a reduced number of sperm and alterations in sperm morphology (IIIB, 6.8.2-14, Miresmaeili et al., 2013; IIIB, 6.8.2-15, Baki, et al., 2014; IIIB, 6.8.2-17, Mathias et al., 2015; IIIB, 6.8.2-18, Thakur et al., 2014; IIIB, 6.8.2-19, Lafuente, et al., 2016; and Gromadzka-Ostrowska et al., 2012). The studies are not performed according to guidelines or the principles of GLP hence fewer animals and dose levels than required in guidelines were used in most of the studies. Therefore, as stated in the CLH-report it is difficult to assess the reliability and relevance of the results.

In conclusion, we dot not consider the data presented as clear evidence of an adverse effect on sexual function and fertility and thus sufficient to classification for Repr. 1B; 360F
Instead, it should be considered whether classification for Repr. 2; 360f is warranted.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	<confidential>	Company-Manufacturer	141
Comment received				
o the very limited available human data do not support a classification as reproductive toxicant, o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France		MemberState	142
Comment received				
In agreement with the proposal of classification: Repr. 1B, H360FD				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	ZVEI - German Electrical and Electronic Manufacturers' Association	Industry or trade association	143
Comment received				
The criteria for classifying silver as a reproductive toxicant have not been conclusively met: o the very limited available data on human toxicological investigations do not support a classification as reproductive toxicant, o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant Extended One-Generation Reproductive Toxicity Study (EOGRTS) (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified data gaps for this endpoint and will allow a conclusive judgement for this endpoint. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201218 ZVEI Silver Applications in EEE and Comments Ag CLH				

Consultation.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	C.HAFNER GmbH + Co. KG	Company-Manufacturer	144

Comment received

The criteria for classifying silver as a reproductive toxicant have not been conclusively met:
o the very limited available human data do not support a classification as reproductive toxicant,
o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and
o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint.

Please refer to the scientific comments submitted by the European Precious Metals Federation (EPMF).

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Belgium	European Precious Metals Federation (EPMF)	Industry or trade association	145

Comment received

Summary of comments on reproductive toxicity (CLH report p.121-194):
The criteria for classifying silver as a reproductive toxicant have not been conclusively met:
o the very limited available human data do not support a classification as reproductive toxicant,
o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and
o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a reprotoxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS with silver acetate (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified data gaps for this endpoint and will allow a conclusive judgement for this endpoint for ionic silver (with read-across to silver depending on ongoing TK studies). During ECHA's Testing Proposal Evaluation for reproductive toxicity endpoints – which included consultation with MSCAs – it was decided that the EOGRTS was required. This is a clear indication that this evaluation process determined insufficient reliable and relevant data were available to confirm classification or not.
For further details / justification, please refer to the attached document pages 34-47.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH Ag Comments FINAL_201217.pdf

Date	Country	Organisation	Type of Organisation	Comment number

17.12.2020	Netherlands		MemberState	146
Comment received				
1. Sexual function and fertility The dossier submitter proposes to classify silver for adverse effects on for sexual function and fertily in category 1B, with heavy weight to the data from the study with silver acetate. It is noted only the highest dose level caused some fertility parameters to be affected in the presence of other toxicity (significant organ weight changes). The adverse effects were limited to 10% lower fertility index and 22% fewer implantations. This study was not GLP compliant. The NL-CA considers there are some uncertainties related to the outcome of this study and therefore a classification in category 2 may be more appropriate based on this study alone. However, numerous other studies indicate silver (nanoparticles) cause changes in several sexual function related parameters (e.g. sperm). There is no confirmation if these findings lead to actual adverse effects on fertility apart from the study with silver acetate. Overall the NL-CA considers the body of evidence to indicate silver is likely to be able to cause adverse effects on sexual function and fertility with minor uncertainty. Classification for effects on sexual function and fertility in category 1B can therefore be supported. 2. Developmental toxicity We agree that there is sufficient evidence to fulfil the classification criteria for adverse effects on development category 1B. There is evidence of developmental toxicity as a result of exposure to a variety of silver containing substances, such as silver chloride, silver acetate, silver zinc zeolite, silver sodium zirconium hydrogenphospate and nanosilver. Some confounding effects such as differences in administration routes, duration of exposure and the presence of zinc or zirconium may have altered the study outcomes. Nevertheless, developmental toxicity, i.e. increased mortality rates of pups, chryptorchidism, and lower pup weights occurred in the majority of the described studies without relevant maternal toxicity. The proposed mechanism for toxicity is copper deficiency due to competitive binding of silver and copper for ceruloplasmin which seems plausible and increases the certainty silver is able to cause developmental toxicity. As this mechanism is considered to be relevant to humans, classification in category 1B is appropriate.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Netherlands	<confidential>	Company-Manufacturer	147
Comment received				
Reproductive toxicity - the criteria for classifying silver as a reproductive toxicant have not been conclusively met: * the very limited available human data do not support a classification as reproductive toxicant * the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility * the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS. The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint.				

Date	Country	Organisation	Type of Organisation	Comment number

17.12.2020	France	FRANCECLAT, BOCI and UFBJOP	Industry or trade association	148
Comment received				
Please find our comments on this specific hazard in the attached document. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments on CLH proposal for silver.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Fachvereinigung Edelmetalle e. V.	Industry or trade association	149
Comment received				
The criteria of classifying silver as a reproductive toxicant have not been consistenty met: o the very limited available human data do not support a classification as repro-ductive toxicant, o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclu-sive judgement for this endpoint. ECHA note – An attachment was submitted with the comment above. Refer to public attachment FVEM comments CLH silver.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Federal Associations of the German Jewellery and Silverware Industry	Industry or trade association	150
Comment received				
The criteria for classifying silver as a reproductive toxicant have not been conclusively met: - the very limited available human data do not support a classification as reproductive toxicant, - the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and - the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a develop-mental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201216-comments-vbv-clh-silver.pdf				

Date	Country	Organisation	Type of Organisation	Comment number

17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	151
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachment in the questionnarie.docx				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	HAGER GROUP	Company-Downstream user	152
Comment received				
Reproductive toxicity - the criteria for classifying silver as a reproductive toxicant have not been conclusively met: o the very limited available human data do not support a classification as reproductive toxicant, o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified data gaps for this endpoint and will allow a conclusive judgement for this endpoint. ECHA note – An attachment was submitted with the comment above. Refer to public attachment CHL Ag- DU contribution- Hager group.docx				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Czech Republic	SAFINA, a.s.	Company-Manufacturer	153
Comment received				
Please see the attached file. ECHA note – An attachment was submitted with the comment above. Refer to public attachment SAFINA_CLH public consultation_silver metal - completed.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Norway	<confidential>	Company-Manufacturer	154
Comment received				
The criteria for classifying silver as a reproductive toxicant have not been conclusively met: - the very limited available human data do not support a classification as reproductive toxicant, - the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility - the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint.				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments CLH Ag -17.12.20.pdf
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Comments CLH Ag - <confidential> - 17.12.20 - confidential info.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Heimerle + Meule GmbH	Company-Manufacturer	155

Comment received

The criteria of classifying silver as a reproductive toxicant have not been consistently met:
o the very limited available human data do not support a classification as reproductive toxicant,
o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and
o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified data gaps for this endpoint and will allow a conclusive judgement for this endpoint.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment H+M comments CLH silver.pdf

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Siemens AG	Company-Manufacturer	156

Comment received

Based on our assessment of the report and the discussion with industry experts, we think that the criteria for classifying silver as reproduction toxic have not been conclusively met. We would like to point out that the very limited available data on human toxicological investigations do not support a classification as reproductive toxicant. Further does the strength of the evidence from animal studies currently not provide clear evidence of an adverse effect on sexual function/fertility, and the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies. Hence we see the assignment of a developmental toxicity classification for elemental silver at this time as being premature.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	<confidential>	Industry or trade association	157

Comment received

The criteria for classifying silver as a reproductive toxicant have not been conclusively met:
- the very limited available human data do not support a classification as reproductive toxicant,
- the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and
- the key studies used in a read-across approach show several deficiencies, uncertainties

and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201214-<confidential>-clh-silver-comments.pdf

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Finland	<confidential>	Company-Manufacturer	158

Comment received

the criteria for classifying silver as a reproductive toxicant have not been conclusively met: the very limited available human data do not support a classification as reproductive toxicant, the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany		MemberState	159

Comment received

pages 121-194
The argumentation for the proposed classification for reproductive toxicity in Category 1B (H360FD) for silver and nanosilver [1-100nm] is not convincing.

No studies, in which the toxicity of elemental silver in massive or powder form was investigated, are available. The proposal is based on studies with silver containing active substances, silver salts and silver nanoparticles.

For classification, it has to be differentiated between the different forms releasing silver ions.
From our point of view, the read across to silver containing active substances is not justified because the substances contain additional elements of possible toxicological significance. For example, zinc may contribute to the developmental toxicity of silver zinc zeolite, which is classified for reproductive toxicity in Category 2 (H361d).
Read across to silver salts may be accepted as worst-case approach where the human health effects are caused by free silver ions. Release rates of silver ions can be expected to differ significantly between elemental, silver in massive or powder form and silver nanoparticles. The solubility of the silver nanoparticles is orders of magnitude higher. Therefore, a read across to silver nanoparticles would also be a worst-case approach.

Due to the large database, only studies discussed by the dossier submitter as relevant for classification were checked in detail. The following issues should be considered when deciding on classification:

a) effects on fertility

The proposed classification for effects on fertility (Repr. 1B, H360F) is based on the reduction of the fertility index (10%) and reduced number of implants (22%) observed in a published study after oral application of 40 mg/kg bw/d silver acetatecitrate (equivalent to 25 mg silver ion/kg bw/d) via drinking water in rats (Sprando et al., 2017). According to the dossier submitter, these findings are supported by various published studies regarding effects of silver nanoparticles on the male reproductive system in rats after oral exposure (gavage).

From our point of view, the small reduction of the fertility index (10%) could be an incidental finding. Are you aware of any historical control data that might be helpful for the assessment of the reduced fertility index and the reduced implantation numbers?

Furthermore, we ask, how the reduced number of implants was interpreted by the dossier submitter. Should this be an indication of pre-implantation loss? If yes, the number of corpora lutea is necessary to calculate the pre-implantation loss. Please note that the observed increased pre-implantation loss in the published study with silver nanoparticles by Yu et al. (2013) should not be regarded as treatment-related because the test material was administered after implantation.

Due to the large database for silver nanoparticles, a detailed examination could not be carried out. However, it is evident that the presented studies with silver nanoparticles are not performed in accordance with test guidelines and GLP principles. Moreover, detailed information on the nanomaterial is lacking in the publications (e.g. regarding the degree of purity). In some publications, only one dose was tested (e.g. Castellini et al. 2014), or clear dose-response relationships were missing (e.g. Gromadzka-Ostrowska et al. 2012), or animal observations were not reported (e.g. Miresmaeili et al. 2013). Additionally, different types of silver nanoparticles have been used in these studies. It has to be mentioned that the amount of silver ions released from the nanoparticles depends among other things on the surface coating. The silver ion exposure in the studies with silver nanoparticles is unclear. Other factors of possible toxicity should also be considered, e.g. translocation of silver nanoparticles and subsequent release of free silver ions or the formation of reactive oxygen species caused by nanoparticles in general compared to elemental silver in massive or powder form.
Altogether, this raises some questions to the relevance of the published studies with silver nanoparticles for classification of silver regarding effects on fertility.
Please note that the observed increased pre-implantation loss in the published study with silver nanoparticles by Yu et al. (2013) should not be regarded as treatment-related because the test material was administered after implantation. Finally, the dossier submitter argues that classification in category 1A based on evidence from humans is not possible since such data is not available (see report on p. 150). However, argyria is a known disease which occurred in humans after prolonged exposure to silver. Does this mean that even in persons sick from argyria no impairment of fertility has been reported? If this is the case, one could possibly argue that this lack of evidence should give rise to doubts to propose for (nano)silver classification in category 1B based on animal data.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	160
Comment received				
Reproductive toxicity - the criteria for classifying silver as a reproductive toxicant have not				

been conclusively met:
o the very limited available human data do not support a classification as reproductive toxicant,
o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and
o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified data gaps for this endpoint and will allow a conclusive judgement for this endpoint.

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	161
Comment received				
No comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	162
Comment received				
see comment_CLH_silver_RAS_AG.pdf attached ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Switzerland	Argor-Heraeus SA	Company-Manufacturer	163
Comment received				
Reproductive toxicity - the criteria for classifying silver as a reproductive toxicant have not been conclusively met: o the very limited available human data do not support a classification as reproductive toxicant, o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified data gaps for this endpoint and will allow a conclusive judgement for this endpoint.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Belgium	Umicore	Company-Manufacturer	164
Comment received				
Reproductive toxicity - the criteria for classifying silver as a reproductive toxicant have not been conclusively met: • human evidence is limited available but does not support a classification as reproductive toxicant, • the strength of the evidence from animal studies does currently not provide clear evidence of an adverse effect on sexual function/fertility, and • the key studies used in the read-across approach are not reliable, as outlined in EPMF's detailed comments. • EPMF is currently performing a TG443 compliant EOGRTS under EU REACH (including DIT and DNT cohorts). The study is designed to fill the identified data gaps for this endpoint and will allow a conclusive judgement for this endpoint. • Moreover, the bio-availability of silver metal is not taken into account in the CLH proposal. EPMF is performing a toxicokinetic study with the anticipated outcome that silver metal could be differentiated from the other silver substances ECHA note – An attachment was submitted with the comment above. Refer to public attachment Umicore public consultation_final 20201215.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	United Kingdom	AeroSpace and Defence (ASD) Industries Association of Europe	Industry or trade association	165
Comment received				
The criteria for classifying silver as a reproductive toxicant have not been conclusively met since the very limited available human data does not support a classification as reproductive toxicant, the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility and the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined by the European Precious Metals Federation (EPMF). Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS under EU REACH including developmental immunotoxicity & developmental neurotoxicity (DIT and DNT) cohorts. The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint.				

Date	Country	Organisation	Type of Organisation	Comment number
14.12.2020	France	<confidential>	Company-Manufacturer	166
Comment received				
The criteria for classifying silver as a reproductive toxicant have not been conclusively met: - the classification as reproductive toxicant is not supported by the very limited available human data,				

- currently no strong proof for a negative impact on sexual function and fertility can be deducted from animal studies, and,
- as discussed in EPMF's detailed comments the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies. From the actually existing data for elemental silver an assignment of a developmental toxicity classification for elemental silver is premature and we strongly recommend to wait for the results of the TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts), performed by the EPMF. The study has been designed to fill the identified datagaps for this endpoint and the results will lead to a secured judgement for this endpoint.

Date	Country	Organisation	Type of Organisation	Comment number
11.12.2020	Germany	<confidential>	Company-Manufacturer	167

Comment received

"Reproductive toxicity - the criteria for classifying silver as a reproductive toxicant have not been conclusively met:
o the very limited available human data do not support a classification as reproductive toxicant,
o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and
o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified data gaps for this endpoint and will allow a conclusive judgement for this endpoint."

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	France	ERCUIS	Company-Manufacturer	168

Comment received

Reproductive toxicity - the criteria for classifying silver as a reproductive toxicant have not been conclusively met:
• the very limited available human data do not support a classification as reproductive toxicant,
• the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and
• the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Consultation européenne sur l'argent ERCUIS_12-2020.pdf

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	Germany	SAXONIA Technical Materials GmbH	Company-Manufacturer	169

Comment received
SAXONIA supports EPMF's currently performed TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	Germany	Doduco	Company-Manufacturer	170
Comment received				
very limited available human data do not support a classification as reproductive toxicant also strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility therefore Doduco is supporting the actual EPMF TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts)				

Date	Country	Organisation	Type of Organisation	Comment number
09.12.2020	France	Comité Colbert	Industry or trade association	171
Comment received				
The very limited human data available do not support a classification as reproductive toxicant. The results from animal studies neither provide clear evidence of an adverse effect on sexual function/fertility. Furthermore, the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Therefore the assignment of a developmental toxicity classification for elemental silver is not relevant at this stage. ECHA note – An attachment was submitted with the comment above. Refer to public attachment LT_Comité_Colbert_ECHA.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
08.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	172
Comment received				
Reproductive toxicity - the criteria for classifying silver as a reproductive toxicant have not been conclusively met: o the very limited available human data do not support a classification as reproductive toxicant, o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified data gaps for this endpoint and will allow a conclusive judgement for this endpoint.				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment HPT_Public Cons. Ag CLH Proposal_AH.pdf

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	173
Comment received				
The criteria for classifying silver as a reproductive toxicant have not been conclusively met: o the very limited available human data do not support a classification as reproductive toxicant, o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility,				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	AURUBIS AG	Company-Manufacturer	174
Comment received				
» Reproductive toxicity - the criteria for classifying silver as a reproductive toxicant have not been conclusively met: - the very limited available human data do not support a classification as reproductive toxicant, - the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and - the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified data gaps for this endpoint and will allow a conclusive judgement for this endpoint ECHA note – An attachment was submitted with the comment above. Refer to public attachment Aurubis comments to Silver CLH proposal 2020-12-18.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France	MONNAIE DE PARIS	Company-Downstream user	175
Comment received				
Not enough data available. Studies still ongoing according to EPMF european precious metals federation.The classification under this risk would not be relevant to date. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 18 ECHA MdP 2020 survey CLH for Silver_VDEF.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United Kingdom	EU BPR Silver Task Force	Company-Downstream user	176
Comment received				

10.10 REPRODUCTIVE TOXICITY (Sections 10.10.1 – 10.10.10, p. 121-194
The proposed basis for the classification of silver as Repr. 1B; H360 FD is not supported by an adequate weight of evidence when considered in the context of the CLP criteria for this endpoint. The classification proposal places undue emphasis on published studies on silver nano-materials. These investigations are of widely varying quality and they present contradictory results as to the reproductive toxicity potential of silver nano particles. Our view is that classification for reproductive effects cannot be assigned to metallic silver based on these nano silver data. For further information please refer to the attached document: Silver - STF comment on Repr 1B H360 - December 2020.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver - STF comment on Repr 1B H360 - December 2020.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	AZUR SPACE Solar Power GmbH	Company-Downstream user	177
Comment received				
The criteria for classifying silver as a reproductive toxicant have not been conclusively met: o the very limited available human data do not support a classification as reproductive toxicant, o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint. We promote to wait for its results and continue the clascification process then.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	178
Comment received				
Reproductive toxicity - never found nor observed in the <confidential>. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Austria	Wirtschaftskammer Österreich		179
Comment received				
see attachment ECHA note – An attachment was submitted with the comment above. Refer to public attachment su_309_StN öK Silber CLH.pdf				

RESPIRATORY SENSITISATION

Date	Country	Organisation	Type of Organisation	Comment

				number
18.12.2020	Italy	<confidential>	Company-Manufacturer	180
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx				

Date	Country	Organisation	Type of Organisation	Comment number
09.12.2020	France	Comité Colbert	Industry or trade association	181
Comment received				
We support the conclusions on page 61. ECHA note – An attachment was submitted with the comment above. Refer to public attachment LT_Comité_Colbert_ECHA.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	182
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachment in the questionnarie.docx				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	183
Comment received				
no comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany		MemberState	184
Comment received				
pages 59-61 We agree with the dossier submitter that no conclusion on classification is possible due to inconclusive data. The comparison with the CLP criteria makes clear that the provided human data from the two reported cases using colloidal silver nasal drops/spray is too weak evidence for respiratory sensitisation caused by silver, taking into account that the protein vehicle is also likely to induce an immune response.				

Date	Country	Organisation	Type of Organisation	Comment number

18.12.2020	Poland	<confidential>	Company-Manufacturer	185
Comment received				
Respiratory Sensitisation - never found nor observed in the <confidential>. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	186
Comment received				
N/A				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	187
Comment received				
No comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	188
Comment received				
see comment_CLH_silver_RAS_AG.pdf attached ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip				

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	189
Comment received				
-				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	190
Comment received				

none ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	191
Comment received				
We are not aware of any hazard originated my metalic silver and we have been using silver for a very long time.				

OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	192
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachment in the questionnarie.docx				

Date	Country	Organisation	Type of Organisation	Comment number
09.12.2020	France	Comité Colbert	Industry or trade association	193
Comment received				
We support the conclusions on page 61. ECHA note – An attachment was submitted with the comment above. Refer to public attachment LT_Comité_Colbert_ECHA.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	AZUR SPACE Solar Power GmbH	Company-Downstream user	194
Comment received				
The criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: o the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and o silver massive should not be classified.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	195
Comment received				
Acute toxicity - never found nor observed in the <confidential>. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	196
Comment received				
-				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	197
Comment received				
none ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	198
Comment received				
We are not aware of any hazard originated my metalic silver and we have been using silver for a very long time.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	aap Implantate AG	Company-Manufacturer	199
Comment received				
The criteria for classification as acute toxic cannot be confirmed. ECHA note – An attachment was submitted with the comment above. Refer to public attachment aap Implantate AG_CLH_public_consultation_non-confidential_CAS 7440-22-4.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment aap Implantate AG_CLH_public_consultation_confidential_CAS 7440-22-4.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	200
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany		MemberState	201
Comment received				
pages 46-56				

Oral: The study/studies relevant for (no) classification were not made clear when comparing with the CLP criteria. However, based on the rat study IIIA 6.1.1-14 (OECD TG 423) with LD50 >2000 mg/kg bw using nanosilver, we agree with the decision no classification for acute oral toxicity.
Dermal: Based on the study with nanosilver IIIA 6.1.2-09 (OECD TG 402) with LD50 >2000 mg/kg bw in rats, we agree with the decision of no classification for acute dermal toxicity.
Inhalation: The dossier submitter stated: "The information in this table is based on information available from the lead registration dossier submitted under REACH. The original study reports are not available to the dossier submitter thus the information cannot be verified." Based on the rat study summary with silver powder from the REACH dossier (OECD TG 436) with LD50 >5.16 mg/L air, we agree with the decision of no classification for acute inhalation toxicity. However, this decision should be based on the original study report.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	202
Comment received				
no comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	203
Comment received				
N/A				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	204
Comment received				
No comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	205
Comment received				
see comment_CLH_silver_RAS_AG.pdf attached				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip

OTHER HAZARDS AND ENDPOINTS – Skin Hazard

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	Germany	SAXONIA Technical Materials GmbH	Company-Manufacturer	206
Comment received				
silver causing skin sensitisation is not known to us based on decades of manufacturing silver based products incl. regular medical check-up of our employees				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	207
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachment in the questionnarie.docx				

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	Germany	Doduco	Company-Manufacturer	208
Comment received				
we are working with silver over 100 years, and even intensive medical check-ups on our workers over the last decades didn't reveal any evidence that silver causes skin sensitisation				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France	MONNAIE DE PARIS	Company-Downstream user	209
Comment received				
Skin corrosion for end user also is not showed and even less proved. There are no clinical cases known. The classification under this risk would not be relevant to date. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 18 ECHA MdP 2020 survey CLH for Silver_VDEF.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
09.12.2020	France	Comité Colbert	Industry or trade association	210
Comment received				
We support the conclusions on page 57. ECHA note – An attachment was submitted with the comment above. Refer to public				

attachment LT_Comité_Colbert_ECHA.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	211
Comment received				
Skin corrosion/irritation - never found nor observed in the <confidential>. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Austria	Wirtschaftskammer Österreich		212
Comment received				
see attachment ECHA note – An attachment was submitted with the comment above. Refer to public attachment su_309_StN öK Silber CLH.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	213
Comment received				
-				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	214
Comment received				
none ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	215
Comment received				
We are not aware of any hazard originated my metalic silver and we have been using silver for a very long time.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Siemens AG	Company-Manufacturer	216
Comment received				
Based on our assessment of the report and discussions with industry experts we like to point out that, we see the criteria for classification as a skin sensitizer as not fulfilled.				

There's no reliable human evidence showing that silver causes skin sensitization and a high number of animal studies with a variety of chemical forms of ionic silver show non-sensitizing potential of silver (note that the animal dataset in the CLH report is incomplete).

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	217

Comment received

no evidence

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland		Individual	218

Comment received

We support the scientific comments submitted by the European Precious Metals Federation (EPMF). Key messages and arguments addressed in EPMF's comments:
• Skin sensitisation - the criteria for classification as a skin sensitiser are not fulfilled:
☐ reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and
☐ a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete).

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	I&P Europe - Imaging and Printing Association e.V.	Industry or trade association	219

Comment received

see attached document

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments to the silver metal CLH public consultation.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	220

Comment received

no comment

ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	221
Comment received				
N/A				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	222
Comment received				
No comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	223
Comment received				
see comment_CLH_silver_RAS_AG.pdf attached ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip				

OTHER HAZARDS AND ENDPOINTS – Eye Hazard

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	224
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx				

Date	Country	Organisation	Type of Organisation	Comment number
09.12.2020	France	Comité Colbert	Industry or trade association	225
Comment received				
We support the conclusions on page 59. ECHA note – An attachment was submitted with the comment above. Refer to public attachment LT_Comité_Colbert_ECHA.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	226
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachment in the questionnarie.docx				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	227
Comment received				
no comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany		MemberState	228
Comment received				
pages 58-59 The dossier submitter concluded that based on the results from eye irritation studies performed with nanosilver, silver does not fulfil criteria for classification. However, it was stated that in the respective rabbit study IIIA 6.1.4-20, the applied dose was only 0.1 mg, which is much lower than 100 mg as recommended in the OECD TG 405. In contrast, the detailed study report states that 100 mg of the test material was applied, which, however, contained only 20.48 % silver. Therefore, it is unclear if eye irritation could be induced by applying the dose recommended in the OECD TG. Reliability of the two supportive studies from the REACH dossier is not given. Furthermore, dosing was not according to OECD TG for one supportive study and was not given for the other. Therefore, based on the information provided in the CLH report classification is not possible instead of "no classification"				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	229
Comment received				
Serious eye damage/eye irritation - never found nor observed in the <confidential>. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH	Company-Manufacturer	230

		& Co. KG		
Comment received				
N/A				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	231
Comment received				
No comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	232
Comment received				
see comment_CLH_silver_RAS_AG.pdf attached ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip				

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	233
Comment received				
-				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	234
Comment received				
none ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	235
Comment received				
We are not aware of any hazard originated my metalic silver and we have been using silver for a very long time.				

OTHER HAZARDS AND ENDPOINTS – Skin Sensitisation Hazard

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	WirtschaftsVereinigung Metalle	Industry or trade association	236
Comment received				
We think that the criteria for classification as a skin sensitiser are not fulfilled as reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking. In addition, a high number of animal studies with a variety of chemi-cal forms of ionic silver show non-sensitising potential of silver. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020-12-18_WVMetalle Comment on CLH Proposal for Silver.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	237
Comment received				
The criteria for classifying silver as a skin sensitizer are not fulfilled. Silver and nanosilver has been used for centuries without observing a sensitising effect in a significant number of people. Also, the CLH report is incomplete, excluding a high number of studies about silver and nanosilver, showing a non-sensitising effect. Respective research performed by our network partners and others can be found in the public attachment. ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United Kingdom	<confidential>	Company-Manufacturer	238
Comment received				
The criteria for classification as a skin sensitiser are not fulfilled: • Reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking and in fact, across three of our European sites that have handled silver powder (and its compounds) for between 25 and 40 years, although only directly involving 5-10 employees at any one time, we have not had any reports of sensitisation or other adverse health effects associated with silver powder handling in our workforce. • A high number of animal studies with a variety of chemical forms of ionic silver show non-sensitising potential of silver (note that the animal dataset in the CLH report is incomplete). ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver products.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	239
Comment received				

As far as we know, the criteria for classification of silver as a skin sensitiser are not fulfilled:
o reliable human evidence showing that silver causes skin sensitisation in a substantial number
of persons is lacking, and
o a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete).

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	aap Implantate AG	Company-Manufacturer	240
Comment received				
The criteria for the classification as skin sensitizing cannot be confirmed. ECHA note – An attachment was submitted with the comment above. Refer to public attachment aap Implantate AG_CLH_public_consultation_non-confidential_CAS 7440-22-4.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment aap Implantate AG_CLH_public_consultation_confidential_CAS 7440-22-4.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United Kingdom	Ames Goldsmith UK Ltd	Company-Manufacturer	241
Comment received				
• Skin sensitisation - the criteria for classification as a skin sensitiser are not fulfilled: o reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete).				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	242
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Bio-Gate AG	Company-Manufacturer	243
Comment received				
- reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and - a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete).				

- Several studies with metallic silver containing cosmetics show that silver in cosmetics improves the appearance of the skin and does lead to side effects. Please see attached study: Müller-Steinmann et al., Prospective dermatologically controlled study of the efficacy of a silver
containing nurturing cream (MicroSilver BG™ 0.1%) in atopic dermatitis, Kosmetische Medizin – Cosmetic Medicine
28., Issue 4, 2008, ISSN 1430-4031.
- there are almost no publications available regarding skin issues with metallic silver. Please see attached publication "Group A., Lea A., Contact Dermatitis With a Highlight on Silver: A Review, WOUNDS 2010;22(12): 311–315" that shows that there are only a handful of reported skin irritations which where mostly caused by silver nitrate and not pure metallic silver. In comparison there is huge amount of publications on pubmed that mention skin issues with copper, and there is also a whole book available: Copper and the Skin by Jurij Hostynek and Howard Maibach (2006, CRC Press, ISBN: 978-1-4200-0943-9)

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Bio-Gate Safety Studies.zip
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Bio-Gate Microsilver BG Confidential Safety Studies.zip

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	244
Comment received				
no comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	<confidential>	Company-Manufacturer	245
Comment received				
o reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete).				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France		MemberState	246
Comment received				
In agreement with the proposal of classification: Skin Sens. 1, H317				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	ZVEI - German	Industry or trade	247

		Electrical and Electronic Manufacturers' Association	association	

Comment received

The criteria for classification as a skin sensitiser are not fulfilled:
o reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and
o a high number of animal studies with a variety of chemical forms of ionic silver show non-sensitising potential of silver (note that the animal dataset in the CLH report is incomplete).

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201218 ZVEI Silver Applications in EEE and Comments Ag CLH Consultation.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	C.HAFNER GmbH + Co. KG	Company-Manufacturer	248

Comment received

The criteria for classification as a skin sensitiser are not fulfilled:
o reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and
o a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete).
Please refer to the scientific comments submitted by the European Precious Metals Federation (EPMF).

Recycling, processing and uses of silver containing materials are well known for many centuries. Over the whole period of time there was no evidence of skin sensitization caused by silver at the exposed worker or consumers.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Belgium	European Precious Metals Federation (EPMF)	Industry or trade association	249

Comment received

Summary of comments on skin sensitisation (CLH report p.62-71):
The criteria for classification of silver as a skin sensitiser are not fulfilled:
o reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and
o a high number of animal studies with a variety of chemical forms of ionic silver show non-sensitising potential of silver (note that the animal dataset in the CLH report is incomplete).
For further details / justification, please refer to the attached document pages 12-19.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH Ag Comments FINAL_201217.pdf

Date	Country	Organisation	Type of Organisation	Comment

				number
17.12.2020	Netherlands		MemberState	250
Comment received				
The dossier submitter proposes a classification for skin sens.1 based on a weight of evidence approach where the individual data have clear limitations. We can agree the skin reactions graded 0.5 in the animal study are likely similar as grade 1 in the OECD test guideline. However, there is some uncertainty. The level of positive response compared to the controls are very limited and considering the limitations of the study due to the scoring and irritating concentrations used and the high background level, it can hardly be taken into account. A limited number of human case reports indicate the ionic form of silver may be sensitizing. However, the number of case reports and limited detailed information are hardly sufficient evidence for classification as a skin sensitizer for silver. More importantly, skin sensitisation is a local effect, therefore it seems inappropriate to classify the natural solid form of silver for skin sensitization based on data with the ionic form of silver. The limited data suggests the ionic form may have some skin sensitization potential. Therefore it is necessary to assess whether skin contact to silver will lead to sufficient local exposure of the ionic form, which is not justified in the dossier. Sufficient exposure to the ionic form does not seem very likely after dermal contact to the solid form of silver. In addition, solid silver is frequently used in jewelry and there does not seem to be any data or case reports that indicate (solid) silver causes dermal sensitization reactions. Overall, the NL-CA does not agree to propose classification for silver as a sensitiser (category 1).				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Netherlands	<confidential>	Company-Manufacturer	251
Comment received				
For the coin industry, silver coins are stored in a plastic capsule. People do not touch them with their hands. Also, proof quality coins are only touched with gloves. Skin sensitisation - the criteria for classification as a skin sensitiser are not fulfilled: * reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking * a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	France	FRANCECLAT, BOCI and UFBJOP	Industry or trade association	252
Comment received				
Please find our comments on this specific hazard in the attached document. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments on CLH proposal for silver.pdf				

Date	Country	Organisation	Type of Organisation	Comment number

17.12.2020	Germany	Fachvereinigung Edelmetalle e. V.	Industry or trade association	253
Comment received				
The criteria for classification of silver as a skin sensitiser are not fulfilled: o reliable human evidence showing that silver causes skin sensitisation in a sub-stantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete). o The recycling and processing of material flows containing silver (including met-allurgical enrichment, chemical processing, melting of Ag or Ag alloys, machin-ing of Ag or Ag alloys) shows no conspicuousness in the hazard analysis after approx. 250 years of production experience with regard to skin irritation or al-lergic reactions. Occupational medical check-ups are inconspicuous and have not led to any occupational group-specific impairment. ECHA note – An attachment was submitted with the comment above. Refer to public attachment FVEM comments CLH silver.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Federal Associations of the German Jewellery and Silverware Industry	Industry or trade association	254
Comment received				
The criteria for classification as a skin sensitiser are not fulfilled: - reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and - a high number of animal studies with a variety of chemical forms of ionic silver show non-sensitising potential of silver (note that the animal dataset in the CLH report is in-complete). ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201216-comments-vbv-clh-silver.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	255
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachment in the questionnarie.docx				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	HAGER GROUP	Company-Downstream user	256
Comment received				
Skin sensitisation - the criteria for classification as a skin sensitiser are not fulfilled: o reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and				

o a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete).

ECHA note – An attachment was submitted with the comment above. Refer to public attachment CHL Ag- DU contribution- Hager group.docx

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Czech Republic	SAFINA, a.s.	Company-Manufacturer	257
Comment received				
Please see the attached file. ECHA note – An attachment was submitted with the comment above. Refer to public attachment SAFINA_CLH public consultation_silver metal - completed.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Norway	<confidential>	Company-Manufacturer	258
Comment received				
The criteria for classification as a skin sensitiser are not fulfilled: - reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking - a high number of animal studies with a variety of chemical forms of ionic silver show non sensitising potential of silver ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments CLH Ag -17.12.20.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Comments CLH Ag - <confidential> - 17.12.20 - confidential info.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Heimerle + Meule GmbH	Company-Manufacturer	259
Comment received				
The criteria for classification of silver as a skin sensitizer are not fulfilled: o reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show non-sensitising potential of silver (note that the animal dataset in the CLH report is incomplete). o The recycling and processing of material flows containing silver (including metallurgical enrichment, chemical processing, melting of Ag or Ag alloys, machining of Ag or Ag alloys) shows no conspicuousness in the hazard analysis after approx. 250 years of production experience with regard to skin irritation or allergic reactions. Occupational medical check-ups are inconspicuous and have not led to any occupational group-specific impairment. ECHA note – An attachment was submitted with the comment above. Refer to public attachment H+M comments CLH silver.pdf				

Date	Country	Organisation	Type of Organisation	Comment number

16.12.2020	Germany	<confidential>	Industry or trade association	260
Comment received				
The criteria for classification as a skin sensitiser are not fulfilled: - reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and - a high number of animal studies with a variety of chemical forms of ionic silver show non-sensitising potential of silver (note that the animal dataset in the CLH report is incomplete). ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201214-<confidential>-clh-silver-comments.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Finland	<confidential>	Company-Manufacturer	261
Comment received				
the criteria for classification as a skin sensitiser are not fulfilled: reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and a high number of animal studies with a variety of chemical forms of ionic silver show non-sensitising potential of silver and the animal dataset in the CLH report is incomplete				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany		MemberState	262
Comment received				
pages 62-71 The dossier submitter concluded classification of silver as Skin Sens. Cat. 1 based on a WoE approach, taking into account human data (case reports primarily for silver nitrate) and two positive Buehler assays (OECD 406 or US-EPA guideline) using silver citrate/laurate solution or silver zeolite. The positives rates from the Buehler tests would allow classification, however, the relatively high rates in the negative controls, the low score of the graded reactions and the presence of citrate/laureate or zeolite limit the significance of the positive results. Effects were seen predominantly with formulations containing silver ions, which appear to permit a more reliable skin exposure, rather than studies with nanosilver. Therefore, the negative result in the GPMT using nanosilver was given lower priority. These issues were discussed comprehensively by the dossier submitter and consequently the WoE approach including the human data was applied. The human data are derived from a book chapter summarising eight case reports, six on silver nitrate and two on colloidal silver. The wording in the summary table indicates a true allergic response in only three of the reports on silver nitrate (Gaul and Underwood, 1948; Agarwal and Gawkrodger, 2002; Fisher, 1987). We agree with the decision of choosing the WoE approach. However, the applied criteria for the final decision for classification are not completely clear. It is not clear, whether criteria of Annex I/3.4.2.2.4.1 were dismissed in place of the criteria of Annex I/3.4.2.2.4.3. We would conclude, that criteria of Annex I/3.4.2.2.4.1 are not met, since the animal data (c) alone are not sufficient for the WoE as they were not considered for classification in the first place and the few episodes of allergic contact dermatitis (e) are not well documented. As for Annex I/3.4.2.2.4.3., we agree that basically the criteria (a) and (e) are fulfilled. However, the data basis of a single book chapter is unsatisfactory. Original study reports of the book chapter were not evaluated. Regarding the frequent exposure by wound dressings and the use of colloidal silver in large area burn injuries in relation to few cases of silver allergy,				

classification should be considered only on a more comprehensive data basis.

In case categorisation for skin sensitisation is taken into consideration, we agree that data on frequency and exposure would be insufficient for sub-categorisation.
However, the human evidence based on a book chapter with a low number of case reports does not warrant classification for skin sensitisation.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	263
Comment received				
Skin sensitization - the criteria for classification as a skin sensitizer are not fulfilled: o reliable human evidence showing that silver causes skin sensitization in a substantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show non-sensitizing potential of silver (note that the animal dataset in the CLH report is incomplete).				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	264
Comment received				
No comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	265
Comment received				
see comment_CLH_silver_RAS_AG.pdf attached ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Switzerland	Argor-Heraeus SA	Company-Manufacturer	266
Comment received				
Skin sensitization - the criteria for classification as a skin sensitizer are not fulfilled: o reliable human evidence showing that silver causes skin sensitization in a substantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show non-				

sensitizing potential of silver (note that the animal dataset in the CLH report is incomplete).

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Belgium	Umicore	Company-Manufacturer	267
Comment received				
Skin sensitisation - the criteria for classification as a skin sensitizer are not fulfilled: • There is very low incidence of human dermal sensitization despite extensive silver exposure (medical, dental, jewelry applications etc.). • a high number of animal studies with a variety of chemical forms of ionic silver show non sensitizing potential of silver (note that the animal dataset in the CLH report is incomplete). • Silver metal should not be classified as a skin sensitizer. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Umicore public consultation_final 20201215.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	United Kingdom	AeroSpace and Defence (ASD) Industries Association of Europe	Industry or trade association	268
Comment received				
The criteria for classification as a skin sensitiser are not fulfilled since reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking and a high number of animal studies with a variety of chemical forms of ionic silver show non-sensitising potential of silver (note that the animal dataset in the CLH report is incomplete).				

Date	Country	Organisation	Type of Organisation	Comment number
14.12.2020	France	<confidential>	Company-Manufacturer	269
Comment received				
The criteria for classification as a skin sensitiser are not fulfilled: - there is a lack of reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons, and - different ionic silver compounds have been used in a high number of animal studies not leading to the conclusion that there is a sensitising potential of silver, Nevertheless, the animal dataset in the CLH report is still incomplete.				

Date	Country	Organisation	Type of Organisation	Comment number
11.12.2020	Germany	<confidential>	Company-Manufacturer	270
Comment received				
"Skin sensitization - the criteria for classification as a skin sensitizer are not fulfilled: o reliable human evidence showing that silver causes skin sensitization in a substantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show non-				

sensitizing potential of silver (note that the animal dataset in the CLH report is incomplete).”

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	France	ERCUIS	Company-Manufacturer	271
Comment received				
Skin sensitisation - the criteria for classification as a skin sensitiser are not fulfilled: • reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and • a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete). ECHA note – An attachment was submitted with the comment above. Refer to public attachment Consultation européenne sur l'argent ERCUIS_12-2020.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
09.12.2020	France	Comité Colbert	Industry or trade association	272
Comment received				
There is no reliable evidence that silver causes skin sensitisation in a substantial number of humans. We also wish to stress that there is a high number of animal studies with a variety of chemical forms of ionic silver which show silver's nonsensitising potential. Please also note in this context that the animal dataset in the CLH report is incomplete. We also wish to state that the classification is based on the textbook “Silver in healthcare” by A. B. G. Lansdown (2010). But this report specifically mentions that « according to the author, many people tolerate metals in their solid state ». Massive silver should therefore not be classified. Please refer to the EPMF full report for detailed analysis. ECHA note – An attachment was submitted with the comment above. Refer to public attachment LT_Comité_Colbert_ECHA.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
08.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	273
Comment received				
Skin sensitization - the criteria for classification as a skin sensitizer are not fulfilled: o reliable human evidence showing that silver causes skin sensitization in a substantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show non-sensitizing potential of silver (note that the animal dataset in the CLH report is incomplete).				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment HPT_Public Cons. Ag CLH Proposal_AH.pdf

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	274
Comment received				
The criteria for classification as a skin sensitiser are not fulfilled: o reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete).				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	AURUBIS AG	Company-Manufacturer	275
Comment received				
» Skin sensitisation - the criteria for classification as a skin sensitiser are not fulfilled: - reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and - a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete). ECHA note – An attachment was submitted with the comment above. Refer to public attachment Aurubis comments to Silver CLH proposal 2020-12-18.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France	MONNAIE DE PARIS	Company-Downstream user	276
Comment received				
Skin sensitisation for end user also is not showed and even less proved. There are no clinical cases known. The classification under this risk would not be relevant to date. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 18 ECHA MdP 2020 survey CLH for Silver_VDEF.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	AZUR SPACE Solar Power GmbH	Company-Downstream user	277
Comment received				
The criteria for classification as a skin sensitiser are not fulfilled for us: o reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking and o a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is				

incomplete).

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	278
Comment received				
Skin sensitization - never found nor observed in the <confidential>. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Austria	Wirtschaftskammer Österreich		279
Comment received				
see attachment ECHA note – An attachment was submitted with the comment above. Refer to public attachment su_309_StN öK Silber CLH.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Finland	Boliden Harjavalta	Company-Manufacturer	280
Comment received				
Skin sensitisation - the criteria for classification as a skin sensitiser are not fulfilled: o reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete).				

OTHER HAZARDS AND ENDPOINTS – Specific Target Organ Toxicity Single Exposure

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	281
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	282
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public				

attachment Public attachment in the questionnarie.docx

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	283
Comment received				
no comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	284
Comment received				
Specific target organ toxicity – single exposure - never found nor observed in the <confidential>. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	285
Comment received				
N/A				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	286
Comment received				
No comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	287
Comment received				
see comment_CLH_silver_RAS_AG.pdf attached ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf				

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	288
Comment received				
-				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	289
Comment received				
none ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	290
Comment received				
We are not aware of any hazard originated my metalic silver and we have been using silver for a very long time.				

OTHER HAZARDS AND ENDPOINTS – Specific Target Organ Toxicity Repeated Exposure

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	291
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential>(003).docx				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	292
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachment in the questionnarie.docx				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	293

Comment received
no comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany		MemberState	294
Comment received				
pages 195-237 We agree with the dossier submitter on the neurotoxicity concern raised by the oral study on pregnant rats using silver nanoparticles (IIIA, 6.8.2-10). We would like to emphasise the importance of bioaccumulation of silver in this context. However, we agree that based on the overall data, criteria for classification are not fulfilled.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	295
Comment received				
Specific target organ toxicity – repeated exposure - never found nor observed in the <confidential>. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	296
Comment received				
N/A				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	297
Comment received				
No comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	298

Comment received
see comment_CLH_silver_RAS_AG.pdf attached ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	299
Comment received				
-				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	300
Comment received				
none ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	301
Comment received				
We are not aware of any hazard originated my metalic silver and we have been using silver for a very long time.				

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	WirtschaftsVereinigung Metalle	Industry or trade association	302
Comment received				
We think that the criteria for classification of massive silver as toxic to the aquatic envi-ronment are not fulfilled either. The available scientific information as well as evidence from internal industry data confirm that a split classification for silver massive versus sil-ver powder is justified. Following the specific guidance developed for the hazard assess-ment of metals would result in a non-classification of massive silver. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020-12-18_WVMetalle Comment on CLH Proposal for Silver.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	303

Comment received
none ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	304
Comment received				
To the best of our knoweledge, the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: o the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and o silver massive should not be classified.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United Kingdom	Ames Goldsmith UK Ltd	Company-Manufacturer	305
Comment received				
• Hazardous to the aquatic environment - the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: o the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and o silver massive should not be classified.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	306
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential>(003).docx				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland		Individual	307
Comment received				
• Hazardous to the aquatic environment - the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: ☐ the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and ☐ silver massive should not be classified. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Bio-Gate AG	Company-Manufacturer	308

Comment received

- the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and silver massive should not be classified.
- due to the special particles of MicroSilver BG Bio-Gate disagrees with the hazardous to the aquatic environment classification for metallic silver powder with special properties like MicroSilver BG. To prove this Bio-Gate started an OECD study according to OECD 202, OECD 210 and OECD 211. Results will be available in Q3/20201.
- regarding persistence - Metallic silver is a chemical element. Thus it cannot be degraded. Just like gold also silver exists stable in elementary form. MicroSilver BG like any other metallic silver is a precious metal, behaving mostly inert. The metallic silver itself is not bioactive, so there is no toxicity related to the elementary metal. The kind of persistence which is relevant for toxicological considerations (e.g. when chlororganic compounds are discussed, that are poorly degraded and maintain their toxicity), cannot be applied for silver or for gold. Both just show stability, but - from a toxcological point of view - that alone should not considered to be persistence.
- regarding bioaccumulation: The fear is that a compound that is persistent and toxic can bioaccumulate over time in biota and even more important is enriching in the food chain. Metallic silver is not bioaccumulative. There are only reports for bioaccumulation of silver compounds that is ionic silver. However, these reports are limited to selected biota and it is known that such bound material is only very difficult to mobilize. So that the required toxic action cannot unfold and passage via the food chain is interrupted. Also given the natural input of silver into the environment or its longtime use in industry there is no evidence for extended associated risks.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Bio-Gate Safety Studies.zip
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Bio-Gate Microsilver BG Confidential Safety Studies.zip

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	I&P Europe - Imaging and Printing Association e.V.	Industry or trade association	309

Comment received

see attached document

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments to the silver metal CLH public consultation.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	310

Comment received

no comment

ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	Eurometaux	Industry or trade association	311

Comment received

In general, Eurometaux would make a strong plea for 1) using all evidence of good quality provided in the registration dossiers or during the Public Consultation, 2) following the (metal specific) CLP guidance without further interpreting it and 3) ensuring consistency with other metal dossiers previously assessed for their environmental hazard and classification.
All these aspects are relevant to the assessment of the environmental aquatic classification review of Silver metal given:
- Only a selective choice of ecotoxicity data has been included in the Dossier Submitters report. As a consequence, not all data available in the registration dossier or in publicly available literature were used. This comment goes beyond the identification of ecotoxicity data and relates also to models like the acute BLM to some extend demonstrating the pH effect at acute level, or the Ticket-Unit World model demonstrating the removal of the soluble ion on a theoretical base

- Several derivations from the published CLP guidance on metals or extended interpretations (e.g. statistical treatment of large ecotoxicity data sets and criteria for a separate classification entry for metals in massive form), further discussed here below under the specific comments.

- There is some lack in consistency with how previous comparable data sets on metals were handled (e.g. in respect to separate entries for the massive and powder form while introducing an entry for the nano form).

- In line with the two previous comments all relevant evidence is available to make a clear and distinguished hazard assessment and classification for the massive and the powder form.

- We noted the intention of Sweden to submit a hazard assessment and classification file for a soluble form (AgNO3). It would have been far more logic to assess first the ecotoxicity and environmental hazard classification of the soluble ion, before assessing the metal form. Indeed, the ecotoxicity of the soluble form is the common base for all Ag compounds including the metal. The metal file could subsequently have been limited to the assessment of the relevancy and robustness of the TDp (OECD 29) results to derive the environmental classification for the metal. It is unclear to us while the Dossier Submitter opted to submit the two files in the opposite way of expectations.

Most positively, we noted that the proposal from the Dossier Submitter recognises the outcome of the Substance Evaluation on Silver in nanoform in respect to the M-factor setting. Furthermore we noted recognition for the importance of the pH dependency of the TDp and ecotoxicity data, the latter at least for the chronic environmental hazard endpoint.

We noted in particular that recent RAC assessments of metal environmental classification cases (Cu flakes and granules, Lead metal and this one on Silver metal) all use somewhat different methods and interpretations of the CLP guidance section on metals (especially in respect to section IV 5.5). In our view this challenges the predictability and transparency of the harmonised classification process.
Eurometaux would therefore call RAC to use all evidence available by screening it for quality and relevance and ensuring the CLP guidance for metals is applied in full and consistently

with previous dossiers.
Complementary to the generic comments, Eurometaux would like to raise some specific comments and input on:
1. The restricted application of the metal's classification scheme
The proposed acute and chronic ERVs for classification are incomplete given:
- Derived on a selective data sets with unknown selection criteria which impacts (limits) the statistical derivation of the ERVs
- No pH dependency has been defined for the acute ecotoxicity data set while a validated acute BLM is available in the registration file which would allow normalisation for pH before the acute ERV and acute environmental hazard class is defined

2. Including ecotoxicity data developed under non-standard conditions for other purposes then hazard assessment for classification
The test conducted by Schlich et al. 2017 for the purpose of the Ag nano Substance Evaluation should not be used for the acute and chronic ERV derivation given tested under circumstances that are non-standard and not relevant to natural conditions (no chloride content). This would require reassessing the Chronic ERV, not the acute ERV, given this chronic reference is the most sensitive value, while for the acute assessment there are several more sensitive values.

3. The splitting of the metal classification entry for the environmental endpoint for the different forms
The 3 Silver metal forms (massive, powder and nano) provide very different dissolution rates and equilibria warranting different classification entries. This difference in transformation dissolution rate covers more than 3 orders of magnitude between the powder and massive form. Not recognising this robust evidence would highly overestimate the hazard for the massive form. While so far, for metals, only an entry for the massive form and for the powder form was applied, it seems that this case warrants a separate entry for the nano form unless the hazard classification entry would be equal to the one that RAC would decide for the upcoming soluble salt case on AgNO3.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Enclosure 2 - Overview of metal environmental classification entries including some history.zip

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	<confidential>	Company-Manufacturer	312
Comment received				
o the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and o silver massive should not be classified.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France		MemberState	313
Comment received				
In agreement with the proposed classification for environment. M-factors estimation: In agreement with a separate environmental classification for nanosilver based on the approach for soluble silver compounds. A recent study (Pang et al. 2020) confirms that the dissolution of AgNPs was dependent on the coating of AgNP with highest dissolution				

according to the type of coating. The study shows that the coated silver nanoparticles seem to behave more like a soluble silver salt than a poorly soluble metal.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	ZVEI - German Electrical and Electronic Manufacturers' Association	Industry or trade association	314

Comment received

The criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled:
o the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and
o silver massive should not be classified.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201218 ZVEI Silver Applications in EEE and Comments Ag CLH Consultation.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	C.HAFNER GmbH + Co. KG	Company-Manufacturer	315

Comment received

The criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled:
o the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and
o silver massive should not be classified.
Please refer to the scientific comments submitted by the European Precious Metals Federation (EPMF).

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Belgium	European Precious Metals Federation (EPMF)	Industry or trade association	316

Comment received

Summary of comments on the environmental hazard assessment (CLH report p.239-272):
• Evidence is available showing rapid removal of silver from the water column.
• T/Dp studies should be recognised and taken into account for classification purposes, and a separate classification entry for nanosilver and silver powder is warranted. In addition, a separate entry for the massive form (not classified for environmental hazards) is justified based on T/Dp data and based on the fact that silver powder is produced by a special process and is not generally generated from the massive metal, and the massive does not produce powders under foreseeable use.
• Not all available data for acute and long-term aquatic hazard have been referred to in the CLH proposal / used for classification.

For further details / justification, please refer to the attached document pages 48-56.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH Ag Comments FINAL_201217.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Netherlands		MemberState	317
Comment received				
Thank you for the proposal for the aquatic toxicity classification of bulk/powdered silver and nano-silver. We agree with the separate classification for nano-silver as its rate of dissolution is much higher than that of bulk silver and powdered silver. As was concluded after the REACH substance evaluation for silver and nanoforms of silver (EC no. 231-131-3), results from tests with nano-silver on daphnids, algae and soil microorganisms indicate that silver nitrate (ionic silver) is equally or more toxic as compared to the silver nanoparticles tested. Consequently, it was concluded that the PNEC values derived from silver nitrate can also serve as PNEC values for the nanoforms of silver that are covered by the REACH registration dossier(s) submitted for Silver. As the proposed classification for nano-silver, obtained through the application of ERVs, is equal to that proposed for silver nitrate, the SEv conclusion is covered by this proposal. However, we are uncertain if the M-factor for chronic aquatic toxicity should be 100 or 1000. The dossier submitter derives an M-factor of 100 on the basis of the ERV applying the M-factors as given in table 4.1.3 of Annex I of the CLP regulation. For comparison, an M-factor of 1000 is derived on the basis of the ratio between T/D and ERV. It is unclear why the M-factor of 100 is finally selected. Furthermore, the upper limit for the selection of M-factors in table 4.1.3 is given as a "smaller than or equal to" symbol (≤). This is in contrast with table IV.1 in the guidance where only "smaller than" symbols are used, but it can be presumed that the table in the regulation is leading A NOEC of 0.1 µg/L would then result in an M-factor of 1000 as also indicated by the T/D-ERV method. On the basis of this it seems that the M-factor should be 1000, also from a precautionary point of view. The dossier submitter is requested to explain their choice for the M-factor of 100.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Netherlands	<confidential>	Company-Manufacturer	318
Comment received				
Hazardous to the aquatic environment - the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: * the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified * silver massive should not be classified				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Fachvereinigung Edelmetalle e. V.	Industry or trade association	319
Comment received				
The criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: o the available scientific and industrial evidence confirm that a split classification for				

silvermassive versus silver powder is justified, and
o silver massive should not be classified.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment FVEM comments CLH silver.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Federal Associations of the German Jewellery and Silverware Industry	Industry or trade association	320

Comment received

The criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled:
- the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and
- massive silver should not be classified.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201216-comments-vbv-clh-silver.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	321

Comment received

no evidence

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachment in the questionnarie.docx

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	HAGER GROUP	Company-Downstream user	322

Comment received

Hazardous to the aquatic environment - the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled:
- the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and
- silver massive should not be classified

ECHA note – An attachment was submitted with the comment above. Refer to public attachment CHL Ag- DU contribution- Hager group.docx

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Czech Republic	SAFINA, a.s.	Company-Manufacturer	323

Comment received

Please see the attached file.

ECHA note – An attachment was submitted with the comment above. Refer to public

attachment SAFINA_CLH public consultation_silver metal - completed.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Norway	<confidential>	Company-Manufacturer	324
Comment received				
The criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: - the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified - silver massive should not be classified. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments CLH Ag -17.12.20.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Comments CLH Ag - <confidential> - 17.12.20 - confidential info.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Heimerle + Meule GmbH	Company-Manufacturer	325
Comment received				
The criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: o the available scientific and industrial evidence confirm that a split classification for massive silver versus silver powder is justified, and o massive silver should not be classified. ECHA note – An attachment was submitted with the comment above. Refer to public attachment H+M comments CLH silver.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Siemens AG	Company-Manufacturer	326
Comment received				
Based on our assessment of the report and discussio with industry experts, we think that the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled. Available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and silver massive should not be classified.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	<confidential>	Industry or trade association	327
Comment received				
The criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: - the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and - massive silver should not be classified.				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201214-<confidential>-clh-silver-comments.pdf

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Finland	<confidential>	Company-Manufacturer	328
Comment received				
the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and silver massive should not be classified.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany		MemberState	329
Comment received				
For environmental classification, contrary to the classification of health hazards, a separate entry for nanosilver seems justified based on the available data.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	330
Comment received				
Hazardous to the aquatic environment - the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: o the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and o silver massive should not be classified.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	331
Comment received				
No comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	332
Comment received				
see comment_CLH_silver_RAS_AG.pdf attached				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Switzerland	Argor-Heraeus SA	Company-Manufacturer	333
Comment received				
Hazardous to the aquatic environment - the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: o the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and o silver massive should not be classified.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Belgium	Umicore	Company-Manufacturer	334
Comment received				
Hazardous to the aquatic environment - the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: • the full dataset of environmental toxicity studies is not taken into account. • the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and • silver massive should not be classified. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Umicore public consultation_final 20201215.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	United Kingdom	AeroSpace and Defence (ASD) Industries Association of Europe	Industry or trade association	335
Comment received				
The criteria for classification of silver metal (massive) as toxic to the aquatic environment is not fulfilled since available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified and silver massive should not be classified the same as silver powder form.				

Date	Country	Organisation	Type of Organisation	Comment number
14.12.2020	France	<confidential>	Company-Manufacturer	336
Comment received				
The criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: - different behavior can be expected for massive and powdered silver, which is confirmed by				

scientific and industrial evidence. This leads to the conclusion, that a split classification for these two forms is justified, and
- there at least is no justification for the classification of massive silver, however it is understood form Eurometaux that all forms of a metal must be considered concurrently. As Kemi has omitted silver massive from its submission, should the submission itself not be rejected?

Date	Country	Organisation	Type of Organisation	Comment number
11.12.2020	Germany	<confidential>	Company-Manufacturer	337
Comment received				
"Hazardous to the aquatic environment - the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: o the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and o silver massive should not be classified."				

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	France	ERCUIS	Company-Manufacturer	338
Comment received				
the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: • the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and • silver massive should not be classified. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Consultation européenne sur l'argent ERCUIS_12-2020.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	Germany	SAXONIA Technical Materials GmbH	Company-Manufacturer	339
Comment received				
Massive silver, as used by our downstream users, should not be classified and strictly split from silver powder classification				

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	Germany	Doduco	Company-Manufacturer	340
Comment received				
it should be distinguished between massive and particle silver; massive silver, as used by our DU, should not be classified available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified				

Date	Country	Organisation	Type of Organisation	Comment number

09.12.2020	France	Comité Colbert	Industry or trade association	341
Comment received				
The criteria for the classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled. The available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified and that massive silver should not be classified. Please refer to the EPMF full report for detailed analysis. ECHA note – An attachment was submitted with the comment above. Refer to public attachment LT_Comité_Colbert_ECHA.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
08.12.2020	France	UITS	Industry or trade association	342
Comment received				
we support the scientific comments sent to you by the European Precious Metals Federation (EPMF) both regarding to human health and the environment. ECHA note – An attachment was submitted with the comment above. Refer to public attachment ARGENT.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
08.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	343
Comment received				
Hazardous to the aquatic environment - the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: o the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and o silver massive should not be classified. ECHA note – An attachment was submitted with the comment above. Refer to public attachment HPT_Public Cons. Ag CLH Proposal_AH.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	344
Comment received				
The criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: o the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and o silver massive should not be classified.				

Date	Country	Organisation	Type of Organisation	Comment number

18.12.2020	Germany	AURUBIS AG	Company-Manufacturer	345
Comment received				
» Hazardous to the aquatic environment - the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: - the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and - silver massive should not be classified Furthermore we would like to emphasise that no powder is generated during production and use of massive silver. High ductility, malleability, conductivity are important physical properties of silver. Pure silver has the highest electrical and thermal conductivity of all the metals. Silver is very malleable and ductile material. These properties allow silver to be formed and stretched into various complex and intricate shapes and surfaces without breaking. This can be seen in many silver articles encountered in everyday life. In addition, silver is resistant to fracture, and it is a relatively soft metal, meaning that it can be easily scratched by other materials. Silver has one of highest physical ductility (0.73) . Silver is a also relatively soft metal (Hardness Mons scale 2.5 – 3). As a consequence of its malleability, ductility and softness silver does not break. Consequently, silver powder is not produced or generated during the production of silver massive or during the industrial and professional uses of silver massive. There is clear and reported evidence that the criteria for a different classification of silver in massive form are fulfilled: - special process is used to produce silver metal powder - massive does not produce powder under reasonably expected use, and - there is a significant difference in dissolution rate of the silver ion into solution from massive silver compared with silver metal powder silver when tested in the OECD Test Guideline 29 (Transformation Dissolution protocol). In line with the CLP guidance and experimental data provided in the REACH registration dossier, Silver massive (> 1 mm) shall not be classified for environmental hazards. More information is provided in the attached document. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Aurubis comments to Silver CLH proposal 2020-12-18.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France	MONNAIE DE PARIS	Company-Downstream user	346
Comment received				
Silver solid (massive) compounds are not hazardous to aquatic environment. Their classification under this risk would not be relevant to date. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 18 ECHA MdP 2020 survey CLH for Silver_VDEF.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	347
Comment received				
Hazardous to the aquatic environment - never found nor observed in the <confidential>.				

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Austria	Wirtschaftskammer Österreich		348
Comment received				
see attachment ECHA note – An attachment was submitted with the comment above. Refer to public attachment su_309_StN öK Silber CLH.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Finland	Boliden Harjavalta	Company-Manufacturer	349
Comment received				
Hazardous to the aquatic environment - the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: o the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and o silver massive should not be classified.				

OTHER HAZARDS AND ENDPOINTS – Physical Hazards

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	350
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential>(003).docx				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	351
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachment in the questionnarie.docx				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France	MONNAIE DE PARIS	Company-Downstream user	352
Comment received				
The classification under this risk would not be relevant to date.				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 18 ECHA MdP 2020 survey CLH for Silver_VDEF.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	353
Comment received				
no comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany		MemberState	354
Comment received				
The physical hazards were evaluated for silver in powder form (macroscale silver) only, for which no classification is proposed. Since the particle size and the specific surface area affects the outcome of the test results, studies should be submitted for silver in nanoform without any surface treatment, otherwise no conclusion on classification is possible. The evaluation on the basis of new studies for nanosilver results from the requirements under Article 8(6) and Article 9(5) of Regulation (EC) No 1272/2008. Thus, the CLH report on nanosilver appears questionable and not robust in terms of classification for physical hazards.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	355
Comment received				
Physical hazards - never found nor observed in the <confidential>. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	356
Comment received				
N/A				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	357
Comment received				
No comment				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	358
Comment received				
see comment_CLH_silver_RAS_AG.pdf attached ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip				

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	359
Comment received				
-				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	360
Comment received				
none ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	361
Comment received				
We are not aware of any hazard originated my metalic silver and we have been using silver for a very long time.				

PUBLIC ATTACHMENTS
1. Input silver CLH - TMC - 18.12.2020.pdf [Please refer to comment No. 3]
2. RECHARGE Silver classificationPublic Consultation.pdf [Please refer to comment No. 4]
3. Aurubis comments to Silver CLH proposal 2020-12-18.pdf [Please refer to comment No. 5, 123, 174, 275, 345]
4. 2020 12 18 ECHA MdP 2020 survey CLH for Silver_VDEF.pdf [Please refer to comment No. 68, 124, 175, 209, 276, 346, 352]
5. Silver - STF comment on Muta 2 H341 - December 2020.pdf [Please refer to comment No. 125]
6. Silver - STF comment on Repr 1B H360 - December 2020.pdf [Please refer to comment No. 176]

7. su_309_StN öK Silber CLH.pdf [Please refer to comment No. 8, 128, 179, 212, 279, 348]
8. 2020-12-18_WVMetalle Comment on CLH Proposal for Silver.pdf [Please refer to comment No. 9, 80, 129, 236, 302]
9. CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf [Please refer to comment No. 10, 72, 81, 130, 190, 197, 214, 234, 237, 289, 300, 303, 360]
10. Silver products.pdf [Please refer to comment No. 11, 82, 131, 238]
11. aap Implantate AG_CLH_public_consultation_non-confidential_CAS 7440-22-4.pdf [Please refer to comment No. 84, 133, 199, 240]
12. 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx [Please refer to comment No. 14, 74, 86, 135, 180, 200, 217, 224, 242, 281, 291, 306, 350]
13. Bio-Gate Safety Studies.zip [Please refer to comment No. 15, 88, 137, 243, 308]
14. Comments to the silver metal CLH public consultation.pdf [Please refer to comment No. 16, 89, 138, 219, 309]
15. TD Europe CLH Consultation Silver_Dec2020_final.pdf [Please refer to comment No. 17, 76, 90, 139, 183, 202, 220, 227, 244, 283, 293, 310, 353]
16. Enclosure 2 - Overview of metal environmental classification entries including some history.zip [Please refer to comment No. 18, 311]
17. 20201218 ZVEI Silver Applications in EEE and Comments Ag CLH Consultation.pdf [Please refer to comment No. 20, 93, 143, 247, 314]
18. Heraeus Nexensos_Public Cons. Ag CLH Proposal.pdf [Please refer to comment No. 22]
19. CLH Ag Comments FINAL_201217.pdf [Please refer to comment No. 23, 95, 145, 249, 316]
20. Comments on CLH proposal for silver.pdf [Please refer to comment No. 26, 98, 148, 252]
21. FVEM comments CLH silver.pdf [Please refer to comment No. 27, 99, 149, 253, 319]
22. 20201216-comments-vbv-clh-silver.pdf [Please refer to comment No. 28, 100, 150, 254, 320]
23. Public attachment in the questionnarie.docx [Please refer to comment No. 67, 101, 151, 182, 192, 207, 226, 255, 282, 292, 321, 351]
24. CETS-comments Silver labelling CAS 7440-22-4 201217.pdf [Please refer to comment No. 30]
25. 2020-12-11 comment public consultation Ag ZVO.pdf [Please refer to comment No. 32]
26. CHL Ag- DU contribution- Hager group.docx [Please refer to comment No. 102, 152, 256, 322]
27. SAFINA_CLH public consultation_silver metal - completed.pdf [Please refer to comment No. 34, 103, 153, 257, 323]
28. Comments CLH Ag -17.12.20.pdf [Please refer to comment No. 35, 104, 154, 258, 324]
29. CAPIEL Comments.pdf [Please refer to comment No. 36]
30. H+M comments CLH silver.pdf [Please refer to comment No. 37, 105, 155, 259, 325]
31. 201214_Stellungnahme_FEEI_CAS_7440-22-4_Upload.pdf [Please refer to comment No. 39]
32. 20201214-<confidential>-clh-silver-comments.pdf [Please refer to comment No. 41, 107, 157, 260, 327]
33. 4388_001.pdf [Please refer to comment No. 44]
34. FEC response to Public consultation_Silver classification proposal.pdf [Please refer to comment No. 45]
35. Silver_consultation_2020_non_confidential.pdf [Please refer to comment No. 47, 78, 111, 161, 187, 204, 222, 231, 264, 286, 297, 331, 357]
36. comment_CLH_silver_RAS_AG_public.pdf [Please refer to comment No. 48, 79, 112, 162, 188, 205, 223, 232, 265, 287, 298, 332, 358]
37. Umicore public consultation_final 20201215.pdf [Please refer to comment No. 50, 114, 164, 267, 334]
38. AG_HMG_FM.pdf [Please refer to comment No. 52]
39. ECHA Silver 20201212.pdf [Please refer to comment No. 54]

40. Heraeus Romania SRL_Public Cons. Ag CLH Proposal_11.12.2020_signed.pdf [Please refer to comment No. 55]
41. Consultation européenne sur l'argent ERCUIS_12-2020.pdf [Please refer to comment No. 57, 168, 271, 338]
42. HPM_RC_Public Cons. Ag CLH Proposal.docx [Please refer to comment No. 59]
43. 201208_Public_Consultation_HW_comments_final.pdf [Please refer to comment No. 60]
44. LT_Comité_Colbert_ECHA.pdf [Please refer to comment No. 62, 69, 120, 171, 181, 193, 210, 225, 272, 341]
45. ARGENT.pdf [Please refer to comment No. 342]
46. HPT_Public Cons. Ag CLH Proposal_AH.pdf [Please refer to comment No. 63, 121, 172, 273, 343]

CONFIDENTIAL ATTACHMENTS
1. Silver Metal letter.pdf [Please refer to comment No. 1]
2. <confidential>.pdf [Please refer to comment No. 2]
3. Silver - <confidential> statement.docx [Please refer to comment No. 7, 70, 127, 178, 185, 195, 211, 229, 278, 284, 295, 347, 355]
4. aap Implantate AG_CLH_public_consultation_confidential_CAS 7440-22-4.pdf [Please refer to comment No. 84, 133, 199, 240]
5. comment.pdf [Please refer to comment No. 87, 136, 218, 307]
6. Bio-Gate Microsilver BG Confidential Safety Studies.zip [Please refer to comment No. 15, 88, 137, 243, 308]
7. Comments CLH Ag - <confidential> - 17.12.20 - confidential info.pdf [Please refer to comment No. 35, 104, 154, 258, 324]
8. Silver_consultation_2020_Schneider_Electric.pdf [Please refer to comment No. 47, 78, 111, 161, 187, 204, 222, 231, 264, 286, 297, 331, 357]
9. comment_CLH_Silver_RAS_AG.zip [Please refer to comment No. 48, 79, 112, 162, 188, 205, 223, 232, 265, 287, 298, 332, 358]