Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

Industrial use of arsenic acid for the treatment of copper foil used in the manufacture of Printed Circuit Board

ECHA/RAC/SEAC: AFA-O-0000006556-67-01/D

Consolidated version

Date: 16 March 2017

Consolidated version of the

Opinion of the Committee for Risk Assessment
and
Opinion of the Committee for Socio-economic Analysis

on an Application for Authorisation

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular Chapter 2 of Title VII thereof, the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) have adopted their opinions in accordance with Article 64(4)(a) and (b) respectively of the REACH Regulation with regard to an application for authorisation for:

Chemical name(s): arsenic acid
EC No.: 231-901-9
CAS No.: 7778-39-4

for the following use:

Industrial use of arsenic acid for the treatment of copper foil used in the manufacture of Printed Circuit Board

Intrinsic property referred to in Annex XIV:

Article 57(a) of the REACH Regulation

Applicant:

CIRCUIT FOIL LUXEMBOURG SARL

Reference number:

11-2120105605-66-0000

Rapporteur, appointed by the RAC: **Sonja KAPELARI**
Co-rapporteur, appointed by the RAC: **Elena CHIURTU**

Rapporteur, appointed by the SEAC: **Åsa THORS**
Co-rapporteur, appointed by the SEAC: **Ioanna ALEXANDROPOULOU**

This document compiles the opinions adopted by RAC and SEAC.

PROCESS FOR ADOPTION OF THE OPINIONS

On 20/11/2015 CIRCUIT FOIL LUXEMBOURG SARL, submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation. On **28/01/2016** ECHA received the required fee in accordance with Fee Regulation (EC) No 340/2008. The broad information on uses of the application was made publicly available at http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation on **10/02/2016**. Interested parties were invited to submit comments and contributions by **06/04/2016**.

The draft opinions of RAC and SEAC take into account the comments of interested parties provided in accordance with Article 64(2) of the REACH Regulation.

The draft opinions of RAC and SEAC take into account the responses of the applicant to the requests that the SEAC made according to Article 64(3) on additional information on possible alternative substances or technologies.

The draft opinions of RAC and SEAC were sent to the applicant on **11/11/2016**.

The applicant informed on **29/11/2016** that it wished to comment the draft opinions of RAC and SEAC according to Article 64(5) and sent his written argumentation to the Agency on **11/01/2017**.

Due to the need to ensure the efficient use of resources and in order to synchronise work on the opinion with the plenary meetings of the Committees the time limit set in Article 64(5) for the adopting of the final opinions has been extended until **16/03/2017**.

ADOPTION OF THE OPINION OF RAC

The draft opinion of RAC

The draft opinion of RAC, which assesses the risk to human health and the environment arising from the use of the substance – including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives – was reached in accordance with Article 64(4)(a) of the REACH Regulation on **3/06/2016**.

The draft opinion of RAC was agreed by consensus.

The opinion of RAC

Based on the aforementioned draft opinion and taking into account written argumentation received from the applicant, the opinion of RAC was adopted by consensus on **10/03/2017**.

ADOPTION OF THE OPINION OF SEAC

The draft opinion of SEAC

The draft opinion of SEAC, which assesses the socio-economic factors and the availability, suitability and technical and economic feasibility of alternatives associated with the use of the substance as described in the application was reached in accordance with Article 64(4)(b) of the REACH Regulation on **15/09/2016**.

The draft opinion of SEAC was agreed by a simple majority.

The opinion of SEAC

Based on the aforementioned draft opinion and taking into account written argumentation received from the applicant, the opinion of SEAC was adopted by a simple majority on **16/03/2017**.

THE OPINION OF RAC

The application included the necessary information specified in Article 62 of the REACH Regulation that is relevant to the Committee's remit.

RAC has formulated its opinion on: the risks arising from the use applied for, the appropriateness and effectiveness of the risk management measures described, the assessment of the risks related to the alternatives as documented in the application, the information submitted by interested third parties, as well as other available information.

RAC confirmed that it is not possible to determine a DNEL for the carcinogenic properties of the substance in accordance with Annex I of the REACH Regulation.

RAC confirmed that there appear not to be any suitable alternatives that further reduce the risk.

RAC confirmed that the operational conditions and risk management measures described in the application limit the risk, provided that they are adhered to, along with the suggested conditions and monitoring arrangements.

THE OPINION OF SEAC

The application included the necessary information specified in Article 62 of the REACH Regulation that is relevant to the Committee's remit.

SEAC has formulated its opinion on: the socio-economic factors and the availability, suitability and technical and economic feasibility of alternatives associated with the use of the substance as documented in the application, the information submitted by interested third parties, as well as other available information.

SEAC took note of RAC's confirmation that it is not possible to determine a DNEL for the carcinogenic properties of the substance in accordance with Annex I of the REACH Regulation.

SEAC confirmed that there appear not to be suitable alternatives in terms of their technical and economic feasibility for the applicant.
SEAC considered that the applicant's assessment of: (a) the potential socioeconomic benefits of the use, (b) the potential adverse effects to human health of the use and (c) the comparison of the two is based on acceptable methodology for socio-economic analysis. Therefore, SEAC did not raise any reservations that would change the validity of the applicant's conclusion that overall benefits of the use outweigh the risk to human health, whilst taking account of any uncertainties in the assessment, provided that the suggested conditions and monitoring arrangements are adhered to.

SUGGESTED CONDITIONS AND MONITORING ARRANGEMENTS

RAC conditions

Description of conditions and monitoring arrangements for review reports

The applicant must implement regular campaigns of occupational exposure measurements (as they already have stated in the information provided to RAC) relating to the use of arsenic acid described in this application. These monitoring campaigns must be based on relevant standard methodologies or protocols and ensure a sufficiently low detection limit. They shall comprise both personal and static (where appropriate) inhalation exposure sampling and be representative of the range of tasks with possible exposure to arsenic acid and of the total number of workers that are potentially exposed. The results of the monitoring must be included in any subsequent authorisation review report submitted.

The information gathered in the monitoring campaigns shall be used by the applicant to review the risk management measures (RMMs) and operational conditions in order to further reduce workers' exposure to arsenic acid. The outcomes and conclusions of this review including those related to the implementation of any additional RMMs must be documented.

The results of the monitoring and of the review of the OCs and RMMs must be maintained, be available to national enforcement authorities and included in any subsequent authorisation review report submitted.

Environmental emissions of arsenic acid to air shall be measured with the results of the monitoring made available to enforcement bodies on request. Measurement campaigns shall be undertaken according to standard sampling and analytical methods, where appropriate.

SEAC Conditions

Description for additional conditions and monitoring arrangements for the authorisation

The applicant shall follow the schedule for substitution activities provided in the application and shall therefore not use more than the following maximum quantities of arsenic acid; 1000 kg in 2020, 800kg in 2022 and 700 kg in 2024.

REVIEW

Taking into account the information provided in the application for authorisation prepared by the applicant and the comments received on the broad information on use the duration of the review period for the use is recommended to be **seven years**.

JUSTIFICATIONS

The justifications for the opinion are as follows:

1. The substance was included in Annex XIV due to the following property/properties:

☒ Carcinogenic (Article 57(a))

☐ Mutagenic (Article 57(b))

☐ Toxic to reproduction (Article 57(c))

☐ Persistent, bioaccumulative and toxic (Article 57(d))

☐ Very persistent and very bioaccumulative (Article 57(e))

☐ Other properties in accordance with Article 57(f) [please specify]:

2. Is the substance a threshold substance?

☐ YES

☒ NO

Justification:

Arsenic acid has a harmonised classification as Carcinogen Cat. 1A with H350 according to Classification, Labelling and Packaging Regulation, (EC) 1272/2008.

The carcinogenic mode of action of arsenic and its inorganic compounds has not been established, but it appears not to be related to direct DNA reactive genotoxicity and therefore it is possible that the arsenic carcinogenicity has a threshold exposure level.

However, the available data do not allow the identification of threshold exposure levels for key events in the modes of action proposed in the scientific literature (RAC/27/2013/07 Rev. 1; Helsinki, 4 December 2013). Therefore arsenic acid is not considered to be a threshold substance.

3. Hazard assessment. Are appropriate reference values used?

Justification:

RAC has established a reference dose response relationship for carcinogenicity of inorganic arsenic compounds (RAC/27/2013/07 Rev.1) which was used by the applicant.

Inorganic arsenic compounds cause lung tumours in both animals and humans, following inhalation, oral or parenteral exposures. Exposure to high levels of arsenic compounds in drinking water has been associated with skin and urinary tract / bladder cancer in humans. Tumours at sites including the adrenal glands, bladder and liver have also been reported in some studies in animals.

However, lung cancer for workers due to inhalation and dermal exposure and for general population due to inhalation and oral exposure is considered to be the critical effect for risk assessment.

Dose response relationships were derived by linear extrapolation. Extrapolating outside

the range of observation inevitably introduces uncertainties. As the mechanistic evidence is suggestive of non-linearity, it is acknowledged that the excess risks in the low exposure range might be an overestimate.

In the socio-economic analysis (SEA) the remaining human health risks are evaluated based on the dose response relationship for carcinogenicity of inorganic arsenic compounds (RAC27/2013/07 Rev.1, agreed at RAC-27).

Are all appropriate and relevant endpoints addressed in the application?

All endpoints identified in the Annex XIV entry are addressed in the application.

4. Exposure assessment. To what extent is the exposure from the use described?

Description:

Short description of the use

Circuit Foil Luxembourg SARL is a downstream user of arsenic acid, based in Wiltz, Luxembourg.

This application for authorisation relates to the production of a wide range of different electro-deposited copper foils used in the manufacturing of Printed Circuit Board. The copper foils undergo a sequence of chemical and electrochemical processing steps to gain special surface qualities.

Arsenic acid and other additives are needed to control the electrolytic treatment in the manufacturing process of the copper foils. This treatment is applied to increase the adhesion of the copper foil (by roughening the surface) to the glass fibre and consists of two steps. After electrodepositing the copper crystals in the form of germs (germination step), these are grown by electrodeposition (nodularisation step). To form germs, the bath is used below the current diffusion limit by reducing the temperature of the bath as well as the copper concentration and the agitation. A risk in this procedure is that hydrogen may be generated, instead of depositing copper. Arsenic acid prevents the release of hydrogen from the copper bath by increasing the cathodic overpotential and is considered essential to the process.

It is important to recognise that the final product, the copper foils, do not contain arsenic acid. Any arsenic acid is removed from finished articles by rinsing.

The applicant estimates annual arsenic acid consumption on the basis of the imported volume. The maximum amount of arsenic acid used is **3.25 tonnes** per annum.

RAC notes that the CSR provides only limited information on the tasks undertaken and their associated operational conditions and risk management measures. The CSR also contains limited information on which personnel undertake each WCS and therefore have potential for exposure, or combined exposure, to arsenic acid. Furthermore, the information related to exposure assessment for humans via the environment and the corresponding risk characterisation for the general population is limited. In an attempt to clarify these issues, RAC requested additional information from the applicant in relation to the following areas of their application:

- Worker Contributing Scenarios (WCS),
- Methodology of exposure assessment for workers (including dermal exposure),
- Risk assessment for workers,
- Methodology of exposure assessment for humans via the environment,
- Risk assessment for humans via the environment,
- Risk management measures (RMMs) and operational conditions (OCs).

The responses of the applicant are incorporated in the RAC assessment.

Exposure scenario

The applicant described one exposure scenario, concerning an industrial use at a single site involving potential exposure of workers as follows:

„Industrial use of arsenic acid for the treatment of copper foil used in the manufacture of Printed Circuit Board"

According to the applicant, the exposure scenario includes all relevant processes and tasks associated with the use of arsenic acid that could result in either environmental or worker exposure. The exposure scenario is comprised of five Worker Contributing Scenarios (WCS) and one Environmental Contribution Scenario (ECS).

Worker exposure

Table 1: Summary of Worker Contributing Scenarios, operational conditions and risk management measures

<table>
<tr><th>Worker Contributing Scenario</th><th>Brief description of the tasks</th><th>Duration/ frequency of tasks**</th><th>Number of workers</th><th>Risk management measures / operational conditions</th></tr>
<tr><td rowspan="2">WCS 1
Delivery and storage (PROC 1)</td><td rowspan="2">Arsenic acid is delivered in 50 kg sealed barrels. The barrels are stored in a locked cabinet near the location of the preparation of arsenic acid solutions to avoid transfer of the barrels.</td><td>Duration:
< 1 h/d
Frequency:
1 x/month</td><td>5**</td><td rowspan="2">Closed system; 5-10 air changes/hour; PPE (nitrile gloves**, safety goggles, protective suit); safety training;</td></tr>
<tr><td colspan="2">Use in closed process, no likelihood of exposure</td></tr>
<tr><td rowspan="2">WCS 2
Dilution of the substance into a large container (PROC 4)</td><td rowspan="2">Arsenic acid is diluted in a concentrated solution (250 g/L).
Concentration of substance in mixture: 80 %.</td><td>Duration:
< 15 min/d
Frequency:
1 x /month**</td><td>4</td><td rowspan="2">Preparation site only; 5-10 air changes/hour; restricted access (4 persons only); PPE (nitrile gloves, safety respirator (APF of 20),</td></tr>
<tr><td colspan="2">Only 4 workers are authorised for performing this task.</td></tr>
</table>

				disposable all-in-one-suit, rubber boots); specific safety training;
WCS 3 Electro-chemical surface treatment (PROC 13)	The concentrated solution of Arsenic acid is automatically diluted to solutions with a concentration < 1 %. These solutions are used for the electrochemical surface treatment of the copper foil in the production hall.	Duration: < 1 h/d Frequency: 5 x /week	30	Lip extraction; specialised room ventilation with more than 10 air changes/hour (effectiveness 90 %); PPE (nitrile gloves, safety goggles, protective suit); safety training; Restricted access to the baths**;
		*Workers are near the bath for 1 hour at maximum.***		
WCS 4 Maintenance of equipment (PROC 8b)	Treatment baths are emptied to a storage vessel and rinsed with water before intervention by maintenance workers. Concentration of substance in mixture: 1 %.	Duration: < 15 min Frequency: 5 x/week	7**	Specialised room ventilation with more than 10 air changes/hour; PPE (nitrile gloves, safety respirator (APF of 20), disposable all-in-one suit); safety training;
WCS 5 Sampling for laboratory analysis and control (PROC 9)**	The samples are collected in a closed flask (including about 200 ml of the sampled solution containing 0.2 g/l of Arsenic acid. Concentration of substance in mixture: 1 %.	< 15 min Frequency: 2,5 x/week	2	Specialised room ventilation with more than 10 air changes/hour; PPE (nitrile gloves, safety goggles, protective suit); safety training;

** This information was provided by the applicant upon RAC´s request for clarification and in the trialogue.

Access to the baths is said to be restricted. The bath containing Cr (VI) is equipped with lip extraction, while general ventilation in the areas of the baths is 5-10 air changes/hour (effectiveness 90%).

The PPE used consists of nitrile gloves, safety goggles and a protective suit. According to the applicant, the replacement of PPE is done by workers themselves or by their supervisor. In addition, spot checks are performed to ensure that PPE is in good condition. Moreover, bimonthly training for safety is conducted for 15 minutes.

The applicant claims that a high security policy based on continual improvement of the procedures, training and information on the risks and the importance of wearing the PPE is implemented.

According to information provided after RAC´s request for clarification regarding WCS2, the applicant indicates that neither a glove box nor other technical measures for dilution are needed as arsenic acid is a liquid product with lower risk of release into the air.

According to information provided on RAC´s request for clarification regarding WCS3, the applicant reports that there are two working areas in the production hall: a zone where the electrochemical treatment is performed and where potential exposure to arsenic acid occurs and a zone considered by the applicant to be without any exposure as in this zone an overpressure is created by air renewal.

Furthermore, the applicant clarifies that the production process is a continuous one (365 days / year; 24 hours / day) and that a team of six workers fulfils the tasks in the production hall per shift. Based on a rotation system the exposure duration in the electrochemical treatment zone (contaminated zone) per worker is limited to 1 hour per shift at maximum.

Regarding maintenance activities, the applicant provided clarifications on RAC´s request regarding the implemented RMMs (e.g. the installations containing arsenic acid are marked with specific warning symbols). In addition, the applicant points out that before performing maintenance activities the respective installations are emptied and rinsed / washed to avoid arsenic acid exposure.

The applicant considers that maintenance work results in an average exposure of 15 min per day (240 days per year). According to the applicant, maintenance activities are not performed regularly (e.g. each week or each month). However, if maintenance intervention is necessary it will take several hours.

Regarding wastewater treatment, the applicant reports that the same workers as those taking care of dilution of arsenic acid are involved in the wastewater treatment activities. According to the applicant, the treatment plant is working automatically and does not require any operations where workers are exposed to arsenic acid.

Exposure estimation methodology:

Inhalation exposure:

The assessment for inhalation exposure provided by the applicant is based on a qualitative assessment (WCS1), on modelling, and on results of air monitoring campaigns.

According to the applicant´s qualitative assessment, there is no potential for inhalation exposure for WCS1.

The air measurements were undertaken with static (one measurement for WCS2) and personal sampling (one measurement for WCS3), each for about 8 hours. For WCS 2 the static monitoring was performed near the dilution zone. As this task usually lasts less than

15 minutes, the applicant states that the measurement represents a worst case. The result of the personal air monitoring (WCS3) was 0.12 µg/m^3.

The exposure assessment for WCS 4 and 5 was done by modelling, using ART, version 1.5. According to the applicant, the modelled data can be assumed as worst case estimates (90th percentile) for an 8 hours exposure. Following RAC´s request for clarification, the applicant pointed out that the RPE was not taken into account for risk characterisation for WCS4 although RPE (APF 20) is used. Besides, the applicant clarified that laboratory activities fall under the exemption for scientific research and development according to their understanding. Therefore the corresponding exposure estimation was removed from the assessment.

On RAC´s request the applicant provided also modelled data for WCS2 and WCS3 to corroborate the measurements results. According to the applicant the difference between the modelling result and the measurement for WCS2 is due to limitations of the model (see footnote under Table 2 for details). According to the applicant, the modelled data for WCS3 are comparable to the measured data.

Table 2: Inhalation exposure

Contributing scenario	**Method of assessment**	**Exposure value (µg/m^3)**	**Exposure estimation corrected for frequency and duration (µg/m^3) per worker**
WCS 1 Delivery and storage (PROC 1)	Qualitative assessment	0	0
WCS 2 Dilution of the substance into a large container (PROC 5)	Measured data (Static measurement)	0.24	3.75 x 10^{-4}
	Modelled data* (ART 1.5)	5.1**	
WCS 3 Electro-chemical surface treatment (PROC 13)	Measured data (Personal sampling)	0.12	0.12
	Modelled data* (ART 1.5)	0.50	
WCS 4 Maintenance of equipment (PROC 8b)	Modelled data (ART 1.5)	0.05	1.56 x 10^{-3}
WCS 5 Sampling for laboratory analysis and control (PROC 9)	Modelled data (ART 1.5)	0.17	2.66 x 10^{-3}

* Upon RAC´s request, the applicant provided modelled data also for WCS2 and WCS3.

** The difference between the modelled data and the measured data seems to be important. However, according to the applicant, the model considers that arsenic acid is directly put into the tank, falling from a wide aperture. The applicant claims that they could not take into account, in the modelling, that arsenic acid is poured through a small aperture that limits the exposure to drops.

The exposure estimates for WCS2 and WCS4 are not corrected for RPE although for both tasks RPE (APF20) is used. Therefore the exposure assessment might be considered as a worst case estimate, according to the applicant.

Dermal exposure:

The exposure assessment for dermal exposure provided by the applicant upon RAC´s request is based on a qualitative assessment (WCS1) and on modelling (WCS2, WCS3, WCS4 and WCS5), using ECETOC TRA, version 3.0.

According to the applicant the modelled data are based on an 8 hours exposure. For impact assessment the exposure estimates were corrected for frequency per worker but they were not corrected for duration of the tasks.

According to the applicant´s qualitative assessment, there is no potential for dermal exposure for WCS1.

Table 3: Dermal exposure

Contributing scenario	**Method of assessment**	**Exposure estimate (µg/kg bw/day)**	**Exposure estimates corrected for frequency (µg/kg bw) per worker**
WCS 1 (PROC 1)	Qualitative assessment	0	0
WCS 2 (PROC 5)	Modelled data (TRA 3.0)	343	17.15
WCS 3 (PROC 13)	Modelled data (TRA 3.0)	7	7
WCS 4 (PROC 8b)	Modelled data (TRA 3.0)	69	0.575
WCS 5 (PROC 9)	Modelled data (TRA 3.0)	34	17.00

Combined exposure:

As the applicant did not consider combined exposure in the CSR, RAC requested additional information from the applicant on this issue.

In reply to this request, the applicant assessed risks per activity as well as for the sum of the activities of a worker during his entire shift, i.e. combined exposure.

Table 4: Combined inhalation exposure for arsenic acid

Contributing scenario / PROC	Corrected exposure estimates (µg/m³)*						
	Worker 1	Worker 2	Worker 3	Worker 4	Worker 5	Worker 6-35	Worker 36-42
WCS 1 /PROC 1	0	0	0	0	0		
WCS 2 / PROC 4		3.75×10^{-4}	3.75×10^{-4}	3.75×10^{-4}	3.75×10^{-4}		
WCS 3 / PROC 13						0.12	
WCS 4 / PROC 8b							1.56×10^{-3}
WCS 5 / PROC 9		2.66×10^{-3}	2.66×10^{-3}				

* Values corrected for frequency and duration.

Table 5: Combined dermal exposure for arsenic acid

Contributing scenario / PROC	Corrected exposure estimates (µg/kg bw/d)*						
	Worker 1	Worker 2	Worker 3	Worker 4	Worker 5	Worker 6-35	Worker 36-42
WCS 1 /PROC 1	0	0	0	0	0		
WCS 2 / PROC 4		17.15	17.15	17.15	17.15		
WCS 3 / PROC 13						7	
WCS 4 / PROC 8b							0.575
WCS 5 / PROC 9		17.00	17.00				

*Values corrected for frequency.

According to the applicant, four workers are involved in more than one WCS. These four workers are all involved in WCS2 which corresponds to the critical operation of diluting the substance. Two of these four workers are involved in WCS1 and the other two workers are involved in WCS5. That means that two workers have to be considered with combined exposure. The combined exposure level for these two workers for inhalation exposure is 3.04×10^{-3} µg/m³ and for dermal exposure is 34.15 µg/kg bw/d.

The applicant points out that these workers are under biomonitoring surveillance. Furthermore, the applicant claims that they have started to conduct biomonitoring three times a year for operators in frequent contact with the chemical products and once a year for all other production operators. Upon RAC´s request, the applicant provided some biomonitoring data of inorganic arsenic and total arsenic in urine which does not contradict the estimated (inhalation and dermal) exposure levels. However, contextual information on the biomonitoring data would be needed in order to be able to interpret the data

properly. RAC further notes that the use of biomonitoring data for exposure assessment in areas with relatively low inhalation / dermal exposure concentrations is rather limited as such. However, according to the applicant, biomonitoring data are mainly used to control the worker´s individual occupational hygiene (including adequate use of PPE).

Uncertainties related to the exposure assessment:

The inhalation exposure assessment provided by the applicant is principally based on either results of measurements or modelled data. There are uncertainties as to the exposure estimation methodology for workers because measured exposure levels (single samples) are available for only two WCS (there are no measurements for the WCS4 "Maintenance of equipment" and WCS5 "Sampling for laboratory analysis and control"). However, for WCS2 and WCS3 the applicant provided additional modelled data on RAC´s request. The applicant provided some reasoning on why the modelled data for WCS2 do not support the result of the measured data. As for WCS3, the modelling does not contradict the measurement result.

As the exposure estimates for WCS2 and WCS4 are not corrected for RPE, the exposure assessment for WCS2 might be considered as a worst case estimate. This might not be the case for WCS4 as maintenance activities in general could rather lead to higher exposure levels. RAC notes that the exposure estimate for WCS3 is based on the result of a personal measurement. RAC notes that the applicant tried to corroborate the single measurement result by modelling. RAC also notes that the modelled data do not contradict the measured data. However, RAC considers a single measurement for a task performed by 30 workers to be a relatively small dataset.

The dermal exposure assessment provided on RAC´s request, is likely to be an overestimate due to the conservatism of the modelling tool used and because the applicant did not correct the exposure estimates for duration of tasks.

RAC notes that the exposure assessment could be considered more representative if underpinned by more measurements. According to the applicant, a monitoring campaign on inhalation exposure for workers is already planned in May 2016. Furthermore, monitoring campaigns and properly assessed biomonitoring data should be used to improve the effectiveness of the implemented RMMs.

Conclusion

RAC considers that

- The description of use provided after RAC´s request for clarification allows drawing conclusions related to exposure situations. RAC considers that the exposure estimates for dermal exposure might be overestimated.

- The methodology used to derive exposure levels is suitable. However, the available monitoring dataset is considered by RAC to be small, which may have compromised its representativeness.

- The information provided related to exposure resulting from the use applied for is considered to be sufficient to be used in a risk assessment and in the risk characterisation.

Environmental releases / Indirect exposure to general population (humans via the environment)

Estimation of releases

The applicant used the Environmental Contributing Scenario "Industrial use of reactive processing aids" (ERC 6b). Upon RAC´s request for clarification and after the trialogue the applicant provided revised data for the exposure assessment.

Aqueous effluents are subject to on-site wastewater treatment before release to municipal sewer. The applicant considers that on-site wastewater treatment (which includes treatment of the effluents from the scrubbers, see below) is highly effective. During wastewater treatment, arsenic acid precipitates (e.g. arsenic oxide, arsenic hydroxide) and is subsequently disposed as sludge (see below). The applicant states that arsenic concentrations in wastewater are measured once a year. Since 2006, the concentration of arsenic has been below a detection limit of 0.001 mg/l on each occasion. Releases to wastewater are therefore based on measured concentrations (a factor of 0.5 was applied to the value of 0.001 mg/l as all data were reported as below the limit of detection) in combination with a flow rate of 21 m^3/hour. The applicant considers that these releases are worst-case estimations.

The applicant states that they have no legal obligation to measure arsenic in their releases to air, thus no measured data are available. The applicant considers that arsenic acid will not normally be present in air due to its low volatility and the fact that the process does not operate above ambient temperature or generate aerosols. However, all exhaust air is passed through scrubbers (that the applicant assume have an efficiency of 90%). No further details of the scrubber system (technical specifications/maintenance regimes) were provided in the CSR. Estimates of releases to air are therefore based on the ERC 6b default value of 0.1%, modified to take account of the removal efficiency of the scrubbers.

According to the applicant, releases to soil are strictly excluded and are therefore considered to be negligible. Regarding waste management, the applicant claims that waste (e.g. sludge obtained by wastewater treatment) is handled according to national/local legislation and sent off site for disposal.

Table 6: Releases to the environment

Release	Release rate	Release per year	Release estimation method and details
Water*	Final release factor: 0.003% Local release rate: 0.00025 kg/day	0.091 kg	Release based on measured data (values < LOD treated as half LOD)and a rate flow of 21 m^3/hour
Air*	Initial release factor: 0.1% Final release factor: 0.01% Local release rate: 0.0009 kg/day	0.325 kg	Based on ERC 6b default (0.1%) and 90% efficiency of the scrubber
Soil	0	0	0

* Upon RAC´s request for clarification, the applicant provided revised data.

Exposure estimation methodology:

The applicant did not initially include an assessment of indirect exposure (and corresponding risks) in their application. After a request for clarification from RAC, the applicant provided a further assessment of indirect exposure to humans via the environment at both local and regional scales based on EUSES modelling.

Table 7: Summary of indirect exposure to humans via the environment

Protection target	Exposure estimate, EUSES, local scale (1 x 1 km)	Exposure estimate, EUSES, regional scale (200 x 200 km)
General population – Inhalation (mg/m^3)	2.475×10^{-7}	1.303×10^{-14}
General population – Oral (mg/kg bw/day)	3.717×10^{-5}	2.759×10^{-9}

Uncertainties related to the assessment of exposure to humans via the environment:

RAC notes that the applicant considers that the use is consistent with the environmental release category (ERC) 6b – "Use of reactive processing aid at industrial site (no inclusion into or onto article)". According to ECHA guidance on use description (R.12) uses where a substance or its transformation products are included into or onto an article at industrial sites, such as the use described in this application, are intended to be captured by ERC 5.

The default release factor to air for ERC 5 (50%) is considerably greater than the default release factor to air for ERC 6b (0.1%). Building an exposure estimate on ERC 5 rather than ERC 6b would result in a final release factor to air (after taking into account the efficiency of the scrubber) of 5%, rather than the value of 0.01% used by the applicant. As no monitoring data are available to corroborate the applicant's modelled release estimates the choice of initial release factor therefore introduces some uncertainty to the applicant's exposure assessment.

However, RAC acknowledges that the default release factors associated with ERCs are intended to be refined based on the efficiency of implemented RMMs (as already undertaken by the applicant) and the physico-chemical properties of the substances (i.e. vapour pressure). During the trialogue the applicant confirmed that the use was conducted at ambient temperature without generation of aerosols. Based on the low volatility of arsenic acid, RAC considers that using a default release factor to air of 50% for this use would be likely to significantly overestimate emissions. As such, RAC supports the use of a lower release factor for this use, although further information on releases, preferably obtained by monitoring, would be useful to reduce uncertainties in any review report for this use.

RAC acknowledges that assessment of indirect exposure to humans via the environment using default assumptions via EUSES is conservative, particularly at the local scale and could lead to an overestimation of risk (and number of statistical cancer cases). In addition, the models used in EUSES for predicting exposure through food are not suitable for metals. Therefore RAC notes that further refinement of models or techniques could

allow a more definitive estimate of indirect exposure in a review report.

Conclusion

RAC considers that

- the description of use provided and clarified on RAC´s request for further information and during the trialogue, including the risk management measures and operational conditions, allows conclusions to be drawn related to exposure situations;

- the revised release and exposure estimates provided by the applicant, which are based on ERC default values, measured emissions and EUSES modelling, are suitable for risk characterisation.

5. If considered a threshold substance, has adequate control been demonstrated?

☐ YES

☐ NO

☒ NOT RELEVANT, NON THRESHOLD SUBSTANCE

Justification:

RAC has concluded that arsenic acid should be considered as a non-threshold carcinogen with respect to risk characterisation.

6. If adequate control is not demonstrated, are the operational conditions and risk management measures described in the application appropriate and effective in limiting the risk?

☒ YES

☐ NO

Justification:

The applicant has estimated cancer risk according to the RAC reference dose response relationship for carcinogenicity of inorganic arsenic compounds (RAC/27/2013/07 Rev. 1, agreed at RAC 27) due to inhalation and dermal exposure.

Worker

Based on exposure for 40 years (8h/d, 5d/week), the excess lifetime lung cancer mortality risk according to the RAC reference dose response relationship is 1.4×10^{-4} per µg As/m^3 for the inhalable particulate fraction and 6.4×10^{-6} per µg As/kg bw/day for the dermal route.

Risk characterisation

The inhalation exposure assessment was based on measured (WCS2 and WCS3) and modelled data (WCS4 and WCS5). The dermal exposure for WCS2, WCS3, WCS4 and WCS5 was based on modelling whereas the dermal exposure for WCS1 (and also the inhalation exposure) was estimated by qualitative assessment.

Table 8: Excess risk estimates for 40 years exposure for workers

Contributing scenario	Dermal route*		Inhalation route**		Number of workers
	Corrected exposure estimates (µg/kg bw/d)*	Excess lung cancer risk	Corrected exposure estimates (µg/m³)*	Excess lung cancer risk	
WCS 1 / PROC 1	0	0	0	0	5
WCS 2 / PROC 4	17.15	1.10×10^{-4}	3.75×10^{-4}	5.25×10^{-8}	4
WCS 3 / PROC 13	7	4.48×10^{-5}	0.12	1.68×10^{-5}	30
WCS 4 / PROC 8b	0.575	3.68×10^{-6}	1.56×10^{-3}	2.19×10^{-7}	7
WCS 5 / PROC 9	17.00	1.09×10^{-4}	2.66×10^{-3}	3.72×10^{-7}	2

* Values corrected for frequency.
**Values corrected for frequency and duration.

Table 9: Excess risk estimates for 40 years exposure for workers for combined exposure

Worker	Number of workers	Excess lung cancer risk for inhalation route*					
		Excess lung cancer risk for dermal route**					
		WCS 1/ PROC 1	WCS 2/ PROC 4	WCS 3/ PROC 13	WCS 4/ PROC 8b	WCS 5/ PROC 9	Combined excess lung cancer risk
W 1	1	0.00					0.00
W2, W3	2	0.00	5.25×10^{-8}			3.72×10^{-7}	4.24×10^{-7}
		0.00	1.10×10^{-4}			1.09×10^{-4}	2.19×10^{-4}
W4, W5	2	0.00	5.25×10^{-8}				5.25×10^{-8}
		0.00	1.10×10^{-4}				1.10×10^{-4}
W6 - 35	30			1.68×10^{-5}			1.68×10^{-5}
				4.48×10^{-5}			4.48×10^{-5}
W35 - 42	7				2.19×10^{-7}		2.19×10^{-7}
					3.68×10^{-6}		3.68×10^{-6}

Note: The grey shaded values represent the excess lung cancer risk for the dermal route.
*Values corrected for frequency and duration.
**Values corrected for frequency.

RAC notes that the applicant did also consider combined exposure for workers for the use of chromium trioxide. However, chromium trioxide is not the subject of this Application for Authorisation.

Indirect exposure to humans via the environment

Based on exposure for 70 years (24 h/d, 7 d/week), the excess lifetime lung cancer mortality risk is 1.0 x 10^{-4} per µg As/m^3 for the inhalable particulate fraction and 1.7 x 10^{-3} per µg As/kg bw/day for the oral route.

Exposure to humans via the environment was estimated, as follows:

Table 10: Excess risk estimates for man via the environment

Protection target	Local scale		Regional scale	
	Exposure Estimate	**Excess lung cancer risk**	**Exposure Estimate**	**Excess lung cancer risk**
Man via Environment – Inhalation (mg/m^3)	2.475 x 10^{-7}	2.475 x 10^{-11}	1.303 x 10^{-14}	1.303 x 10^{-18}
Man via Environment – Oral (mg/kg bw/day)*	3.717 x 10^{-5}	6.32 x 10^{-8}	2.759 x 10^{-9}	4.690 x 10^{-12}
Man via Environment - Combined		6.345 x 10^{-8}		4.691 x 10^{-12}

Evaluation of the risk management measures

The RMMs and OCs are sufficiently described following the applicants responses to RAC´s request for clarification. In addition, RAC acknowledges that the applicant has put efforts into improving their RMMs (both workplace- and environment-related).

Conclusion

RAC considers that the estimates provided of excess lung cancer risk for workers and for indirect exposure to humans via the environment are sufficiently reliable to allow health impact assessment.

The RMMs are generally appropriate and effective in limiting the risks to workers and the general population. However, the strategy for monitoring worker exposure and environmental releases is not considered to be sufficiently developed. RAC considers that the exposure assessment should be supplemented with additional monitoring data to increase its reliability. Additional monitoring should be representative of all tasks with potential for arsenic acid exposure.

7. Justification of the suitability and availability of alternatives

7.1 To what extent is the technical and economic feasibility of alternatives described and compared with the Annex XIV substance?

Description:

Summary of the analysis of alternatives undertaken by the applicant

The applicant is the only producer of copper foil in the EU and holds about 75% of the market share in the EU. The remaining 25% is covered by imports, mainly from Japan, South Korea and China. The applicant has applied for an authorisation for the use of both chromium trioxide and arsenic acid, in the production of printed circuit board, in two separate applications.

Arsenic acid is used during the manufacturing process of electro-deposited copper foils for printed circuit boards. The applicant is currently using 3.25 tonnes of arsenic acid per year as an additive to control electrolytic treatment during the manufacturing process of copper foils. The role of arsenic acid is to prevent the release of hydrogen gas and to enable copper to deposit during the production of the foil. Once finished the copper foil contains less than 0,1 % arsenic.

The applicant states that the company has been working for the past 10 years on developing a production process that is free of arsenic acid. The applicant provided a report on the testing of several potential alternatives under different test conditions (including temperature, density, copper concentration and chloride concentration). They have carried out literature reviews and laboratory tests in order to find a promising substitute. Based on this work they identified candidates for substitution that were taken forward in the semi-industrial tests. This R&D work resulted in the identification of a suitable alternative, the identity of which is claimed confidential, while the final test report is available in French and is confidential as well. For this reason the term "alternative (A)" is used in this opinion when referring to the arsenic acid-free alternative.

Over the past five years the applicant has industrialised alternative (A). Currently, about 30% of the copper foil production of the applicant is arsenic acid free, and copper foils for new products are systematically manufactured without the use of arsenic acid. The applicant has shown that they have implemented a flexible production line for both arsenic acid and arsenic acid free manufacture. According to the substitution schedule provided by the applicant all copper foil will be produced without the use of arsenic acid by 2030. The applicant has informed its customers that, after 2030, it will no longer sell copper foils produced with arsenic acid. The timeline for this remaining substitution has been documented in the application[1].

Technical feasibility

The aim of treating the copper foil with arsenic acid is to increase the adhesion of the copper foil on the glass fabric during the formation of the printed circuit. The applicant has shown that when arsenic acid is replaced with alternative (A) in the production of copper foil, equivalent physical and technical properties and results are achieved. Furthermore, copper foil produced using alternative (A) fulfils the same quality criteria as

[1] http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/12449/term

copper foil produced using arsenic acid, but the shape and surface are said and shown by the applicant to be somewhat different. The applicant states that because of these differences the cooper foils would need to be requalified by their customers.

Economic feasibility

As the chemical products do not represent a high cost in the manufacture of copper foil the applicant regards the alternative (A) to be affordable. According to the information presented by the applicant all chemical products required for the manufacture of a copper foil represent 0.1 euro out of 2 euros, i.e. 5% of the total manufacturing cost. The investments needed in order to fully replace the use of arsenic acid in the production line of the copper foil have already been implemented and will not have any further impacts on the total price of copper foil.

The applicant concludes that alternative (A) is economically feasible (in terms of its affordability) and available but that it would bring negative impacts on the applicant's sales if used for all copper foils before technical approval has been carried out by all customers in the supply chain. SEAC considers that the applicant has interpreted the concept of economic feasibility in the narrow sense of whether it is technically affordable for the applicant, rather than in relation to assessing the broader business impacts for the applicant if introduced. SEAC thus note that the conclusion of the applicant should therefore be that alternative (A) is currently not economically feasible.

The applicant states that the colour of the arsenic acid-free copper foil and the colour of the copper foil produced with arsenic acid are different. This is the main obstacle identified by the applicant to fully substitute the production to arsenic acid free copper foil, as a copper foil with a different colour is presumed by the customers to be a different product, indicating a different oxidation level. Therefore a new product cannot be placed on the market before being technically approved also by the customer without the applicant losing the market share as its customer will turn to other suppliers not subject to REACH authorisation requirements.

SEAC conclusion on the analysis of alternatives

SEAC concludes that both the technical and economic feasibility of the use of the alternatives was to a sufficient extent described and compared to arsenic acid. SEAC further recognises that a substitution is ongoing and that copper foil manufactured with alternative (A) is available for technical approval by all customers in the supply chain.

7.2 Are the alternatives technically and economically feasible before the sunset date?

☐ YES

☒ NO

Justification:

The applicant's conclusion on technical feasibility of the alternatives

The applicant showed that when arsenic acid is replaced with alternative (A) in the production of copper foil, the same physical and technical properties and results are achieved. Furthermore that copper foil produced with alternative (A) fulfils the quality

criteria that are obtained with the copper foil manufactured using arsenic acid. The surface and shape of the deposits are however somewhat different when comparing copper foil manufactured either with or without the use of arsenic acid. Therefore the applicant's customers would want to requalify the arsenic free product.

The applicant's conclusion on economic feasibility of the alternatives

Alternative (A) is according to the applicant available and affordable. The applicant has already made the necessary investments to implement alternative (A) and to fully substitute arsenic acid in the production line of the copper foil. As stated in 7.1, the chemicals used in the production do not represent a high proportion of the production costs of copper foil according to the applicant and the price of the final copper foil does not increase due to the use of alternative (A).

If an authorisation would be granted, the applicant would be required to continue to produce the copper foil in two separate production lines, one using arsenic acid and the other using alternative (A) (the machines used are the same but require a change of electrolysis bath). The applicant states that this is an additional negative economic impact that indicates that the applicant has an incentive to carry out a full substitution as soon as possible.

The additional cost of the substitution of the arsenic acid used in the manufacture of products already supplied to the market is related to the technical approval and qualification tests required by the customers in the supply chain.

According to the applicant the substitution of arsenic acid during the manufacturing process of the copper foil will be considered by the customers in the supply chain as a change in product, which needs to be technically approved and tested before being used in the manufacturing of subsequent products. As stated by the applicant the system for technical approval and test is as follows. Two suppliers are selected by the downstream electronic producers for all components. Both will have to be able to supply the same components throughout the products technical lifecycle. If the supplier, for any reason, is not able to deliver the same product to its customers (as referred to in their contract) then he is excluded from further supply of the affected product and the other supplier is used instead. As explained by the applicant this is the reason why the substitution of foil produced without the use of arsenic takes time. Each downstream electronic product must first reach the end of its product technical lifecycle before the use of arsenic acid can be replaced by the alternative (A). After the substitution to alternative (A) has been carried out the electronic product using this copper foil is recognized by the customers as a new product. Usually the technical approval takes place following the decision to launch a new electronic product. Technical approval is according to the applicant never carried out for existing products already supplied to the market. As some products have a longer technical product lifecycle, the applicant must therefore be able to supply the copper foil throughout their technical product lifecycle. As the electronic products concerned are heterogeneous, the time needed and the specific demand for technical approval is not the same for all products. The demands from customers are also different throughout the supply chain.

For new products, however, the applicant declared that copper foil will be produced with alternative (A) so that over the next 12 years the use of arsenic acid would be progressively phased out. The applicant provided a plan for substitution activities (see

Table 11 in section 10) according to which about 77% (in weight) of the use of arsenic acid will already be substituted by 2020.

SEAC conclusion on technical and economic feasibility

SEAC concludes that the alternative (A) is technically feasible and affordable for the applicant before the sunset date for 30% of his production. SEAC notes that alternative (A) provides equivalent physical and technical properties to the foil. SEAC also notes that investments have already taken place and the production site already has a 100% capacity to produce the alternative.
For new types of electronic products SEAC confirms that the applicant has provided verifiable information that shows that a technically and economically feasible alternative is available. The remaining 67% of the current production of copper foil, in which arsenic acid is still used, consists of products already placed on the market. For these remaining uses the applicant states that technical approval needs to be made by their customers in the supply chain in order for the copper foil to be feasible for the end user.

Although it is not clear to SEAC how and under what circumstances the technical approval is conducted down the supply chain, SEAC accepts the applicant's claim that the alternative (A) still needs to be technically approved by the customers and that the timing of approval is aligned with the product lifecycle and that a forced shift to the alternative (A) could result in some loss of customers and corresponding sales for the applicant to other suppliers outside of the EU. SEAC notes that the possibilities for the applicant to influence the response of customers are limited, particularly where there are long supply chains from the copper foil to the finished article. The applicant is unable to know or control or have influence over all elements in the supply chain but can have a dialogue and cooperation with its first line of customers. Nevertheless, SEAC recognises that there are continuing incentives for the applicant to shift their customers to the alternative. The fact that they have successfully done so gives credence to their position to shift to the alternative, whilst at the same time wanting to minimise risks to the business from a loss of the market in the interim until all production has shifted to the alternative.

SEAC notes that the application concerns products that have different technical lifetimes and for some sectors (automobile, aviation and military) these can be particularly long (the applicant has estimated that 15 years are needed for completely phasing out the use of arsenic acid, counting from 2015). However SEAC cannot verify that all, or even a majority, of the applicant's customers would reject a copper foil produced with alternative (A) (in respect of a technical approval) if supplied before the end of the product lifecycle. Nevertheless, such technical approval can only come about with the agreement of the customer. SEAC has not been able to verify the share of the customers or sales affected. This would require further information about the number of customers that could accept the alternative and how the sales would be affected from selling the alternative.

As the applicant is the only producer in the EU and holds 75% of the market share it seems likely to SEAC that the company would be able to preserve parts of its EU market share when only supplying foil manufactured with alternative (A). SEAC took account of and considered the following when identifying this uncertainty; increased costs for customers for transport of the foil from Asia, that the customers would have to find a new second supplier if not using the service of the applicant any longer, and additional costs

for running technical approval test for this copper foil. Furthermore, the applicant has not provided any information of the impacts and costs to the company of losing the customers.

According to information provided by the applicant, substances can be and are sometimes substituted for commercialised products requiring type approval during their lifecycle. SEAC finds that an earlier substitution before the end of the products' technical lifecycle is something users in the supply chain are trying to avoid, but if necessary, planned, and prioritised it cannot be excluded that it sometimes occurs. The applicant has presented information about a case where the customer agreed to change the specification during a life cycle. Consultation with customers in the supply chain was carried out by the applicant, but the extent of this consultation was not enough for SEAC to verify the remaining time needed for technical approval of the remaining substitution. According to the applicant such consultation was difficult due to the relatively long supply chain to the final downstream user. SEAC was unable to verify if the customers consider the components produced without arsenic acid to constitute a change in product due to the change in colour or whether the customers would reject such components and switch to competitors in order to continue to purchase copper foil produced with arsenic acid. Further uncertainties relate to the actual cost for technical approval carried out by the customers. This claim was not substantiated by the applicant. How important the increased operational cost is to the customers has not been communicated by the applicant nor its customers. SEAC has not been presented with any numbers or figures of such impacts. Furthermore SEAC notes, from the information provided by the applicant, that the colour of the circuit foil is not part of the key technical specifications. Uncertainties remain whether customers have the possibility in the scope of their contractual agreement to reject copper foil solely based on the colour if the property of the foil is the same.

According to the applicant the costs of the two lines are not significant but provide an incentive for the applicant to substitute as soon as possible. In the production line when changing to the arsenic free copper foil production the applicant only changes the solution of the passivation. SEAC however question the economic viability of maintaining two production lines after 2020 for the scheduled sales percentage.

It will be possible to substitute 77% of the use in weight by 2020. After 2020 about four customers[2] representing 23% of the sales (in weight), would still need the copper foil produced with arsenic acid and after 2022 three customers would remain representing 18% of the sales (in weight). After 2024 still three customers would remain representing 15% of the sales. These percentages indicate that the work on substitution will bring a fairly rapid substitution during the first four years after the sunset date.

SEAC concludes that as copper foil for new printed circuits is developed without the use of arsenic acid, the alternative (A) is technically feasible and affordable to the applicant. The applicant has presented a plan for substitution activities which shows an on-going substitution of arsenic acid by alternative (A). At the time of submission of the application, the applicant had already substituted 30% of its production. According to the applicant's plan for substitution activities, an additional production volume of about 3% will be substituted by the sunset date. The remaining production volume (67%) cannot be substituted before the sunset date because of the time required by the applicant's customers for technical approval. SEAC concludes that alternative (A) is economically not feasible by the sunset date for about 67% of the applicant's production.

[2] The total number of customers today for all copper foils are 150.

7.3 To what extent are the risks of alternatives described and compared with the Annex XIV substance?

Description:

The applicant has been working for 10 years on the replacement of arsenic acid. On the basis of literature searches and laboratory tests the applicant has identified some alternative substances and treatments.

Among the tested alternative treatments, changes in deposition conditions like temperature, current density, copper and chloride concentration were considered as well as adding an ion or multiple ions to the solution.

After semi-industrial tests, one substance was finally determined as the best alternative, however this alternative is confidential.

7.4 Would the available information on alternatives appear to suggest that substitution with alternatives would lead to overall reduction of risk?

☒ YES

☐ NO

☐ NOT APPLICABLE

Justification:

The applicant has already determined an alternative substance which is able to replace arsenic acid in the treatment of copper foil used in the manufacturing of Printed Circuit Board.

According to the applicant, 30% of the copper foil production already utilises the alternative (A) solution. They also claim that any new copper foil is systematically produced without any arsenic acid. However, according to the applicant, the full replacement of arsenic acid cannot be implemented by the sunset date as the product has to undergo the whole qualification process in the supply chain. Although the physical and technical properties of the copper foil with and without arsenic acid are equivalent, the colour of the foil treatment is very different.

Conclusion

As no exposure scenarios/risk assessment were presented for the alternative (A) substance and as this substance has not yet a harmonised classification, the judgement on this issue is difficult. RAC notes that some notifiers classified the alternative (A) substance as Carc. Cat. 2 according to the CLP Classification and Labelling inventory. However, the alternative (A) substance is neither established as a human carcinogen nor as a persistent bioaccumulative and toxic substance.

RAC notes that substitution is the aim of REACH regarding SVHC substances included in Annex XIV. Nevertheless RAC would like to encourage the applicant to evaluate the risks of the alternative (A) substance in order to define adequate risk management measures and operational conditions.

7.5 If alternatives are suitable (i.e. technically, economically feasible and lead to overall reduction of risk), are they available before the sunset date?

☐ YES

☐ NO

☒ NOT RELEVANT

Justification:

Alternative (A) is found by SEAC to be a suitable alternative that is available before the sunset date for new copper foil production and is already used by the applicant for about 1/3 of its current production.

No suitable alternative was however identified for the remaining uses of copper foil manufactured with arsenic acid due to economical infeasibility for products with a longer technical product lifecycle. The applicant concludes that alternative (A) is technically feasible but that it must be technically approved by all of the customers in the supply chain before being fully suitable.

8. For non-threshold substances, or if adequate control was not demonstrated, have the benefits of continued use been adequately demonstrated to exceed the risks of continued use?

☒ YES

☐ NO

☐ NOT RELEVANT, THRESHOLD SUBSTANCE

Justification:

Additional statistical cancer cases

The estimated number of additional statistical cancer cases has been calculated using the excess risk value presented in section 6 and the estimation of the number of exposed people provided by the applicant. It reflects the expected statistical number of cancer cases for an exposure over the working life of workers and entire life for general population.

RAC notes that these calculations are based on the estimation of exposed populations as provided by the applicant.

Table 11: Estimated additional statistical cancer cases. 40 years of exposure.

Group of worker	Number of Worker per group	Combined excess lung cancer risk	Estimated cancer cases for inhalation route	Estimated cancer cases for dermal route
W 1	1	0.00		
W2, W3	2	4.24×10^{-7}	8.49×10^{-7}	
		2.19×10^{-4}		4.38×10^{-4}
W4, W5	2	5.25×10^{-8}	1.05×10^{-7}	
		1.10×10^{-4}		2.20×10^{-4}
W6 - 35	30	1.68×10^{-5}	5.04×10^{-4}	
		4.48×10^{-5}		1.34×10^{-3}
W35 - 42	7	2.19×10^{-7}	1.53×10^{-6}	
		3.68×10^{-6}		2.58×10^{-5}
Estimated cancer cases			5.06×10^{-4}	2.03×10^{-3}
Total number of estimated cancer cases			**2.53×10^{-3}**	

Note: The grey shaded values represent the values for dermal risk and the corresponding cancer cases. These values are likely to be overestimated.

Table 12: Estimated additional statistical cancer cases. 70 years of exposure.

Protection target	Local scale		Regional scale	
	Excess lung cancer risk	Estimated lung cancer cases	Excess lung cancer risk	Estimated lung cancer cases
Man via Environment – Inhalation (µg/m^3)	2.475×10^{-8}	1.61×10^{-4}	1.303×10^{-15}	6.52×10^{-9}
Man via Environment – Oral (µg/kg bw/day)	6.32×10^{-5}	4.11×10^{-1}	4.690×10^{-9}	2.35×10^{-2}
Total number of cancer cases				**4.35×10^{-1}**

In the submitted application, the applicant did not provide an analysis of the risks for man via the environment. However, in response to the questions from RAC and SEAC, the applicant provided additional information and quantification of the lung cancer cases for the general population based on the assumption that 6,500 people (local scale) live close to the applicant's production site in Wiltz (Luxembourg). According to the applicant's assumptions about 5 million people live in an area of 200 x 200 km (regional scale). RAC considered the estimated cancer cases reported in Table 9 for 70 years exposure to be an

overestimate because the applicant considered all people living near Wiltz instead for considering only the number of people living at a local scale of 1 km^2 around the plant. Moreover, SEAC noted that the estimated cancer cases were based on the current amount of arsenic acid used, although this amount will be reduced following the applicant's substitution activities. This also results in an overestimation since the risks will be reduced (at the same proportion) given the linearity of the dose response curve.

Costs of continued use (HH)

The applicant quantified the related economic burden in accordance with different methodologies. The applicant monetised the lung cancer risk of the continued use of arsenic acid at its production plant taking the following into account:

- ECHA document on reference dose response relationship for inorganic arsenic compounds.
- Epidemiology of lung cancer and risk factors.
- Medical treatments for lung cancer and its associated costs.
- Productivity loss due to lung cancer.
- Estimation of the welfare impacts of cancer morbidity and mortality using the willingness-to pay (WTP).
- Uncertainty analysis.

As no data on the economic impacts of lung cancer cases in Luxembourg was available for the applicant the average health costs found for several countries and for the EU was used instead. In addition, a literature review regarding medical treatment costs of lung cancer was carried out. Based on this information, the applicant calculated the annual average treatment costs of lung cancer in Luxembourg to be €18,500 and the corresponding total average health care costs of a lung cancer patient to be €100,000.

The excess lifetime risk (ELR) of lung cancer for both workers and the general population was assessed using the RAC's dose-response relationships for inorganic arsenic compounds[3]. The corresponding economic burden of lung cancer (i.e. the direct and indirect costs of lung cancer) was estimated based on a rescaling of the statistical cancer cases reported in Tables 8 and 9. The discount rate applied was 4% over 7 and 12 years. The health impact assessment was scaled to 7 and 12 years to coincide with possible review period recommendations and to match the assessment of the economic impacts. SEAC considers the calculations to be appropriate and in accordance with the ECHA guidelines.

When estimating the indirect costs related to cancer the applicant follows the ECHA guidance on valuation of morbidity and mortality. The applicant uses a value of statistical life (VSL) of €1.2 million for quantifying the welfare loss from the increment in mortality risk. The associated cost related to cancer morbidity used a willingness to pay (WTP) to avoid cancer of €400,000.

[3] As the applicant provided new information during the opinion making process, the figures reported in the opinion do not coincide with those provided in the application.

The risk of lung cancer for workers was monetized by the applicant at €650 (over 7 years) and €1,000 (over 12 years). For the general population the corresponding risk was quantified at €60,000 (over 7 years) and €90,000 (over 12 years).

The applicant performed an uncertainty analysis using more conservative assumptions about the duration of the workers' tasks (8 hours) and a higher value of statistical life for cancer (€5 million). The monetised residual risk of lung cancer for workers increased to €2,000 (over 7 years) and €3,500 (over 12 years), respectively. For the general population the corresponding risk increased to €183,000 (over 7 years) and €313,000 (over 12 years) respectively.

The applicant declared that some of the uncertainties in the health impact assessment are related to the direct costs for treatment of diseases and the estimation of production loss. Regarding treatment costs, the applicant assumed that follow-up costs are of the same magnitude as the main treatment costs. When estimating production losses, the applicant assumed that workers diagnosed with lung cancer would not resume work during the treatment period. The applicant considered the above points to result in a conservative (overestimating) assessment of the cancer burden.

SEAC considers the health impact assessment to be conservative (given the overestimation of risk) but generally in accordance with the ECHA guidelines on SEA.

Benefits of continued use (cost of non-use scenario)

The applicant compared the benefits of continued use based on a non-use scenario where the company would shut down its operations in the EU and the production of copper foil would relocate to South Korea (where its main shareholder, Doosan, is based). In the non-use scenario, the applicant would not build a new plant but buy an existing facility to save time and facilitate the relocation process. The applicant claims that this would be the only option that would allow a supply by the applicant to those customers who need more time to substitute to arsenic acid-free copper foils. Alternatively, the customers would buy the copper foils from another supplier and competitor outside the EU. To SEAC's understanding the relocation to South Korea would also include the production of the copper foil free from arsenic acid.

SEAC concurs with the applicant that the assessed non-use scenario is the most plausible scenario if an authorisation was not granted for the copper foil produced using arsenic acid. As production costs in Asia tend to be lower than in Europe, it seems unlikely that the applicant would split the production to two sites—one in Luxembourg and one in South Korea. If the applicant only relocated its production of arsenic acid containing copper foil to Asia, it would still be subject to an authorisation requirement for the use of chromium trioxide.

The applicant assessed the non-use scenario both from the applicant's and from society's perspective. The applicant's perspective is applied when assessing the investment costs for launching the production in South Korea, whilst the societal perspective is applied when considering the impacts on the European economy and the indirect economic impacts to the customers due to the relocation.

According to the applicant, all of the 250 employees would lose their job as a result of the relocation. Even though Luxembourg is one of the EU Member States with the lowest long-term unemployment and highest GDP per capita, it is clear that the impact on the

unemployment of a shutdown and relocation would be economically important. The applicant did not quantify these impacts. Whilst SEAC reasons that most of the affected workers would find a new job within a period of one to two years, SEAC concurs with the applicant's conclusion that the social cost of frictional unemployment would be a negative impact associated with the non-use scenario.

Although the applicant has currently a market share of 75% in the EU, it states that the total quantity of copper foil supplied to the EU market would not be affected in the non-use scenario. However, the applicant claimed that its customers could expect higher prices because of the additional cost for transportation. Also for the part of the copper foil production already manufactured without arsenic acid the non-use scenario would bring unnecessary negative impacts such as longer transports and increased storage costs.

The applicant reasons that the non-use scenario could lead to a domino effect resulting in a possible relocation of its European customers within the electronic industry to Asia as well. The reasons mentioned are increased costs for all EU customers, increased costs for transportation, lack of flexibility and increased time for delivery. SEAC was unable to assess the plausibility of this scenario effect.

The benefits of continued use quantified by the applicant included in its assessment of the economic impacts of the non-use scenario included:

- investments that the applicant would have to make in the "non-use" scenario;
- the residual value of the investments made into the building in Luxembourg;
- the loss of the added value of the production of copper foils in the EU;
- costs for transport for importing copper foils from the new production site (that would be located in South Korea).

In total, the applicant calculated that the benefits of continued use would be in a range between €380 million (over 7 years) and €480 million (over 12 years)[4]. SEAC noted that the applicant included the value added forgone to measure its economic losses. However, welfare impacts should be measured in terms of the expected profit losses as those correspond to the loss in producer surplus. Doing so would reduce the benefits of continued use by roughly €60 million to €90 million. SEAC concludes that correcting this would not have a major impact on the net benefits of continued use.

SEAC conclusion

SEAC concurs with the applicant's assessment of the monetised excess life time risk for lung cancer. SEAC concludes that the benefits of continued use are somewhat overstated and that a more reasonable estimate would be in the order of €300 million (over 7 years) to €400 million (over 12 years). The applicant included an uncertainty analysis, with the conclusion that the benefits of continued use outweigh the associated risks by at least three orders of magnitude. SEAC therefore considers the applicant's conclusion that the benefits outweigh the risks of continued use to be justified.

[4] The applicant has also estimated the sum of the monetised risks from the two applications (Arsenic acid and Chromium trioxide) and compared them to the benefits of continued use. Even then, the conclusion that benefits outweigh the risks by at least 3 orders of magnitude remains valid.

9. Do you propose additional conditions or monitoring arrangements

☒ YES

☐ NO

RAC Conditions

Description for additional conditions and monitoring arrangements for the authorisation:

None

Description of conditions and monitoring arrangements for review reports:

The applicant must implement regular campaigns of occupational exposure measurements (as they already have stated in the information provided to RAC) relating to the use of arsenic acid described in this application. These monitoring campaigns must be based on relevant standard methodologies or protocols and ensure a sufficiently low detection limit. They shall comprise both personal and static (where appropriate) inhalation exposure sampling and be representative of the range of tasks with possible exposure to arsenic acid and of the total number of workers that are potentially exposed. The results of the monitoring must be included in any subsequent authorisation review report submitted.

The information gathered in the monitoring campaigns shall be used by the applicant to review the risk management measures (RMMs) and operational conditions (OCs) in order to further reduce workers' exposure to arsenic acid. The outcomes and conclusions of this review including those related to the implementation of any additional RMMs must be documented.

The results of the monitoring and of the review of the OCs and RMMs must be maintained, be available to national enforcement authorities and included in any subsequent authorisation review report submitted.

Environmental emissions of arsenic acid to air shall be measured with the results of the monitoring made available to enforcement bodies on request. Measurement campaigns shall be undertaken according to standard sampling and analytical methods, where appropriate.

Justification:

An authorisation of a non-threshold carcinogenic substance should be based on a robust and well justified exposure and emissions assessment. In the present case, the recommended monitoring arrangements would address the uncertainties in the emission and exposure assessment.

SEAC Conditions

Description for additional conditions and monitoring arrangements for the authorisation:

The applicant shall follow the schedule for substitution activities provided in the application and shall therefore not use more than the following maximum quantities of arsenic acid; 1000 kg in 2020, 800kg in 2022 and 700 kg in 2024.

Justification:

The aim for the proposed conditions is to phase out the specific use when possible according to the schedule provided by the applicant (see section 7.2).

Description of conditions and monitoring arrangements for review reports:

None

10. Proposed review period:

☒ Normal (7 years)

☐ Long (12 years)

☐ Short (…. _years)

☐ Other:

RAC's advice:

RAC has not given any specific advice on the length of the review period. The uncertainties identified by RAC regarding the calculations of cancer cases for dermal exposure and the indirect exposure to humans via the environment are not considered to be high. RAC has recommended conditions and monitoring arrangements. There is no specific recommendation on risk control that would lead to a short review period based on the RAC assessment.

SEAC's considerations

The applicant has applied for a 12 year review period in order to guarantee the supply of copper foil manufactured with arsenic acid to remaining customers for products with a long technical product lifecycle. The applicant has provided a detailed plan for substitution activities. According to this plan, 85% of the applicant's production will be substituted by 2024 (the duration of a normal review period). The remaining 15% will be substituted, leading to a 100% substitution by 2030 (due to a further substitution of additional 4% in 2027 and a stop of delivery in 2030 for the remaining 11%).

SEAC considers it likely that the use of arsenic acid would only be used for products already placed on the market. The applicant has stated that arsenic acid will not be tested for new copper foil. Furthermore the price of the final copper foil does not increase due to the use of alternative (A).

Given this incentive and the information provided from the applicant about agreements that have been reached with a major client to substitute, as indicated in the timeline for substitution, SEAC considers that an earlier substitution might be agreed by additional clients and that the negative economic impacts of running parallel production lines provide an incentive for the applicant to work towards a substitution.

The applicant claims that, the time when substitution of alternative (A) is possible, is directly linked to each product's technical lifecycle. It is indicated that the technical product lifecycle can be 15 years or longer for some sectors. According to the application the most difficult products to substitute are the ones for military use. These represent 5% of the products currently on the market using copper foil supplied by Circuit Foil. Other products that could require longer time to substitute are critical electronic systems with great

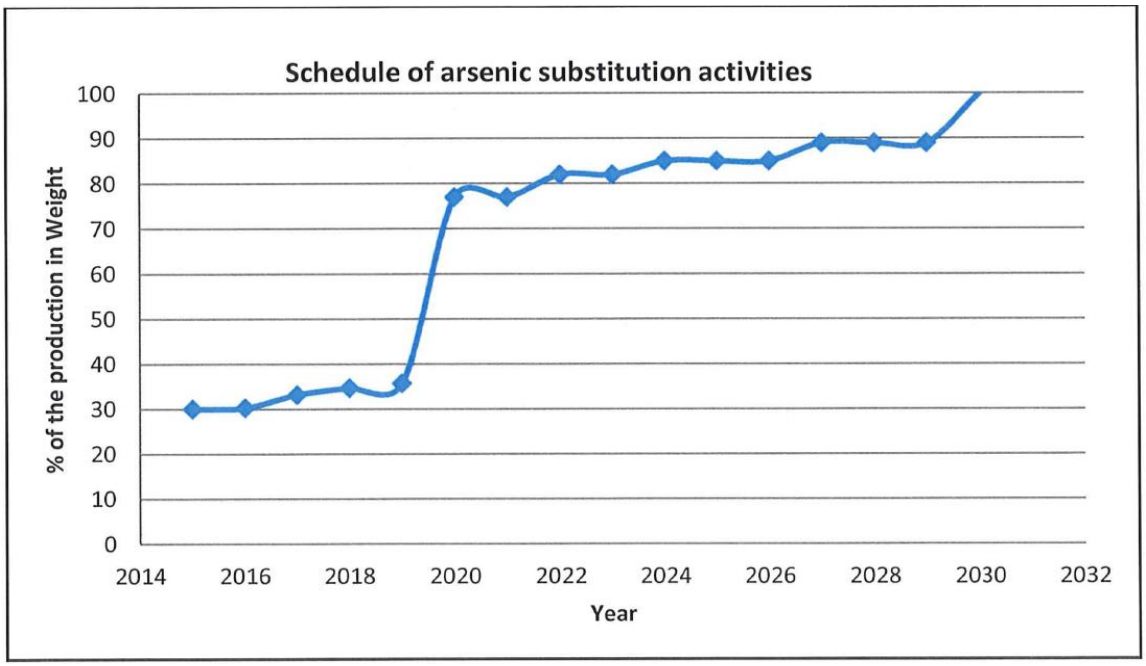
longevity like ground radar, gas transmission systems or high end electronic measurement equipment and medical devices. According to the applicants transitional plan 11% of the total sales of copper foil manufactured with the use of arsenic acid could still remain in 2030. The applicant has however informed its concerned customers that they will not provide any copper foil manufactured with arsenic acid after 2030.

The applicant provided a plan for substitution activities (see Table 11 below) according to which about 77% (in weight) of the use of arsenic acid will already be substituted by 2020.

Table 13: Schedule of substitution of arsenic acid in 2020 – 2030 from the applicant's copper foil production

	2020	2022	2024	2027	2030
Substituted with alternative (A)	77%	82%	85%	89%	100%
Remaining use of arsenic acid per year	1 tonne	800 kg	700 kg	500 kg	0 kg

Source: calculated by SEAC with information from the application (see Socio-Economic Analysis (non- confidential report)[1], Table 3/p13)).



When assessing the application in relation to the criteria for a long review period SEAC finds that some of these criteria were met for about 15% of the applicant's sales for which the applicant's sales the technical product life cycle relating to its customers products is longer than the normal review period of seven years. The applicant has stated that, as the customers will in most cases not substitute before the end of the product life cycle, they would lose customers if only copper foil manufactured without arsenic acid was produced.

One of the main issues concerning the recommendation of the review period is the time required for technical approval and the reluctance of downstream users to change their product design mid product-life cycle. The applicant states that once a product has been developed it is very difficult to change a part of the product. As the applicant is far upstream in the supply chain the direct customers are mainly companies that are manufacturers of parts, which again may be parts of other parts of an article. A small

modification in a production process may cause unexpected performance in the final product downstream and therefore the applicant states that a modification requires a new technical approval, as it cannot be assumed that the product will perform in exactly the same way after a substitution. SEAC also notes that the applicant has provided information of cases were technical approval of alternative (A) has been agreed by customers before the end of product life cycle. As the physical and technical properties are said to be the same, when more experience has been gained, SEAC considers a transition to alternative (A) could be more related to the need for communication and information from the applicant to the customers.

The broad use of copper foil is a reason for uncertainty as the applicant has not been able to collate an inventory of cases where a modified product might cause a performance problem issue, since the applicant does not have access to necessary information from downstream users/customers. SEAC has therefore not been able to evaluate whether customers would still, also after the seven year review period, demand expensive tests and technical approval solely because of the different appearance (colour of surface of the copper foil). SEAC considers the colour of the circuit foil not to be part of the key technical specifications and question whether customers in the scope of their contractual agreement and with regard to the sometimes very long supply chains would reject copper foil solely based on the colour.

SEAC conclusion

When assessing the application in relation to review period, SEAC took note of the applicant's plan for substitution activities used for moving to the arsenic acid free copper foil production. Based on the information provided by the applicant, a full substitution would take until 2030 (the applicant has communicated a stop of delivery in 2030 for the remaining 11% of the total sales). If a review period of seven years was granted the applicant could for business activities thereafter:

- submit a review report in order to extend the authorisation or

- stop producing copper foil with arsenic acid or

- relocate the production of copper foil with arsenic acid to outside the EU.

SEAC finds that none of these scenarios indicates that the applicant would have to exit the market, especially as the volume of the arsenic acid free copper foil would make up to 80% or more of the current business volume. Based on the applicant's assessment a suitable alternative would be available for almost 80% of the business volume at the end of a seven year review period. Information from the applicant also show example of that a transition can take place sooner implying that the volume might be even higher.

In case the applicant after a seven year review period stops producing copper foil with arsenic acid the remaining customers could either accept or test the copper foil without arsenic acid, also taking later experiences to be gained into consideration.

SEAC concludes based on its assessment that a review period of seven years is justified from the information presented by the applicant. A normal review period would give the applicant and its customer's time to further work on the substitution and the technical approval needed.

11. Did the Applicant provide comments to the draft final opinion?

☒ YES

☐ NO

11a. Action/s taken resulting from the analysis of the Applicant's comments:

☒ YES

☐ NO

☐ NOT APPLICABLE

Justification:

SEAC has further edited the text of the opinion taking the comments received by the applicant into consideration. Some amendments were made to clarify the following aspects:

- The assessments and conclusions of SEAC were further edited to improve clarity and to make use of more neutral wording.
- The conclusion on technical and economic feasibility was not changed but the justifications were further edited and clarified regarding e.g. the contractual agreements between the applicant and its customers, the need for technical approval and the content of the technical specifications. For example text was edited in order to clarify that the colour of the foil is different but that the physical properties are not. Alternative (A) fulfils the quality criteria as it has the same properties and since the results achieved are equivalent.
- The conclusion regarding the length of review period was not changed but the text of the justification was further edited to clarify the assessment made and the considerations taken into account by SEAC.