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.

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Last data extracted on 30.05.2024

Substance name: benzenamine, *N*-phenyl-, reaction products with 2,4,4-trimethylpentene
CAS number: 68411-46-1
EC number: 270-128-1
Dossier submitter: France

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
24.04.2024	Germany		Individual	1
Comment received				
The submission of the current dossier is accompanied by the submission of a CLH dossier for reaction products of diphenylamine with nonene, branched based on the read-across to EC No. 270-128-1, CAS No. 68411-46-1.				

Date	Country	Organisation	Type of Organisation	Comment number
03.05.2024	Germany	<confidential>	Company-Downstream user	2
Comment received				
<confidential> supports the proposal and position of ATC (ATC Document 156, April 2024). ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment 270-121_CLH.zip				

Date	Country	Organisation	Type of Organisation	Comment number
03.05.2024	Germany	<confidential>	Company-Manufacturer	3
Comment received				
We strongly agree with the comment given by the „Additive Technical Committee" (ATC). In addition, we want to add the following: C4:C8 SDPAs are used as antioxidants in lubricants, hydraulic oils, greases, metal working fluids and anticorrosive agents. Classification of the antioxidants as Repr. 1 will also require classification of end products, resulting in restriction or even ban for consumer products from the market. In addition, professional and industrial users will strongly refuse these products due to incompliance between classification and corporate guidelines. When enriched with C4:C8 SDPAs lubricants become suitable and effective especially for transport, power generation (greases for wind turbines) and other industrial, heavy duty and energy uses that are important to reach the goals of the EU Green Deal. C4:C8 SDPA				

enriched lubricants effectively and sustainably reduce friction and wear, they provide cooling and sealing properties of the fluid and add important corrosion-inhibiting effects.

Alternative antioxidants are currently not available by our suppliers. Alternatives seem to be less effective, less sustainable, less compatible with current formulations and thus much more expensive when considering the entire product developing process.

Regarding the current classification we trust the information from our supplier as it is also the lead registrant and data owner. For the proposed CLH dossier, we cannot assess neither whether the test results for classification are valid, nor whether read-across from C9-SDPA to C4:C8-SDPA is acceptable. Following the test results (OECD 421 and OECD 443) from the registration dossier and based on the evaluation of all available date, our supplier (lead registrant) concludes the C4:C8-SDPA requires classification Repr. 2, H361f. There is no evidence for a stronger classification.

Date	Country	Organisation	Type of Organisation	Comment number
02.05.2024	Germany	<confidential>	Industry or trade association	4

Comment received

Die <confidential> stimmt mit der Bewertung des „Dossier Sumitters (DS)" nicht überein. Die Einstufung des Stoffes „Benzenamin, N-Phenyl-, Reaktionsprodukte mit 2,4,4-Trimethylpenten (EC 270-128-1)" als Repr. 1B (H360 FD) und Aquatic Chronic 2 (H411) ist nicht gerechtfertigt. Bei der Durchsicht des Dossiers wurden diverse Unzulänglichkeiten bei den aufgeführten Daten festgestellt. Diese beeinträchtigen die Gesamtbeurteilung der toxikologischen Relevanz und des Schweregrads der beobachteten Befunde.
Eine korrekte und vollständige Zusammenfassung aller verfügbaren Nachweise und eine fundierte Datenbewertung sind die Mindestvoraussetzung für eine solide Entscheidung über die Einstufung.
<confidential> bittet daher den Dossier Submitter (DS), den Berichterstatter und das Risk Assessment Committee (RAC) die vorhandenen Daten sowie die eingereichten Informationen des ATC (Technical Committee of Petroleum Additive Manufacturers in Europe) erneut zu prüfen und in die Entscheidung in das weitere Verfahren bezüglich der Einstufung mit einzubeziehen.

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment 2024-05-02 Profile <confidential>.pdf

Date	Country	Organisation	Type of Organisation	Comment number
02.05.2024	Germany	<confidential>	Industry or trade association	5

Comment received

Die <confidential> stimmt mit der Bewertung des „Dossier Sumitters (DS)" nicht überein. Die Einstufung des Stoffes „Reaction products of diphenylamine with nonene, branched (EC 701-385-4)" als Repr. 1B (H360FD) und Aquatic Chronic 1 (H410) ist nicht gerechtfertigt. Bei der Durchsicht des Dossiers wurden diverse Unzulänglichkeiten bei den aufgeführten Daten festgestellt. Diese beeinträchtigen die Gesamtbeurteilung der toxikologischen Relevanz und des Schweregrads der beobachteten Befunde.
Eine korrekte und vollständige Zusammenfassung aller verfügbaren Nachweise und eine fundierte Datenbewertung sind die Mindestvoraussetzung für eine solide Entscheidung über die Einstufung.
<confidential> bittet daher den Dossier Submitter (DS), den Berichterstatter und das Risk

Assessment Committee (RAC) die vorhandenen Daten sowie die eingereichten Informationen des ATC (Technical Committee of Petroleum Additive Manufacturers in Europe) erneut zu prüfen und in die Entscheidung in das weitere Verfahren bezüglich der Einstufung mit einzubeziehen.

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment 2024-05-02 Profile <confidential>.pdf

Date	Country	Organisation	Type of Organisation	Comment number
02.05.2024	Belgium	ATIEL	Industry or trade association	6

Comment received

ATIEL is the Technical Association of the European Lubricants Industry and represents the leading European and international engine oil manufacturers and marketers. ATIEL is downstream user of the substance Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC 270-128-1).
ATIEL is aware that our response to the CLH public consultation should focus on comments regarding the proposed classification and should be scientific in nature. However, ATIEL would like to point out the consequences if the proposed classification by the dossier submitter (DS) is adopted. The impact on the EU economy would be significant, and ATIEL strongly encourage RAC, member state authorities and the Commission to base their decision for future harmonized classification on scientifically sound weight of evidence and reliable interpretations of the available toxicology data.
Classification of Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC 270-128-1) as Reproductive Toxicity Category 1B (H360FD) will lead to an unwarranted and generic restriction under the EU REACH Regulation on the majority of consumer uses of lubricating oils (containing the substance at ≥0.3% - by addition to REACH Annex XVII entry 30), as well as increasing the risk of a later Authorisation or wider scoping Restriction proposal under EU REACH..
Additionally, ATC members are of the view that there are currently no viable alternative antioxidants. Therefore, there will be significant impacts on ATIEL member companies who are producers of lubricants and their customers which will include Original Equipment Manufacturers (OEMs).
The substituted diphenylamine's Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene is a crucial antioxidant in lubricant formulations. Even if it is typically used at very low concentration in lubricant mixtures, it has a critical effect on the lifespan, durability, and technical performance of lubricants. It reduces the need for replacement/top-up of the lubricants in vehicles. It has a very important role for strategic uses in the energy transition (wind power, electrical vehicles, energy efficiency of internal combustion engines and others) and contributing to sustainability goals of the EU green deal. Currently there are no other types of antioxidant substances able to replace the substituted diphenylamines that can provide the same durability and technical performances. Just to reiterate, performance lubricants are critical for the transport sector and all types of industries and play a key role for the energy transition and sustainability.
A potential classification as Reproductive Toxicity Category 1B poses substantial challenges to the lubricant industry. Many lubricant formulations in Europe will become classified as Reproductive Toxicity Category 1B, rendering them unsuitable for sale. With no current technical alternative available, reformulation would not be possible by the time of application of the harmonized classification, which will lead to a significant gap for European economy with an impact on green deal objectives.
This would be particularly disruptive for automotive lubricants packed in smaller quantities (e.g., 3, 5 liters) commonly sold to both the general public and professionals such as

garages. It’s important to note that while lubricants are perceived as consumer products, they are primarily for professional use.
Lubricants are added when the car is produced (first fill) by the OEMs and then are recirculated in closed system in the car. In time it is possible to have to top up a part of the oil or to replace the oil completely. While consumers may occasionally top up their lubricants, the operation of complete oil replacement is typically handled by professionals due to the complexity of modern vehicle systems. Even topping up is limited in terms of frequency and duration, with minimal exposure time and infrequent occurrences (takes less than 2-3 minutes and it is done at maximum few times per year). Due to the very low vapor pressure of the substance, exposure via inhalation is negligible. Dermal exposure is of low relevance as it is very unlikely that the substance will penetrate skin barrier. Used oils are collected as hazardous waste by certified waste disposal companies. In most cases, disposal is by incineration. Therefore, it can be assumed that there is only very low risk of exposure to people and / or the environment.
In conclusion, in the case of classification of Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene as Reproductive Toxicity Category 1B, the repercussions would be felt across the lubricant industry and not only, with high consequences for socio-economic landscape in Europe.

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment 2024 April _ ATIEL_CLH SDPA_EC 270-128-1_V2 final.pdf

Date	Country	Organisation	Type of Organisation	Comment number
02.05.2024	Belgium	ATIEL	Industry or trade association	7

Comment received

ATIEL is the Technical Association of the European Lubricants Industry and represents the leading European and international engine oil manufacturers and marketers. ATIEL is downstream user of the substance Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC 270-128-1).
ATIEL is aware that our response to the CLH public consultation should focus on comments regarding the proposed classification and should be scientific in nature. However, ATIEL would like to point out the consequences if the proposed classification by the dossier submitter (DS) is adopted. The impact on the EU economy would be significant, and ATIEL strongly encourage RAC, member state authorities and the Commission to base their decision for future harmonized classification on scientifically sound weight of evidence and reliable interpretations of the available toxicology data.
Classification of Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC 270-128-1) as Reproductive Toxicity Category 1B (H360FD) will lead to an unwarranted and generic restriction under the EU REACH Regulation on the majority of consumer uses of lubricating oils (containing the substance at ≥0.3% - by addition to REACH Annex XVII entry 30), as well as increasing the risk of a later Authorisation or wider scoping Restriction proposal under EU REACH..
Additionally, ATC members are of the view that there are currently no viable alternative antioxidants. Therefore, there will be significant impacts on ATIEL member companies who are producers of lubricants and their customers which will include Original Equipment Manufacturers (OEMs).
The substituted diphenylamine's Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene is a crucial antioxidant in lubricant formulations. Even if it is typically used at very low concentration in lubricant mixtures, it has a critical effect on the lifespan, durability, and technical performance of lubricants. It reduces the need for replacement/top-up of the lubricants in vehicles. It has a very important role for strategic

uses in the energy transition (wind power, electrical vehicles, energy efficiency of internal combustion engines and others) and contributing to sustainability goals of the EU green deal. Currently there are no other types of antioxidant substances able to replace the substituted diphenylamines that can provide the same durability and technical performances. Just to reiterate, performance lubricants are critical for the transport sector and all types of industries and play a key role for the energy transition and sustainability.
A potential classification as Reproductive Toxicity Category 1B poses substantial challenges to the lubricant industry. Many lubricant formulations in Europe will become classified as Reproductive Toxicity Category 1B, rendering them unsuitable for sale. With no current technical alternative available, reformulation would not be possible by the time of application of the harmonized classification, which will lead to a significant gap for European economy with an impact on green deal objectives.
This would be particularly disruptive for automotive lubricants packed in smaller quantities (e.g., 3, 5 liters) commonly sold to both the general public and professionals such as garages. It's important to note that while lubricants are perceived as consumer products, they are primarily for professional use.
Lubricants are added when the car is produced (first fill) by the OEMs and then are recirculated in closed system in the car. In time it is possible to have to top up a part of the oil or to replace the oil completely. While consumers may occasionally top up their lubricants, the operation of complete oil replacement is typically handled by professionals due to the complexity of modern vehicle systems. Even topping up is limited in terms of frequency and duration, with minimal exposure time and infrequent occurrences (takes less than 2-3 minutes and it is done at maximum few times per year). Due to the very low vapor pressure of the substance, exposure via inhalation is negligible. Dermal exposure is of low relevance as it is very unlikely that the substance will penetrate skin barrier. Used oils are collected as hazardous waste by certified waste disposal companies. In most cases, disposal is by incineration. Therefore, it can be assumed that there is only very low risk of exposure to people and / or the environment.
In conclusion, in the case of classification of Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene as Reproductive Toxicity Category 1B, the repercussions would be felt across the lubricant industry and not only, with high consequences for socio-economic landscape in Europe.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2024 April _ ATIEL_CLH SDPA_EC 270-128-1_V2 final.pdf

Date	Country	Organisation	Type of Organisation	Comment number
02.05.2024	Belgium	ATIEL	Industry or trade association	8

Comment received

ATIEL is the Technical Association of the European Lubricants Industry and represents the leading European and international engine oil manufacturers and marketers. ATIEL is downstream user of the substance Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC 270-128-1).
ATIEL is aware that our response to the CLH public consultation should focus on comments regarding the proposed classification and should be scientific in nature. However, ATIEL would like to point out the consequences if the proposed classification by the dossier submitter (DS) is adopted. The impact on the EU economy would be significant, and ATIEL strongly encourage RAC, member state authorities and the Commission to base their decision for future harmonized classification on scientifically sound weight of evidence and reliable interpretations of the available toxicology data.
Classification of Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene

(EC 270-128-1) as Reproductive Toxicity Category 1B (H360FD) will lead to an unwarranted and generic restriction under the EU REACH Regulation on the majority of consumer uses of lubricating oils (containing the substance at ≥0.3% - by addition to REACH Annex XVII entry 30), as well as increasing the risk of a later Authorisation or wider scoping Restriction proposal under EU REACH..
Additionally, ATC members are of the view that there are currently no viable alternative antioxidants. Therefore, there will be significant impacts on ATIEL member companies who are producers of lubricants and their customers which will include Original Equipment Manufacturers (OEMs).
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A potential classification as Reproductive Toxicity Category 1B poses substantial challenges to the lubricant industry. Many lubricant formulations in Europe will become classified as Reproductive Toxicity Category 1B, rendering them unsuitable for sale. With no current technical alternative available, reformulation would not be possible by the time of application of the harmonized classification, which will lead to a significant gap for European economy with an impact on green deal objectives.
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In conclusion, in the case of classification of Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene as Reproductive Toxicity Category 1B, the repercussions would be felt across the lubricant industry and not only, with high consequences for socio-economic landscape in Europe.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2024 April _ ATIEL_CLH SDPA_EC 270-128-1_V2 final.pdf

Date	Country	Organisation	Type of Organisation	Comment number
02.05.2024	Belgium	ATIEL	Industry or trade association	9

Comment received
ATIEL is the Technical Association of the European Lubricants Industry and represents the leading European and international engine oil manufacturers and marketers. ATIEL is downstream user of the substance Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC 270-128-1). ATIEL is aware that our response to the CLH public consultation should focus on comments regarding the proposed classification and should be scientific in nature. However, ATIEL would like to point out the consequences if the proposed classification by the dossier submitter (DS) is adopted. The impact on the EU economy would be significant, and ATIEL strongly encourage RAC, member state authorities and the Commission to base their decision for future harmonized classification on scientifically sound weight of evidence and reliable interpretations of the available toxicology data. Classification of Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC 270-128-1) as Reproductive Toxicity Category 1B (H360FD) will lead to an unwarranted and generic restriction under the EU REACH Regulation on the majority of consumer uses of lubricating oils (containing the substance at ≥0.3% - by addition to REACH Annex XVII entry 30), as well as increasing the risk of a later Authorisation or wider scoping Restriction proposal under EU REACH.. Additionally, ATC members are of the view that there are currently no viable alternative antioxidants. Therefore, there will be significant impacts on ATIEL member companies who are producers of lubricants and their customers which will include Original Equipment Manufacturers (OEMs). The substituted diphenylamine's Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene is a crucial antioxidant in lubricant formulations. Even if it is typically used at very low concentration in lubricant mixtures, it has a critical effect on the lifespan, durability, and technical performance of lubricants. It reduces the need for replacement/top-up of the lubricants in vehicles. It has a very important role for strategic uses in the energy transition (wind power, electrical vehicles, energy efficiency of internal combustion engines and others) and contributing to sustainability goals of the EU green deal. Currently there are no other types of antioxidant substances able to replace the substituted diphenylamines that can provide the same durability and technical performances. Just to reiterate, performance lubricants are critical for the transport sector and all types of industries and play a key role for the energy transition and sustainability. A potential classification as Reproductive Toxicity Category 1B poses substantial challenges to the lubricant industry. Many lubricant formulations in Europe will become classified as Reproductive Toxicity Category 1B, rendering them unsuitable for sale. With no current technical alternative available, reformulation would not be possible by the time of application of the harmonized classification, which will lead to a significant gap for European economy with an impact on green deal objectives. This would be particularly disruptive for automotive lubricants packed in smaller quantities (e.g., 3, 5 liters) commonly sold to both the general public and professionals such as garages. It’s important to note that while lubricants are perceived as consumer products, they are primarily for professional use. Lubricants are added when the car is produced (first fill) by the OEMs and then are recirculated in closed system in the car. In time it is possible to have to top up a part of the oil or to replace the oil completely. While consumers may occasionally top up their lubricants, the operation of complete oil replacement is typically handled by professionals due to the complexity of modern vehicle systems. Even topping up is limited in terms of frequency and duration, with minimal exposure time and infrequent occurrences (takes less than 2-3 minutes and it is done at maximum few times per year). Due to the very low vapor pressure of the substance, exposure via inhalation is negligible. Dermal exposure is of low relevance as it is very unlikely that the substance will penetrate skin barrier. Used oils are collected as hazardous waste by certified waste disposal companies. In most cases, disposal is by incineration. Therefore, it can be assumed that there is only very low risk of exposure

to people and / or the environment.
In conclusion, in the case of classification of Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene as Reproductive Toxicity Category 1B, the repercussions would be felt across the lubricant industry and not only, with high consequences for socio-economic landscape in Europe.

Date	Country	Organisation	Type of Organisation	Comment number
11.04.2024	United Kingdom	ATC (Additive Technical Committee)	Industry or trade association	10
Comment received				
This substance has proven to be a highly effective antioxidant for lubricants which are essential for transport, power generation and a range of other industries. Use of this substance in lubricants allows equipment and vehicle manufacturers to comply with increasingly stringent fuel efficiency and emission targets, to enhance hardware durability, and to reduce the use of chemicals and mineral oils, thereby benefitting the European economy, society and environment and contributing to the sustainability goals of the EU Green Deal. The Restriction on consumer uses (per REACH Annex XVII) of the majority of lubricating oils that would directly arise from the proposed Reprotoxicity Category 1B CLH, would lead to the loss from the market of a widely used anti-oxidant having the above benefits, without any obvious existing viable alternative of equivalent performance and safety characteristics. ECHA note – An attachment was submitted with the comment above. Refer to public attachment EC 270-128-1 CLH - ATC Comments Public Consultation.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
01.05.2024	United States of America	American Chemistry Council	Industry or trade association	11
Comment received				
Please accept the attached comments from the American Chemistry Council. ECHA note – An attachment was submitted with the comment above. Refer to public attachment ACC SDPA_Committee for Risk Assessment_CLH_EC 270-128-1_30April2024_Redacted.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment ACC SDPA_Committee for Risk Assessment_CLH_EC 270-128-1_30April2024.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
29.04.2024	India	<confidential>	Company-Manufacturer	12
Comment received				
We hereby confirm our support for Document 156 – EC 270-128-1 CLH – ATC Comments Public Consultation and Document 157 – EC 701-385-1- ATC Public Consultation.				

Date	Country	Organisation	Type of Organisation	Comment number
29.04.2024	Germany	<confidential>	Company-Downstream	13

			user	
Comment received				
Substituted diphenyl amine (SDPA) substances are one of the most effective antioxidant for the use in Lubricants. They are used for decades and have shown high performance and have proven to be the most effective antioxidant chemistry in a wide range of applications. They are used in high performance lubricants, high performance greases and also in standard lubricants and standard greases, in various applications. Such Lubricants are essential for transport, power generation and many other industrial uses. Lubricants are key to reduce energy consumption, reduce wear and therefore reduce CO2 emissions and help to extend lifetime of components. Alltogether Lubricants additised with such substances contribute to the sustainability goals of the Eurpean Green Deal and they support all industries and the EU to achieve these goals. At the moment alternatives with the same performance are not known to us. According to our knowledge the development and approval of alternatives in the whole supply chain takes years. The CLH classification would have a big impact on the lubricants industry and also the industries in the supply chain Therefore we support the Documents of ATC Europe No. 155, 156				

Date	Country	Organisation	Type of Organisation	Comment number
28.04.2024	Japan	<confidential>	Company-Manufacturer	14
Comment received				
We disagree with the proposal of the dossier submitter (DS) to classify the Substituted Diphenylamine (DPA), benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC 270-128-1, CAS 68411-46-1) and reaction products of diphenylamine with nonene (EC 701-385-4) into the Reprotoxic Category 1B. The Technical Committee of Petroleum Additive Manufacturers in Europe (ATC) has issued and posted two documents (Document 156 and Document 157) on the ATC Website (https://www.atc-europe.org/) to explain their opinions about this CLH proposal. The ATC concluded that the CLH report did not show enough data to justify the DS proposal and disagrees with the DS proposal. We would like to provide our comments related to the potential consequences by categorization of the SDPA into Repro Cat.1B. These substances have been widely used as very effective anti-oxidants in variety of lubricants and greases for several decades, including engine oils. Both modern gasoline and diesel engines require very high performance in terms of high temperature oxidation controls. These SDPAs are the major and important substances to meet these requirements defined by industry engine oil standards. According to the technical data sheets from the suppler, recommended treat rate is 0.3 ~ 1.0% range. If these SDPAs are categorized as Repro Cat.1B, they will be restricted, and it is likely that they cannot be added to lubricant products at the effective level to provide current oxidation control performance. These engine oils which meet modern industry specifications have contributed to reduce CO2 emission by improving fuel efficiency of engines and reduce waste engine oils by extending their drain intervals over the decades of industry efforts. Development of alternative new anti-oxidants or new formulations without SDPA to replace most of current engine oil products in the market will require significant research and development works which require years of efforts. Since alternative substances will have chemically active natures, it will be possible case that they have similar or higher toxic concerns. If these substances are overly regulated, it will cause significant impact to various industries and markets in the EU and prevent the Green Deal from being achieved. Thus, we would like to propose that this CLH proposal should not be implemented at this point and should be reviewed only when additional data is available.				

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

Date	Country	Organisation	Type of Organisation	Comment number
25.04.2024	Germany	BASF SE	Company-Manufacturer	15

Comment received

CLH Dossier Reaction products of Benzenamine, N-phenyl-, reaction products with 2,4,4-Trimethylpentene
EC 270-128-1
Statement on page 65 regarding the impurities in the CLH report.

We would like to provide as SIEF member, additional information to the ATC Document 156 regarding the following point in the CLH report:

10.10.11Assessment of the reliability of the read-across (in line with the ECHA Read-Across Assessment Framework, RAAF). Page 64

Specifically, the statement on page 65 regarding the impurities.

"Impurities
The constituents of the two substances and the compositions of the two substances are presented in the tables 2, 3, 4 and 5 of the confidential Annex There are no impurities that have been identified that would lead to substance classification for reproduction. As the manufacturing process is similar for both substances, and the starting material is equivalent, it is expected that the impurities profile are comparable."

According to the literature, the alkylation reaction occurs from the aromatic compound (Diphenylamine, DPA) over the double bond (olefine), for that reason the kinetic of the reaction is different depending on the kind of olefine used. In addition to the olefin reactivity, the stoichiometry and reaction conditions (temperature) are different, in both processes.
Therefore, the impurities profile is not expected to be comparable, because most of it comes from completely different alkylating agents.

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Statement on page 65 regarding the impurities in the CLH report_Final_2024_04_24 (002).pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.04.2024	Germany	JS_68411-46-1	Industry or trade association	16

Comment received

Substance: Benzeneamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene
CAS number 68411-46-1, EC number 270-128-1
The Registrants under REACH (SIEF) support the comments (ATC doc 156) submitted by the ATC.
In addition, the SIEF would like to point out that the read-across was removed as far as possible in the latest dossier update submitted and further data required for complete removal of the read-across is currently ongoing; reports allowing for another dossier update

are expected until end of 2024.

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment 68411-46-1_CLH_confidential data submission_2024-04-24.pdf

HEALTH HAZARDS – Reproductive toxicity

Date	Country	Organisation	Type of Organisation	Comment number
29.04.2024	Germany	<confidential>	Company-Downstream user	17
Comment received				
We support the Documents of ATC Europe No. 155, 156				

Date	Country	Organisation	Type of Organisation	Comment number
01.05.2024	United States of America	American Chemistry Council	Industry or trade association	18
Comment received				
Please accept the attached comments from the American Chemistry Council. ECHA note – An attachment was submitted with the comment above. Refer to public attachment ACC SDPA_Committee for Risk Assessment_CLH_EC 270-128-1_30April2024_Redacted.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment ACC SDPA_Committee for Risk Assessment_CLH_EC 270-128-1_30April2024.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
02.05.2024	Belgium	ATIEL	Industry or trade association	19
Comment received				
Taking into consideration the detailed technical comments prepared by The Additive Technical Committee (ATC) (Document 156, April 2024) on the proposed harmonised classification and labelling for EC 270-128-1, ATIEL agree with ATC in that the proposed classification as toxic to reproduction category 1B for effects on fertility (H360F) and on development (H360D) do not appear to be justified based on the available toxicology data. Please find additional comments in the attached document named "2024 April _ ATIEL_CLH SDPA_EC 270-128-1". ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment 2024 April _ ATIEL_CLH SDPA_EC 270-128-1_V2 final.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
02.05.2024	Belgium	ATIEL	Industry or trade association	20
Comment received				
Taking into consideration the detailed technical comments prepared by The Additive Technical Committee (ATC) (Document 156, April 2024) on the proposed harmonised classification and labelling for EC 270-128-1, ATIEL agree with ATC in that the proposed classification as toxic to reproduction category 1B for effects on fertility (H360F) and on				

development (H360D) do not appear to be justified based on the available toxicology data. Please find additional comments in the attached document named "2024 April _ ATIEL_CLH SDPA_EC 270-128-1".

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2024 April _ ATIEL_CLH SDPA_EC 270-128-1_V2 final.pdf

Date	Country	Organisation	Type of Organisation	Comment number
02.05.2024	Belgium	ATIEL	Industry or trade association	21

Comment received

aking into consideration the detailed technical comments prepared by The Additive Technical Committee (ATC) (Document 156, April 2024) on the proposed harmonised classification and labelling for EC 270-128-1, ATIEL agree with ATC in that the proposed classification as toxic to reproduction category 1B for effects on fertility (H360F) and on development (H360D) do not appear to be justified based on the available toxicology data. Please find additional comments in the attached document named "2024 April _ ATIEL_CLH SDPA_EC 270-128-1".

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2024 April _ ATIEL_CLH SDPA_EC 270-128-1_V2 final.pdf

Date	Country	Organisation	Type of Organisation	Comment number
02.05.2024	Belgium	ATIEL	Industry or trade association	22

Comment received

aking into consideration the detailed technical comments prepared by The Additive Technical Committee (ATC) (Document 156, April 2024) on the proposed harmonised classification and labelling for EC 270-128-1, ATIEL agree with ATC in that the proposed classification as toxic to reproduction category 1B for effects on fertility (H360F) and on development (H360D) do not appear to be justified based on the available toxicology data. Please find additional comments in the attached document named "2024 April _ ATIEL_CLH SDPA_EC 270-128-1".

Date	Country	Organisation	Type of Organisation	Comment number
24.04.2024	Germany		Individual	23

Comment received

Fertility and sexual function:
We support the proposed classification for benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene as a reproductive toxicant category Repr. 1B, H360F.

Rationale: Clear evidence of adverse effects on fertility was demonstrated in reliable, GLP-compliant studies. Specifically, the EOGRT study performed with the test substance (dose: up to 167 mg/kg bw/day) demonstrated a statistically significant reduction in implantations in females of parental (-15.1 %) and progeny generations (-17.1 %), observed in the absence of overt systemic maternal toxicity. The identified target organs (liver and thyroid) could not account for the observed adverse effect on fertility.

In other studies, conducted either with the substance or with its analogue, a similar pattern

of adverse effects on fertility was observed.

Developmental toxicity:
The adverse effect on brain parameters and neuronal integrity, constituting the developmental neurotoxicity effects, were identified as the main concern by the DS.

Brain dimensions/ morphometry: A statistically significant decrease in brain length (-3.2 %) in high dose males of Cohort 2A cannot be explained by the observed reduction in the body weight (< 10 %). For the other cohort (2B) a reduction in the brain length of 2 % ($p > 0.05$) was demonstrated. The biological significance of the reduced brain length cannot be dismissed.

Furthermore, an increase in the width of corpus callosum by 16 – 17 % ($p > 0.05$) in high-dose males and females indicates a further structural change caused by in utero exposure to the substance. From a toxicological perspective, corpus callosum is the area in the brain which is sensitive to the maternal thyroid hormone insufficiency, resulting in formation of heterotopias (localised neurons that failed to migrate), see https://doi.org/10.1210/en.2006-1276.

Startle response: A decrease in habituation (-57 %) during the startle response measurements was demonstrated in high-dose males (Cohort 2A). This finding may be indicative of a change in the behavioural responses in this group of treated males. However, no further behavioural changes were reported in the functional observation battery or cage observations.

Axonal degeneration of thoracic cord was observed in 9/10 males of Cohort 2A, but not in the Cohort 2B males. At the same time, no other areas (e.g., lumbar cord, proximal sciatic nerve or proximal tibial nerve) were investigated in the Cohort 2B males.

Thyroid hormones: In spite of the performed thyroid hormone measurement in PND4 pups, indicative of a profound reduction in T4 in high-dose males (-37 %) and females (-16 %), the low number of pups used in the high dose group ($n = 2$ per sex) precludes conclusiveness of this observation.

Taken together, the findings support the conclusion that exposure to the classified substance causes developmental neurotoxicity. Considering some uncertainty of histopathological findings of axonal degeneration, which otherwise would represent clear evidence of DNT supported by the findings of changes in brain length, corpus callosum width and decreased habituation, a potential alternative classification category for the effects on development could be considered (i.e. Repr. 2, H360d).

A RAC note (RAC/62/2022/05) is summarised in the report that addresses developmental neurotoxicity and neurotoxicity under the current CLP hazard classes. This note has an influence on the proposal of the DS. Unfortunately, this note was not included in the documents of the public consultation and could not be easily found on the internet. This RAC note is very interesting and should be made available to a wider audience to better understand the rationale of the DS.

Date	Country	Organisation	Type of Organisation	Comment number
11.04.2024	United Kingdom	ATC (Additive Technical Committee)	Industry or trade association	24

Comment received
ATC disagrees with the assessment of the dossier submitter and does not consider the proposed CLH of Reprotoxicity Category 1B (H360 FD) as warranted based on the available toxicology data for the reasons explained in the attached document. ECHA note – An attachment was submitted with the comment above. Refer to public attachment EC 270-128-1 CLH - ATC Comments Public Consultation.pdf

Date	Country	Organisation	Type of Organisation	Comment number
03.05.2024	United Kingdom	Health and Safety Executive	National Authority	25
Comment received				
'The DS has proposed a classification of Repr. 1B for developmental effects based primarily on histopathological changes in the spinal cord and impairment of acoustic startle response, both reported in cohort 2A in the EOGRTS. There are a number of uncertainties with the data and therefore we would welcome a discussion on the following points: • Thoracic spinal cord degeneration is reported in cohort 2A males. It would be useful to discuss the severity of these effects and any likely functional consequences that are expected/observed as outlined in paragraph 83 of OECD TG 443. It would also be useful to address any functional deficiencies that are observed in any of the other available studies (90-day repeat-dose and EOGRTS), specifically those which may be attributable to thoracic spinal cord degeneration. • In the acoustic startle response test, a decrease in mean maximal amplitude is observed in cohort 2A in conjunction with a decrease in F1 and F2 pup bw. We note that a decrease in pup bw is a covariant of the acoustic startle response (as mentioned in Section 3.2.2, Tyl et al, 2008). It would be useful to provide a comment for the decrease on pup weight and any potential effect on the acoustic startle response.'				

Date	Country	Organisation	Type of Organisation	Comment number
03.05.2024	Germany	<confidential>	Company-Manufacturer	26
Comment received				
as already mentioned i the general comment: Following the test results (OECD 421 and OECD 443) from the registration dossier and based on the evaluation of all available date, our supplier (lead registrant) concludes the C4:C8-SDPA requires classification Repr. 2, H361f. There is no evidence for a stronger classification. Classification of the antioxidants as Repr. 1 will also require classification of end products, resulting in restriction or even ban for consumer products from the market. In addition, professional and industrial users will strongly refuse these products due to incompliance between classification and corporate guidelines.				

Date	Country	Organisation	Type of Organisation	Comment number
24.04.2024	Germany	JS_68411-46-1	Industry or trade association	27
Comment received				
In support of these comments, the SIEF would like to submit the following confidential attachments: - Historical control data available for OECD 421 and 422 studies from the years 2015-2017				

conducted at WIL Research Europe.
- Detailed historical control data on fertility and litter parameters from OECD 421 and 422 studies from the years 2015-2022, provided by Experimental Toxicology Department of BASF.
- Detailed historical control data on fertility and litter parameters from OECD 443 studies from the years 2017-2022, provided by Experimental Toxicology Department of BASF.
- Detailed historical control data on auditory startle test data observed in DNT and EOGRTS studies between 2013 and 2022, provided by Experimental Toxicology Department of BASF
- Expert statement of examining pathologist on neuromorphometrics and neurohistopathological findings in OECD 443 findings in DNT cohort together with historical control data of the relevant parameters.
The SIEF would like to ask the dossier submitter, rapporteur and the members of RAC to take the comments brought forward by ATC as well as the additional information submitted in the attachments into account prior to taking a decision on the classification and labelling of Benzeneamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene.

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment 68411-46-1_CLH_confidential data submission_2024-04-24.pdf

ENVIRONMENTAL HAZARDS – Hazardous to the aquatic environment

Date	Country	Organisation	Type of Organisation	Comment number
29.04.2024	Germany	<confidential>	Company-Downstream user	28
Comment received				
We support the Documents of ATC Europe No. 155, 156				

Date	Country	Organisation	Type of Organisation	Comment number
02.05.2024	Belgium	ATIEL	Industry or trade association	29
Comment received				
aking into consideration the detailed technical comments prepared by The Additive Technical Committee (ATC) (Document 156, April 2024) on the proposed harmonised classification and labelling for EC 270-128-1 ATIEL agree with ATC in that the proposed classifications hazardous to the aquatic environment does not appear to be justified based on the available ecotoxicology data. Please find additional comments in the attached document named "2024 April _ ATIEL_CLH SDPA_EC 270-128-1". ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment 2024 April _ ATIEL_CLH SDPA_EC 270-128-1_V2 final.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
02.05.2024	Belgium	ATIEL	Industry or trade association	30
Comment received				
Additive Technical Committee (ATC) (Document 156, April 2024) on the proposed harmonised classification and labelling for EC 270-128-1 ATIEL agree with ATC in that the proposed classifications hazardous to the aquatic environment does not appear to be justified based on the available ecotoxicology data. Please find additional comments in the				

attached document named "2024 April _ ATIEL_CLH SDPA_EC 270-128-1".

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2024 April _ ATIEL_CLH SDPA_EC 270-128-1_V2 final.pdf

Date	Country	Organisation	Type of Organisation	Comment number
02.05.2024	Belgium	ATIEL	Industry or trade association	31

Comment received

aking into consideration the detailed technical comments prepared by The Additive Technical Committee (ATC) (Document 156, April 2024) on the proposed harmonised classification and labelling for EC 270-128-1 ATIEL agree with ATC in that the proposed classifications hazardous to the aquatic environment does not appear to be justified based on the available ecotoxicology data. Please find additional comments in the attached document named "2024 April _ ATIEL_CLH SDPA_EC 270-128-1".

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2024 April _ ATIEL_CLH SDPA_EC 270-128-1_V2 final.pdf

Date	Country	Organisation	Type of Organisation	Comment number
02.05.2024	Belgium	ATIEL	Industry or trade association	32

Comment received

aking into consideration the detailed technical comments prepared by The Additive Technical Committee (ATC) (Document 156, April 2024) on the proposed harmonised classification and labelling for EC 270-128-1 ATIEL agree with ATC in that the proposed classifications hazardous to the aquatic environment does not appear to be justified based on the available ecotoxicology data. Please find additional comments in the attached document named "2024 April _ ATIEL_CLH SDPA_EC 270-128-1".

Date	Country	Organisation	Type of Organisation	Comment number
24.04.2024	Germany		Individual	33

Comment received

We support the classification as Aquatic Chronic 2. Additionally, we would propose to classify the substance with Aquatic Acute 1 with the following considerations:
The acute aquatic toxicity key study with Daphnia magna results in an EL50 of 51 mg/L based on loading rates. In the study, test substance concentrations were analysed but it was stated that the effects observed could not be clearly attributed to the components analyzed in the WAFs (the mean measured concentrations were all in the same range - 0.32, 0.30, 0.63, and 0.36 mg/L – but there was a loading dose – effects – relationship). The water solubility described was 1.6 mg/L (with uncertainties – components solubility was described as lower). The highest loading rate in the acute Daphnia toxicity test was 100 mg/L with 100 % effect (immobile). Using the water solubility of 1.6 mg/L (highest loading rate) where 100 % effect was observed, the EL50 at the loading rate of 51 mg/L would result in a concentration of
51 %*1.6 mg/L = 0.816 mg/L. This would mean that a classification with Aquatic Acute 1 would be necessary.

Date	Country	Organisation	Type of Organisation	Comment

				number
26.04.2024	United Kingdom	Health and Safety Executive	National Authority	34
Comment received				
benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC: 270-128-1; CAS: 68411-46-1). The CLH report does not propose an Aquatic Acute hazard classification. The DS considers that the relevant endpoint from the Unpublished 2004 acute Daphnia magna study is an EL50 of 51 mg/L based on nominal concentrations. This study employed WAFs with nominal loadings of 4.6, 10, 22, 46 and 100 mg/L. Corresponding measured concentrations are quoted as 0.32, 0.63, 0.63 and 0.36 mg/L for the four highest treatments. We note increasing immobilisation was observed and 100% immobilisation occurred at the measured concentration of 0.36 mg/L. It is not clear in the CLH report or accompanying Annex which component of the UVCB was used for analytical verification and whether these measured concentrations are relevant to describe the overall substance concentrations, although we note all 'measured concentrations' are quoted to be within the 0.1 to 1 mg/L hazard classification range. Is further information available on the analytics performed? Table 41 in the CLH report presents effects showing 0-100% immobilisation with increasing effects. On this basis, and depending on the analytical information, we wonder if a EC50 can be considered to lie within the range of WAFs tested corresponding to mean measured concentrations between 0.1 to 1 mg/L. This would result in an acute hazard classification of Aquatic Acute 1, M-factor 1 if relevant and reliable. In addition, this would result in an Aquatic Chronic 1, M-factor 1 classification through the use of the surrogate method given that analytical information is not available for the long-term Daphnia study.				

Date	Country	Organisation	Type of Organisation	Comment number
01.05.2024	United States of America	American Chemistry Council	Industry or trade association	35
Comment received				
Please accept the attached comments from the American Chemistry Council. ECHA note – An attachment was submitted with the comment above. Refer to public attachment ACC SDPA_Committee for Risk Assessment_CLH_EC 270-128-1_30April2024_Redacted.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment ACC SDPA_Committee for Risk Assessment_CLH_EC 270-128-1_30April2024.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
11.04.2024	United Kingdom	ATC (Additive Technical Committee)	Industry or trade association	36
Comment received				
ATC disagrees with the assessment of the dossier submitter and does not consider the proposed CLH of Aquatic Chronic Category 2 (H411) as warranted based on the available ecotoxicology data for the reasons explained in the attached document.				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment EC 270-128-1 CLH - ATC Comments Public Consultation.pdf

PUBLIC ATTACHMENTS
1. 2024 April _ ATIEL_CLH SDPA_EC 270-128-1_V2 final.pdf [Please refer to comment No. 7, 20, 30]
2. 2024 April _ ATIEL_CLH SDPA_EC 270-128-1_V2 final.pdf [Please refer to comment No. 8, 21, 31]
3. ACC SDPA_Committee for Risk Assessment_CLH_EC 270-128-1_30April2024_Redacted.pdf [Please refer to comment No. 11, 18, 35]
4. SDPA TDS.zip [Please refer to comment No. 14]
5. EC 270-128-1 CLH - ATC Comments Public Consultation.pdf [Please refer to comment No. 10, 24, 36]

CONFIDENTIAL ATTACHMENTS
1. 270-121_CLH.zip [Please refer to comment No. 2]
2. 2024-05-02 Profile <confidential>.pdf [Please refer to comment No. 4]
3. 2024-05-02 Profile <confidential>.pdf [Please refer to comment No. 5]
4. 2024 April _ ATIEL_CLH SDPA_EC 270-128-1_V2 final.pdf [Please refer to comment No. 6, 19, 29]
5. ACC SDPA_Committee for Risk Assessment_CLH_EC 270-128-1_30April2024.pdf [Please refer to comment No. 11, 18, 35]
6. Statement on page 65 regarding the impurities in the CLH report_Final_2024_04_24 (002).pdf [Please refer to comment No. 15]
7. 68411-46-1_CLH_confidential data submission_2024-04-24.pdf [Please refer to comment No. 16, 27]