Committee for Risk Assessment

RAC

Annex 3
Records
of the targeted public consultation in relation to the classification of acute toxicity

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide

EC Number: 272-697-1
CAS Number: 68909-20-6

CLH-O-0000006735-67-01/F

Adopted

5 December 2019

ANNEX 3 - RECORDS OF THE TARGETED PUBLIC CONSULTATION IN RELATION TO THE CLASSIFICATIO OF ACUTE TOXICITY OF SILANAMINE, 1,1,1-TRIMETHYL-N-(TRIMETHYLSILYL)-, HYDROLYSIS PRODUCTS WITH SILICA

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

The proposal for the harmonised classification and labelling (CLH) of (Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica, EC 272-697-1; CAS 68909-20-6) was submitted by France and was subject to a consultation, from 04.03.2019 to 03.05.2019. The comments received by that date are compiled in Annex 2 to the opinion.

During its December 2019 meeting, the Committee for Risk Assessment (RAC) concluded that this substance should be classified as Acute Tox 2 via the inhalation route (H330) with an ATE of 0.45 mg/L, as well as STOT RE 2; H373 (lungs, inhalation). Since some of the studies leading to the acute toxicity classification were not summarised in the CLH report during the consultation, an ad hoc consultation of the documents in which these studies have been summarised was launched from 03.02.2020 to 17.02.2020. The comments received are listed below.

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Substance name: Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica
EC number: 272-697-1
CAS number: 68909-20-6
Dossier submitter: France

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2020	Italy	Grace GmbH	Company-Manufacturer	1
Comment received				
please attached documents ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 Expert Statement Dekant Bosch HDMS treated SAS.zip ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment 2020 Expert Statement Dekant Bosch HDMS treated SAS.pdf				
RAC response				
Thank you for the comment. Please see the response to comment #11				

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2020	Japan	Japan Business Machine and Information System Industries Association	Industry or trade association	2
Comment received				
Japan Business Machine and Information System Industries Association (JBMIA) appreciates the opportunity to give our comments on the proposal for Harmonized Classification and Labelling for silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide.				

*About JBMIA: Japan Business Machine and Information System Industries Association (JBMIA) is the industry organization which aims to contribute the development of the Japanese economy and the improvement of the office environment through the comprehensive development of the Japanese business machine and information system industries and rationalization thereof. The advancement of information technology has brought about sophistication of the age of digitalization and networking and resulted in significant changes in the office environment accordingly. In response to the shift of business emphasis from the hardware to total business solutions including products, JBMIA carries out active committee/group activities regarding important issues that the industries are confronting in and outside Japan by conducting investigations and researches regarding the policy proposals, international cooperation, prevention of warming, environment preservation, standardization, product safety, etc., by deepening the association with the sales and software-related companies, as well as the manufacturers. Japan Business Machine Information System Industries Association (JBMIA) Address: Lila-Hijirizaka, 3-4-10 Minato-ku, Tokyo 108-0073 Japan TEL: +81-3-6809-5010 FAX: +81-3-3451-1770 https://www.jbmia.or.jp/index.php
RAC response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2020	United States		Individual	3
Comment received				
Please refer to the attachment for Cabot Performance Chemicals comments. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Cabot Performance Chemicals comments to CLH proposal on HMDZ td SAS.pdf				
RAC response				
Thank you for the comment. Please refer to the response to comment #11.				

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2020	Germany	Evonik Resource Efficiency GmbH	Company-Manufacturer	4
Comment received				
Evonik Resource Efficiency GmbH welcomes the opportunity to comment on the CLH recommendation made by the Risk Assessment Committee (RAC), extending the classification and labeling proposal of synthetic amorphous silica (SAS) treated with hexamethylsilazane (CAS nr 68909-20-6) to Acute Inhalation Toxicity Category 2 (Fatal if inhaled). ECHA note – An attachment was submitted with the comment above. Refer to public attachment Evonik comment on AT2 CLH.2_20200217.pdf				
RAC response				
Thank you for your comment. Please refer to the response to comment #11.				

OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2020	United States		Individual	5
Comment received				
Cabot Performance Chemicals respectfully requests RAC to re-assess the current data together with the mechanistic study that has commenced (the first acute inhalation study with SAS comparing representative SAS forms (incl. surface treated SAS) under standardized testing conditions. Special attention is paid to exposure characterization incl. particle size determination). Cabot Performance Chemicals also requests the Authority to wait after the complete data set has been submitted to ECHA prior to re-assessing and making a classification determination on acute toxicity of HDMZ surface treated SAS. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Cabot Performance Chemicals comments to CLH proposal on HMDZ td SAS.pdf				
RAC response				
Thank you for your comment. Please see the response to comment #11.				

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2020	Germany	Wacker Chemie AG	Company-Manufacturer	6
Comment received				
The proposal to classify Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica as Acute Tox 2 is not in agreement with the most recent scientific interpretation of the data referenced in the targeted consultation. A Statement is attached to address this issue. ECHA note – An attachment was submitted with the comment above. Refer to public attachment WACKER comment on aute tox 2 classification proposal.pdf				
RAC response				
Thank you for the comment. Please see response to comment #11.				

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2020	Germany	Evonik Resource Efficiency GmbH	Company-Manufacturer	7
Comment received				
Evonik comment on classification of synthetic amorphous silica treated with hexamethylsilazane (CAS no. 68909-20-6; "Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica") as Acute toxicity Category 2 (H330) via the inhalation route with an ATE of 0.45 mg/L (dusts and mists). ECHA note – An attachment was submitted with the comment above. Refer to public attachment Evonik comment on AT2 CLH.2_20200217.pdf				

RAC response
Thank you for the comment. For a comprehensive response, please see RAC response to comment #11.

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2020	Germany		Individual	8

Comment received

Acute inhalation studies with some types of surface-modified (hydrophobic) synthetic amorphous silicas (SAS) indicated high mortality resulting in four hour LC50 values that ranged from 80 to > 2,000 mg/m3. Formally, some of the LC50 values with surface-modified SAS are in the range of guidance values for classification regarding acute inhalation toxicity under GHS.
However, lethality of surface-modified SAS under toxicity testing conditions is due to airway obstruction by the large particle load received. This results in suffocation. Thus, lethality is not due to a specific property of SAS. LC50 values obtained with non-surface modified (hydrophilic) SAS were generally higher as compared to surface-modified SAS (ECETOC, 2006). The differences in potency between SAS to cause lethality can be explained by differences in agglomerization kinetics.
Suffocation as a cause of lethality in rodents after inhalation of SAS under toxicity testing conditions has no relevance to humans exposed to SAS placed on the market. The particle size distribution of the SAS used in the inhalation toxicity testing is significantly reduced to fulfill testing guideline requirements (MMAD < 4 µm) to generate respirable particles and therefore is widely different from the particle sizes (MMAD > 100 µm) of commercially used SAS. This aspect needs to be considered in hazard definition of surface-modified SAS. SAS placed on the market only contain a very small mass percentage of respirable particles that may reach the deeper respiratory tract and specifically the terminal bronchioli that are susceptible to obstruction. Lethality due to suffocation therefore should not be used as basis for classification. Moreover, as CLP requires classification of materials based on information that "shall relate to the forms and physical states in which the substance is placed on the market and in which it can reasonably expected to be used", the observations made in the acute inhalation toxicity studies with much smaller particles as compared to those used commercially have no/very limited relevance for classification.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment SAS-acute-comments_Redacted.pdf
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment SAS-acute-comments.pdf

RAC response
Thank you for the comment. For a comprehensive response, please see RAC response to comment #11.

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2020	Italy	Grace GmbH	Company-Manufacturer	9
Comment received				
please see attached documents ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 Expert Statement Dekant Bosch HDMS treated SAS.zip ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment 2020 Expert Statement Dekant Bosch HDMS treated SAS.pdf				
ECHA response				
Thank you for the Expert Statement. For a comprehensive response, please see RAC response to comment #11.				

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2020	Japan	Japan Business Machine and Information System Industries Association	Industry or trade association	10
Comment received				
This substance, Synthetic amorphous silica (SAS) treated with hexamethylsilazane, is proposed to be classified as Acute Inhalation Toxicity, Category 2 under CLP Regulation. Since RAC's view on the proposed classification has not been published, we unfortunately cannot confirm it. However, based on the reasons below, we do not consider that this substance can be concluded its classification of Acute Inhalation Toxicity according to scientific reviews of the existing available studies. In addition to CLH Report (2018), JACC No.51, ECETOC (2006）which has been designated as the relevant document for this consultation concludes the same. The reasons: Acute inhalation toxicity of SAS is complex and all study results need to be interpreted with caution due to issues of particle generation, particle size measurements and stability of respirable particles in the test atmospheres. On the other hand, there is a big concern that the study (Cab-O-Sil TS610 Cabot (1994a) on which this proposed classification is based, did not show the toxicity of SAS appropriately. Although deaths were observed at a concentration of 540 mg/m3 in this study, there are possibilities that the cause of these deaths were not due to SAS's toxicity, but suffocation due to physical obstruction of the animals' airways. There are the following viewpoints presented on page 99 of the JRCC No.51, ECETOC (2006）. "8.1.4 Summary and evaluation Numerous acute inhalation toxicity studies have been conducted on both hydrophilic and hydrophobic SAS. For hydrophilic SASs, LC50 values are higher than the highest technically achievable concentrations. The mortality observed with hydrophobic SAS is				

due to suffocation associated with the extremely high particle numbers administered and not with any intrinsic toxicity of the SAS tested."

The OECD Guidance 39 (2018) paragraph 69 also notes that:
"At very high concentrations, dry powder aerosols and chemically reactive liquid aerosols (e.g. polymers) tend to form conglomerates in the proximal nose causing physical obstruction of the animals' airways (e.g. dust loading) and impaired respiration which may be misdiagnosed as a toxic effect."

There may be also major methodological deficiencies in the SAS studies. The reliability of the test method must be justified by test parameters, such as various test concentrations, particle size control and measurement, exposure time, equipment type and whole-body study designs. It is absolutely necessary to verify that there is no problem with the reliability of the studies in order to use test data for the classification.

It is our strong desire that the proposed classification will be fully discussed by stakeholders after detailed consideration of this proposal including your view on the above concerns is clarified.

RAC response

Thank you for the commentFor a more comprehensive response, please see RAc response to comment #11.

Date	Country	Organisation	Type of Organisation	Comment number
16.02.2020	Belgium		Individual	11

Comment received

Acute inhalation toxicity studies with surface-treated SAS use a form of test material with a much higher respirable fraction than is present in commercial surface-treated SAS products. The non-specific toxicity observed in acute inhalation animal studies, including obstruction of the airways, is a result of the high respirable fractions. The observed respiratory failure accompanied by a complete or partial obstruction of the respiratory tree, labored breathing, histopathology findings highlighting pulmonary tissue congestion, edema and lung hemorrhage are consistent with suffocation symptoms due to the presence of foreign material in the respiratory tree. Therefore, the acute inhalation studies do not represent a unique toxicological behavior of the commercial surface-treated SAS products, especially the HMDZ-treated silica and no classification for Acute Inhalation Toxicity is warranted on the basis of these studies. Details comments are provided in the public attachment section. Confidential appendixes are submitted in the confidential section.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Cabot comments to CLH public consultation on HMDZ-treated sas_Final.pdf
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Confidential appendixes 1 to 4 - Cabot.pdf

RAC response

Thank you for the comment. RAC would like to respond in total both to the procedural issues and to the scientific discussion raised by the Industry.

A. Procedural Issues

- The name silanamine was used from the beginning of the CLH process and it appears that industry was aware of this since the Members of the Association of Synthetic Amorphous Silica Producers, ASASP, a Cefic Sector Group and others participated in the CLH process (by providing comments during the original Public Consultation). The agenda which is made available prior to a plenary meeting of the Committee for Risk Assessment (RAC) indeed included a reference to "silanamine", which has consistently been used in the context of its full name in the harmonized classification and labelling (CLH) process, including the registry of intention, the CLH report, the announcement of the public consultation of the CLH report for the substance as well as the agenda for the RAC-51 meeting. Thus, RAC believes that the industry claim of *lack of fair notice* is not substantiated.
- RAC did not recognize any data gap during the extensive discussion on the acute toxicity by inhalation endpoint. However, it is noted that during the Targeted Consultation Industry have flagged that a study has been planned to address issues which Industry have raised in their comments regarding the acute toxicity mechanism of action.
- Targeted consultations for CLH proposals are launched in case further information is needed on a particular hazard class, or if comments are sought on e.g. a specific additional document. As these consultations are targeted, the length of the commenting period (2 weeks is standard) is normally shorter than the usual consultation on a CLH proposal. The acute inhalation endpoint was open during the original consultation of the CLH report for commenting and although the dossier submitter used only one study for the evaluation of the endpoint, the ECETOC (2006) review, where most of the studies used by RAC for the CLH evaluation were taken from, is referenced in the CLH report and was commented on in the context of another hazard class (specific target organ toxicity after repeated exposure). In addition, Industry did not dispute the mechanistic study for acute inhlalation included in the CLH report, which showed inflammation in the deeper areas of the lung and not suffocation due to obstruction of airways.

B. Scientific Questions

- Indeed the majority of the studies were done before the OECD Guideline 403 was adopted (September 2009) but they were done by Industry and the reliability evaluation was performed by ECETOC. ECETOC's code of reliability is based on the Klimisch scale. The ECETOC review was published in 2006 and the reliability assessment of all studies included in the review was not disputed by any interested parties. Contrary to Industry's argument, the studies in the ECETOC report were reviewed and scored in all reliability categories. Specifically, most of the acute imhalation studies used in the ECETOC review were of reliability 1. Moreover, the specific studies are internationally recognized having been referenced in many reviews. RAC is not aware of the reliability evaluations having previously been questioned. Neither revised evaluation criteria nor a list of the deficiencies recognized in these studies have been provided. However, for the studies in the ECETOC review

only the results of the studies and not the actual raw data were available to RAC. In addition, in some cases the details of the experimental design and performance were vague or unknown. Therefore, RAC has decided not to rely upon the reliability evaluation of the studies performed by ECETOC, and use all studies from the open literature in a weight of evidence approach. On the other hand studies of the CLH report and the CAR were attributed a Klimisch reliability score since the raw data were available and the rating was used in the opinion document.

- Regarding the particle size argument, Industry has argued that the % of respirable particles of SASs placed on the market is low. SASs are commercialized by the industry as nanomaterials and as such are being classified. RAC concludes that the available studies clearly show that hydrophobic SAS (all three forms discussed in the opinion document) have an acute inhalation effect in the rat. There are several studies supporting the acute inhalation classification with experimental LC_{50} values pointing to a classification between categories 2 and 3. In the study #2 with SAS-DDS – Cab-O-Sil TS610 of the Table summarizing acute inhalation toxicity studies with all three forms of hydrophobic SAS available in the open literature, the conditions of the study were according to OECD TG 403, regarding MMAD, exposure type and period and observation time, and gave an LC_{50} of 0.45 mg/L, and this study can be considered to be a key study for the purposes of classification and for establishing an ATE, although this approach is rather conservative. It should be noted that the LC_{50} of 0.45 mg/L is also the value accepted in the EPA HPV evaluation for SAS-DDS which was done in 2011 and was sponsored by the major manufacturers of SAS. The specific study was evaluated as reliable without restrictions and comparable to a guideline study by ECETOC. During this targeted consultation, Industry has not provided any arguments against the validity of study #2.
- In acute toxicity studies conducted via the inhalation route, it is intended that the substance is respirable. It is noted in the CLP regulation (Annex I, Section 3.1.2.3.2), under the heading "*Specific considerations for classification of substances as acutely toxic by the inhalation route*", that "*Of particular importance in classifying for inhalation toxicity is the use of well articulated values in the high toxicity categories for dusts and mists. Inhaled particles between 1 and 4 microns mean mass aerodynamic diameter (MMAD) will deposit in all regions of the rat respiratory tract. This particle size range corresponds to a maximum dose of about 2 mg/l. In order to achieve applicability of animal experiments to human exposure, dusts and mists would ideally be tested in this range in rats*". This is consistent with the test guidelines for acute inhalation toxicity with aerosols, which requires rodents to be exposed to an aerosol containing primarily respirable particles (with a MMAD of 1–4 µm), so that particles can reach all regions of the respiratory tract.
- Please note that according to the CLP Guidance, "Reasonably expected use of a substance or mixture" includes the following:

  Any process, including production, handling, maintenance, storage, transport or disposal.
  All technical operations/manufacturing activities like e.g. spraying, filing, and sawing.

Any putative consumer contact through e.g. do-it-yourself or household chemicals.
All professional and non-professional uses including reasonably foreseeable accidental exposure, but not abuse such as criminal or suicidal uses.

Furthermore, "reasonably expected use" is also related to any consumer disposal or any work in which a substance or mixture is used, or intended to be used irrespective of its present limited use or use pattern. In considering this, it is reasonable to use the data from particles of the substance which are in the respirable range in a relevant species (the rat). In any case, the burden of proof is with the person placing a substance or mixture on the market.

Table. Acute inhalation studies, LC_{50} values

Species/ Reference/ Year of the study$	**Substance**	**LC_{50}(mg/L) Classification****
BR Rat/ ECETOC 2006, Becker *et al*. 2013/ Cabot 1982 Study #1*	SAS-DDS (Aerosil R972, Degussa) Particle size/MMAD* 0.15 µm Exposure: 1h	> 2.28 No mortalities observed
Wistar rats/ ECETOC 2006, EPA 2011, Becker *et al*. 2013/Cabot 1994 Study #2*	SAS-DDS, (Cab-O-Sil TS610) Particle size/MMAD*: 0.8-1 µm/1.175-1.275 µm Exposure: 4h	0.45 **Acute Tox. 2 H330**
Wistar rats/ ECETOC 2006/Cabot 1994 Study #3*	SAS-HMDS (Cab-O-Sil TS530) Particle size/MMAD: 0.95-2.15 µm Exposure: 4h	0.09-0.84 Acute Tox. 2 H330 or Acute Tox. 3 H331
BR rats/ Becker 2013 EPA 2011 Cabot revised 2003 Study #4*	SAS-DDS Particle size/MMAD: 1.24 µm Exposure: 4h	0.52-1.12 Acute Tox. 3 H331 or Acute Tox. 4 H332
SD rats/ ECETOC 2006/ Wacker 1996 Study #5*	SAS-HMDS, HDK SKS130 Particle size/MMAD: < 0.2 µm Exposure: 4h	1.65 Acute Tox. 4

SD rats/ ECETOC 2006/ Wacker 1996 Study #6*	SAS-DDS, HDH SKS130 Particle size/MMAD: 7.2-7.7 µm Exposure: 4h	> 2.2 (40% mortality)
SD rats/ ECETOC 2006/ Wacker 1996#	SAS-HMDS***, HDK SKS 300 Particle size/MMAD < 0.1 µm Exposure: 4h	0.09 **Acute Tox. 2** H330
SD rats/ ECETOC 2006/ Wacker 1996#	SAS-HMDS***, HDK SKS 300 Particle size/MMAD = 7.0-7.1 µm	0.5 **Acute Tox. 2** H330
Wistar Rat/ CLH report A6.1.3/ Degussa 1983	SAS-DDS (Aerosil R974) Particle size/MMAD = 2.9 µm Exposure: 4h	> 0.48

$ *All open literature references, where the study is reviewed are mentioned, along with the Industry performing the study and the year of the study*

* *Refer to Table on Acute inhalation toxicity studies with all three forms of hydrophobic SAS available in the open literature*

** *Refer to values for dusts and mists in Table 3.1.1 of Annex I of CLP*

*** *Becker et al. 2013 provides particle size dimensions in µm; ECETOC 2006 provides Particle size/MMAD (Mass Median Aerodynamic Diameter calculated by Cascade impactor) in µm; MMAD is defined as the aerodynamic diameter at which 50% of the particles by mass are larger and 50% are smaller*

No details apart from the LC_{50} are provided

- From the available studies it can be seen that surface area and particle size are factors that influence the outcome of the aforementioned studies. The test guidelines for acute inhalation toxicity with aerosols requires rodents to be exposed to an aerosol containing primarily respirable particles (with a Mass Median Aerodynamic Diameter (MMAD) of 1–4 µm), so that particles can reach all regions of the respiratory tract. For instance, solid materials are often micronised to a highly respirable form for testing, but in practice exposures will be to a dust of much lower respirability. In the case of the hydrophobic SAS, RAC is of the view that the intrinsic size of the substances is the nanoform and not the agglomerate, hence they are considered nanomaterials. RAC, nevertheless, acknowledges that these exposures may not necessarily reflect realistic conditions for SAS HMDS and other hydrophobic SAS.
- Industry has not provided any reference on other similar substances having the same mechanism for lethality due to suffocation. In addition, no histopathological findings were reported supporting this mechanism. For example, tardieu spots on the lungs should have been reported in the pathology investigations. Moreover, there were no clinical signs associated with suffocation reported in the studies available for acute inhalation toxicity. In addition, the same findings are observed both in single dose experiments at non-lethal doses and in repeated dose toxicity studies, where the lungs were consistently the target tissue. The majority of these effects were

reversible. Suffocation would not be a reversible effect. The cluster of the histopathological findings point rather to acute respiratory distress syndrome due to high inflammation attack than to suffocation.

OTHER HAZARDS AND ENDPOINTS – Specific Target Organ Toxicity Repeated Exposure

Date	Country	Organisation	Type of Organisation	Comment number
16.02.2020	Belgium		Individual	12

Comment received

The CLH proposal does not take into account the most recent and up to date data on inhalation toxicity of the substance. According to current criteria for pathology assessment, the only available subchronic inhalation study with AEROSIL® R 974 did not demonstrate the occurance of focal interstitial fibrosis and displayed complete reversibility of all observed lung lesions (AnaPath, 2016; ELP, 2016; Weber et al., 2018). Moreover, the CLH proposal is also considered incomplete, because it does not take into account all additional available scientific information pertaining to the inhalation toxicity of SAS materials.
The available information from animal inhalation toxicity and human exposure studies paired with the known toxicokinetic characteristics of synthetic amorphous silica, including hydrophobic DDS surface-treated SAS 'AEROSIL® R 974' and HMDZ surface-treated SAS does not warrant a classification as STOT RE 2 (H373). The effects observed in the available animal inhalation study with AEROSIL® R 974 are not adverse and fully reversible. The material does not cause organ damage or dysfunction (i.e., no progressive fibrosis of the lung or systemic toxicity have been observed) and effects should be considered as an adaptive response by the rat to a prolonged exposure to a high particle concentration. The CLP Regulation states that H373 should not be applied when toxicological changes are the result of an adaptative response or where a species-specific mechanism of toxicity has been demonstrated (EC, 2008; ECHA, 2017).

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Cabot comments to CLH public consultation on HMDZ-treated sas_Final.pdf
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Confidential appendixes 1 to 4 - Cabot.pdf

RAC response

Thank you for the comment but the specific endpoint was not open for commenting during the targeted consultation.

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2020	Italy	Grace GmbH	Company-Manufacturer	13

Comment received

please see attached documents

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 Expert Statement Dekant Bosch HDMS treated SAS.zip

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment 2020 Expert Statement Dekant Bosch HDMS treated SAS.pdf
RAC response
Thank you for the comment but the specific endpoint was not open for commenting during the targeted consultation.

PUBLIC ATTACHMENTS
1. Cabot Performance Chemicals comments to CLH proposal on HMDZ td SAS.pdf [Please refer to comment No. 3, 5]
2. WACKER comment on aute tox 2 classification proposal.pdf [Please refer to comment No. 6]
3. Evonik comment on AT2 CLH.2_20200217.pdf [Please refer to comment No. 4, 7]
4. SAS-acute-comments_Redacted.pdf [Please refer to comment No. 8]
5. 2020 Expert Statement Dekant Bosch HDMS treated SAS.zip [Please refer to comment No. 1, 9, 13]
6. Cabot comments to CLH public consultation on HMDZ-treated sas_Final.pdf [Please refer to comment No. 11, 12]

CONFIDENTIAL ATTACHMENTS
1. SAS-acute-comments.pdf [Please refer to comment No. 8]
2. 2020 Expert Statement Dekant Bosch HDMS treated SAS.pdf [Please refer to comment No. 1, 9, 13]
3. Confidential appendixes 1 to 4 - Cabot.pdf [Please refer to comment No. 11, 12]