

## COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during ad hoc consultation are made available in this table as submitted by the webform. Please note that the comments displayed below may have been accompanied by attachments which are not published in this table.

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

**Last data extracted on 19.02.2020**

**Substance name: Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica**

**CAS number: 68909-20-6**

**EC number: 272-697-1**

**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				

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>

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

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

#### **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

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2020	Germany	Wacker Chemie AG	Company-Manufacturer	6

Comment received				
<p>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.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment WACKER comment on aute tox 2 classification proposal.pdf</p>				

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2020	Germany	Evonik Resource Efficiency GmbH	Company-Manufacturer	7

Comment received				
<p>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).</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment Evonik comment on AT2 CLH.2_20200217.pdf</p>				

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

Comment received				
<p>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 &gt; 2,000 mg/m<sup>3</sup>. 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.</p> <p>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 agglomeration kinetics.</p> <p>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 &lt; 4 µm) to generate respirable particles and therefore is widely different from the particle sizes (MMAD &gt; 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.</p>				

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

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				

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				
<p>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.</p> <p>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.</p> <p>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/m<sup>3</sup> 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.</p> <p>There are the following viewpoints presented on page 99 of the JRCC No.51, ECETOC (2006) .</p> <p>"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."</p>				

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.

Date	Country	Organisation	Type of Organisation	Comment number
16.02.2020	Belgium		Individual	11
Comment received				
<p>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.</p> <p>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</p>				

## **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				
<p>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 occurrence 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</p>				

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 adaptive 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

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				

#### 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]