ASASP | Association of Synthetic Amorphous Silica Producers

ASASP Downstream Users Forum meeting

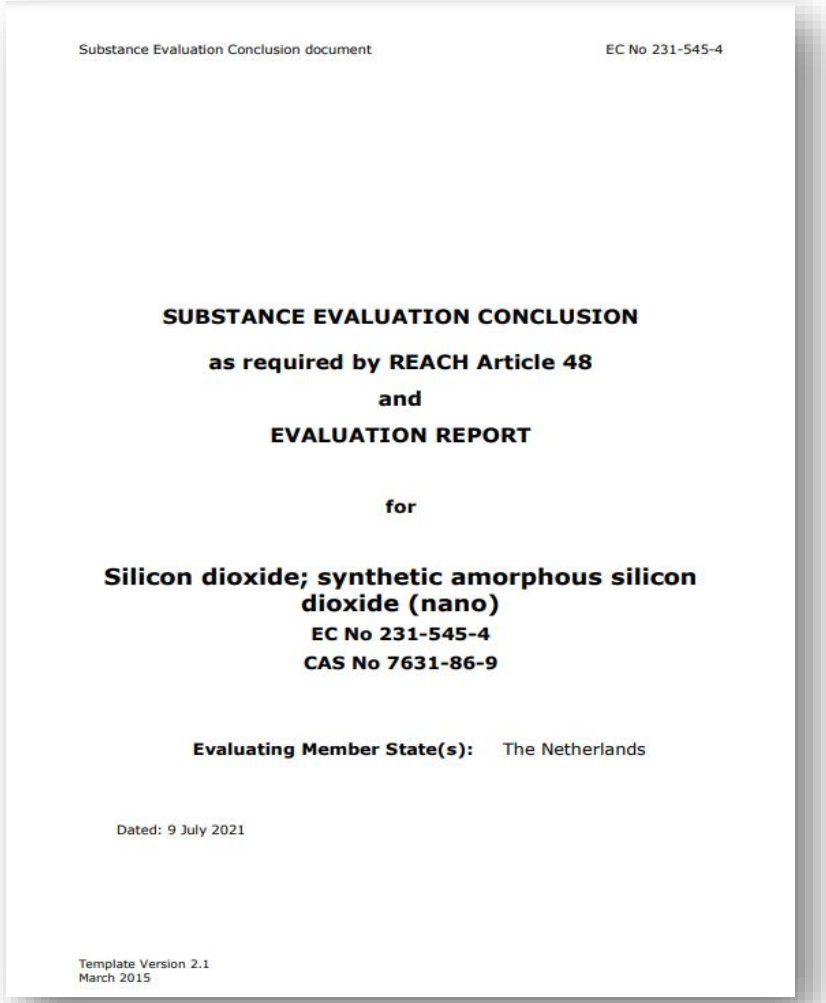
09 July 2024

Agenda

1. Opening and introduction
2. Compliance with competition laws
3. ASASP strategy on Silicon Dioxide ongoing CLH process
4. Downstream Users Forum engagement
5. Questions & Answers
6. Closure

3. ASASP strategy on Silicon Dioxide ongoing CLH process

SAS Substance Evaluation



Substance Evaluation Conclusion document EC No 231-545-4

SUBSTANCE EVALUATION CONCLUSION

as required by REACH Article 48

and

EVALUATION REPORT

for

Silicon dioxide; synthetic amorphous silicon dioxide (nano)

EC No 231-545-4

CAS No 7631-86-9

Evaluating Member State(s): The Netherlands

Dated: 9 July 2021

Template Version 2.1
March 2015

4. FOLLOW-UP AT EU LEVEL

4.1. Need for follow-up regulatory action at EU level

4.1.1. Harmonised Classification and Labelling

At present there is no harmonised classification for SAS.

The concern investigated was repeated dose toxicity via the inhalation route of exposure. The concern was founded on the outcome of various repeated dose inhalation studies. The new 90-day inhalation study (Anonymous, 2020), as generated upon the request in the substance evaluation decision, provides additional information on repeated dose inhalation toxicity, including insight in the effects induced, the influence of surface area on toxicity, and (ir)reversibility of the effects.

Adverse effects were observed in the nose, lungs and lymph nodes in particular after exposure to the low surface area form (SAS 2 in the study).

The adverse effects induced by the high surface form (SAS 1) were more limited in incidence, less severe and mostly reversible. Also noteworthy is the recent evaluation of a closely related substance Silanamine (1,1,1- trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (EC No 272-697-1, CAS RN 68909-20-6)) by the ECHA's Committee for Risk Assessment (RAC) in December 2019 (ECHA, 2019). RAC concluded that a classification as, amongst others, STOT RE Cat 2, H373 (lungs, inhalation) is justified.

The effects induced by silanamine are very similar to those induced by SAS, including inflammation of the lung tissue, fibrogenesis and possibly fibrosis.

Based on the adverse effects observed the evaluating Member State Competent Authority (eMSCA) concludes that there is sufficient ground to draft a proposal for harmonised classification and labelling (CLH) for the endpoint repeated dose toxicity via inhalation.

https://echa.europa.eu/documents/10162/5f238e67-e159-1fba-1f7f-23df7c25a4fb

CLH dossier (1)

Silicon dioxide

EC / List no: 231-545-4 **CAS no:** 7631-86-9

CLP Annex VI Index number	
Further substance information	
Status	Consultation
Date of intention	01-Mar-2013
Expected date of submission	31-Oct-2023
Submitted for accordance check	07-Dec-2023
Final submission date	06-May-2024
Withdrawal date	
Legal deadline for opinion adoption	05-Nov-2025
Submitter	Netherlands
Submitter's email	bureau-reach@rivm.nl

ALL UNTREATED FORMS
Pyrogenic
Precipitated
Gel
Colloidal

ECHA
EUROPEAN CHEMICALS AGENCY

https://echa.europa.eu

Dossier submitter: The Netherlands

CLH dossier (2)

Proposed harmonised classification by the dossier submitter	STOT RE 1, H372
Proposed specific concentration limits by the dossier submitter	(respiratory tract) (inhalation)
Regulatory programme	▪ Chemical registered under REACH ▪ Active substance in Biocidal Products
Remarks	
Start of consultation	10-Jun-2024
Deadline for commenting	09-Aug-2024
Hazard classes open for commenting	Specific target organ toxicity — repeated exposure
CLH report	clh_rep_Silicon_dioxide_en.pdf
Annexes to the CLH report	clh_rep_annex_Silicon Dioxide_en.zip

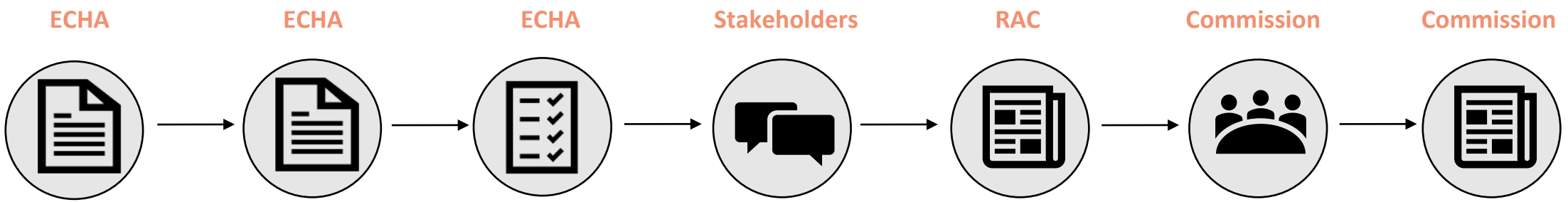
A substance is classified as a **Specific Target Organ Toxicant (STOT)** if it produces specific target organ toxicity/systemic effects that are not specifically addressed elsewhere in the CLP/GHS

ECHA
EUROPEAN CHEMICALS AGENCY

https://echa.europa.eu

Consultation is open

CLH timeline (indicative)



Intention submitted by NL	NL submits CLH dossier	ECHA accordance check	ECHA 2 months public consultation	RCOM to be published. RAC to take dossier (no SEAC involved) and adopt opinion within 18 months from accordance check	CARACAL - Inclusion of RAC opinion in ATP	Adoption of ATP (delegated act). Beginning 18 months transition period for new classification
March 2022	**7 December 2023**	**January 2024**	**10 June-9 August 2024**	**RAC opinion by 5 November 2025**	**2026**	**2028-2029**
Dossier sent to LR ✓	✓	✓	**ASASP to submit comments and engage with key MSs**	**ASASP to send experts**	**ASASP to engage with COM**	

Highlights from CLH dossier

- CLH dossier from the Dutch authorities:
  - STOT RE 1 classification proposed on all untreated forms
  - Target organ has been changed from lung to respiratory tract
  - Wrong assumption that all SAS particles are respirable i.e. reaching the alveoli
  - Many scientific flaws and contradictions in the dossier
  - The latest REACH dossier has not been taken in consideration, but rather reference to publications

ASASP 5 key messages

SAS is a substance with no intrinsic toxicity

SAS is being proposed for classification based on adaptive, unspecific inflammatory effects which are generic to all particles regardless of the substance.

Classifying a substance based only on its particle effects deviates from the CLP scope because the hazard identification process should assess the intrinsic properties of substances to determine its potential to cause harm.

SAS is safe as placed on the market

The assumption made by the CLH Report Submitter that all untreated SAS forms are respirable is a fundamental error.

More than 90% of SAS forms, as placed on the market, are not respirable.

OECD repeated dose inhalation studies require particles to be intentionally modified to be respirable for the test animals to create effects. **Inhalation testing is therefore not conducted on SAS forms as placed on the market**.

Effects observed in studies are particle-related effects, not to be regulated by CLP

The proposed **cut-off limit** concentrations for STOT-RE classification by CLP (Annex I 3.9) are **unrealistically high**.

Repeated dose inhalation studies show that inflammation is triggered by respirable particles at concentrations below these limits.

SAS shows **reversible inflammation**, caused by physical conditions, not intrinsic properties of the substance itself.

Rats are more sensitive to particles than humans

As shown by inhalation studies on various materials, not just SAS.

This is due to the **anatomy of rat lungs**, which are predisposed to more severe inflammation.

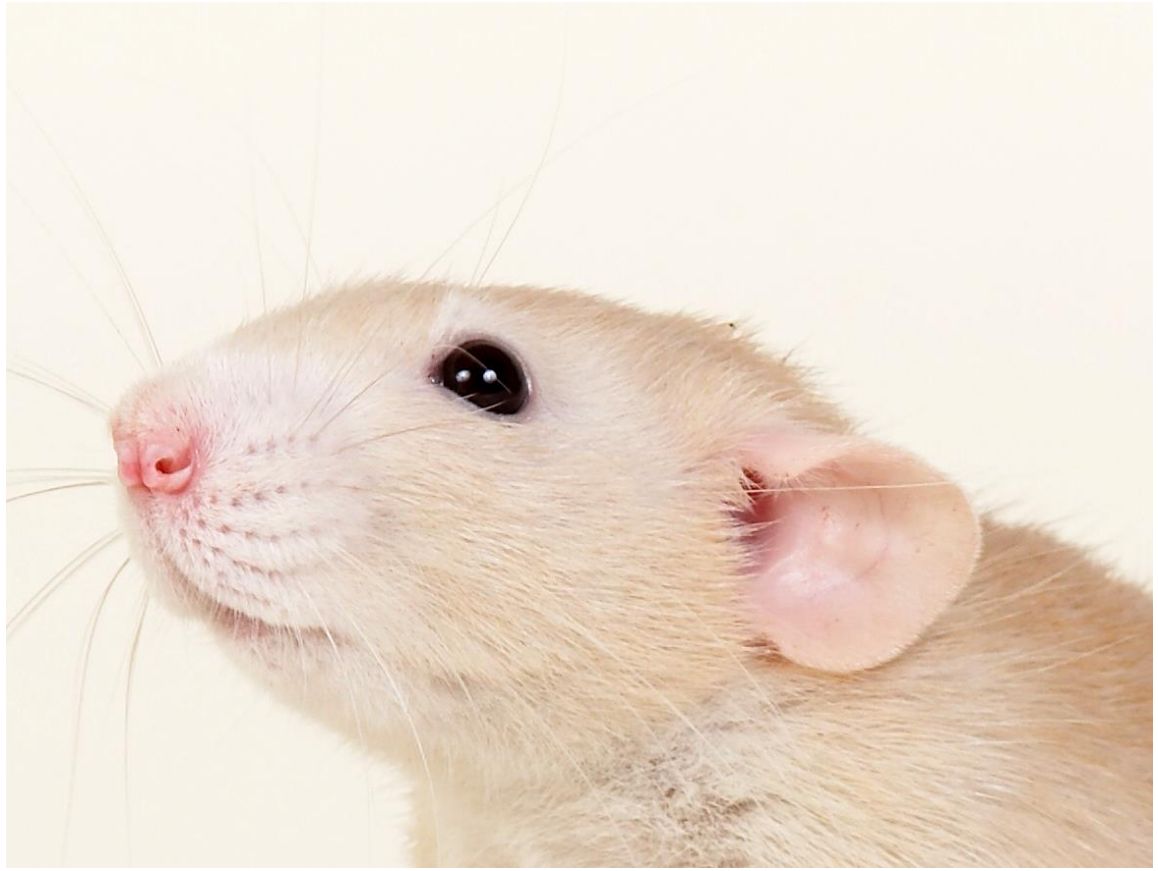
Over 40+ years of human health data supports this, showing no respiratory toxicity in humans.

The whole respiratory tract is not affected

The proposal by the CLH Report Submitter to classify the whole respiratory tract is made on wrong interpretation of artefact effects in the nasal cavities caused by aerosol preparation

These effects are not relevant for human health hazard assessment.

The adaptive inflammatory effects observed in the studies are restricted to the lungs and its associated lymph nodes.



Regulatory consequences & impact on industry

- First step to restrict SAS e.g., in consumers applications (GRA and substances of concern)
- Risk mitigation measures for worker safety
- Could require revision to plant operating permit
- Change in waste disposal conditions
- Labeling and packaging
- Transport & storage conditions will change (warehouse and procedure for hazardous materials)
- Supply chain communication
- New safety data sheet

SAS will be the 4th classification of no/low toxicity particles and the same scenarios will repeat for many other particulate substances

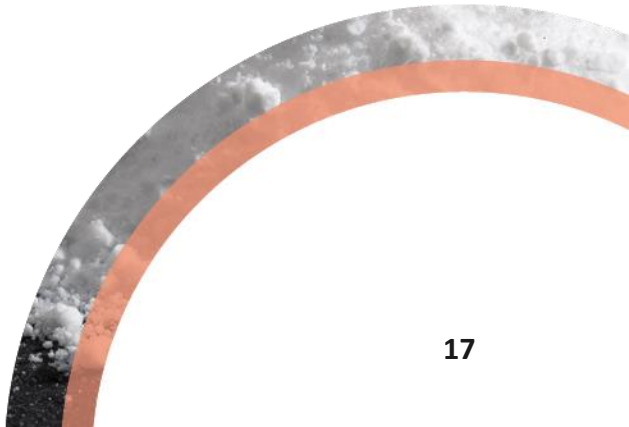
- **Disproportionate industry impact**
- **No safety value for consumers and workers**

ASASP & SASforREACH Advocacy Strategy

- Based on the above key elements, ASASP & SASforREACH is:
  - Closely reviewing and commenting the CLH proposal
  - Preparing comments to public consultation
  - Engaging leading expertise to prepare a science-based contribution
  - Joining forces with other industry actors working on the same matter (particles effects)
  - Starting the outreach to key MSs

4. Downstream Users Forum engagement

How you can you support us?



How can you support us?

- Provide inputs into the public consultation by:
  - supporting ASASP & SASforREACH position
  - strengthening the importance of SAS in downstream users sectors

We will provide you with our key messages to prepare for the public consultation

5. Questions & Answers

Follow us on Linkedin!

ASASP - SYNTHETIC AMORPHOUS SILICA PRODUCERS: ABOUT | LINKEDIN

ASASP | Association of Synthetic Amorphous Silica Producers

Thank you!

www.asasp.eu

A sector group of Cefic

European Chemical Industry Council - Cefic aisbl

EU TRANSPARENCY REGISTER N°64879142323-90