aSASp Association of Synthetic Amorphous Silica Producers

Brussels, 20 October 2021

Synthetic Amorphous Silica (SAS) and Animal Testing

The objective of this document is to present the position of the Association of Synthetic Amorphous Silica Producers (ASASP) in respect to animal testing.

ASASP member companies are fully committed to animal welfare and the reduction of animal testing to the lowest possible level. We are therefore using options such as computer models and structure activity relationship, read-across information, cell based *in vitro* testing, and other techniques to help reduce *in vivo* tests, in line with regulatory requirements (e.g. under REACH, animal testing should be the last resort) and in line with corporate social responsibility.

Whenever alternative methodologies are available, scientifically recognized, reliable, predictive and legally acceptable, we are committed in using these alternatives to animal testing in the development of new forms of the SAS substance and the necessary characterization and registration of existing products.

Active work to reduce animal tests

As part of our efforts, ASASP members have been actively participating and driving projects such as Nanoscreen[1], Nanosolutions[2], GRACIOUS[3] or Gov4Nano[4], in order to develop methods for *in vitro* toxicological assessment of SAS without the use of animal tests.

Nonetheless, due to legal requirements within the EU, and also international chemical legislation, national chemical inventories, workers' safety and product safety, a full waiving of all animal tests on SAS is unfortunately not possible in the foreseeable future.

Animal tests for cosmetic purposes after 2013

Animal tests for cosmetic purposes have not been conducted in the past, or currently, and are not planned in the future by ASASP or any ASASP member company.

[1] Nanoscreen was headed by Dr. P. Wick (Empa) and Prof Dr. H. Hofmann (EPFL) and brings together partners from Industry Cetics Healthcare Technologies, Midatech and the Swiss Federal Office of Public Health.

[2] Nanosolutions project under Biological Foundation for the Safety Classification of Engineered Nanomaterials (ENM), 1 April 2013 - 31 March 2017, funded under FP7-NMP, Grant agreement ID: 309329.

[3] GRACIOUS project received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 760840.

[4] Gov4Nano has received funding from the European Union's Horizon 2020 and innovation programme under grant agreement No 814401.

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Animal tests for other regulations

Occasionally, post-2013 animal studies have been conducted when legally required by other legislations such as REACH (see ECHA Board of Appeal Case A-009-2016 from 2018) or EFSA (see call for data: EFSA-Q-2018-00773). Animal studies have only been conducted where required by law.

Animal tests performed on SAS without participation of ASASP members

Most of the analytical and toxicological testing on SAS is done by ASASP member companies jointly or individually to meet regulatory requirements. However, tests on SAS might also be conducted by other companies or research facilities without the knowledge or consent of ASASP.

ASASP does not have control over testing done by other companies or institutions worldwide. Once published, these tests must be considered by European authorities and if relevant, they eventually appear on the ECHA homepage or in communications from other European legal bodies. ASASP or its member companies cannot take any responsibility for those tests on SAS.

Animal tests published on the ECHA's dissemination website concerning the REACH registration of SAS

The following table represents an overview of the published studies, including comments on the test rationale, testing proposals, and justification for *in vivo* studies wherever *in vitro* test possibilities meanwhile exist.

Date		Test Guideline (TG)	Test
2013	Study report date	OECD 489	DNA damage and/or repair
2013	Study report date	OECD 474	Cytogenicity/erythrocyte micronucleus
Sept 2014	Study period start date	OECD 423	Acute Oral Toxicity
Sept 2014	Study period start date	OECD 404	Acute Dermal Irritation/Corrosion
Sept 2014	Study period start date	OECD 405	Acute Eye Irritation
Nov 2014	Study period start date	OECD 405	Acute Eye Irritation
Jan 2015	Study period start date	OECD 429	Skin Sensitisation
May 2015	Study period start date	OECD 429	Skin Sensitisation
Feb 2018	Study period start date	OECD 413	Sub-chronic Inhalation Toxicity
May 2019	Study period start date	OECD 436	Acute Inhalation Toxicity
2019	Study report date	OECD 429	Skin Sensitisation

Information about the tests listed in the table above:

OECD 489 / 474 tests (2013):
The 2013 tests resulted from the "NanoGEM" Project, which was a research project on nanomaterials, funded by the German Federal Ministry of Education and Research (BMBF) and industry. ASASP was neither the initiator nor the study-owner. The special type of silica used for these studies was a functionally modified colloidal silica, which falls under the definition of "synthetic amorphous silica" by REACH, but is not used by ASASP companies as a raw material for the cosmetic industry.

OECD 404 / 405 / 423 / 429 (2014, 2015, 2019):
In recent years, *in vitro* irritation and sensitization tests have become more and more reliable. ASASP member companies has never conducted *in vivo* tests on animals if not necessary for one of the following reasons:

- Tests needed for international (non-EU) registrations: The table above might give the impression that some tests have been performed multiple times redundantly, which would not be in accordance with animal welfare. These tests were performed on SAS modified with different treatment agents. Testing of the individual products was necessary for international (non-EU) registrations, due to the difference in treatment agent. Several countries (e.g. China) did not accept *in vitro* results, but insisted on *in vivo* testing for their chemical inventories or other national regulations.

- Tests needed to be conducted for regulatory purposes other than European REACH registrations: The European Food Safety Agency (EFSA) has requested a chronic oral toxicity study with E 551 (call for data EFSA-Q-2018-00773).

- Tests for workers safety legislation: To ensure workers' safety, sometimes *in vivo* testing is required outside the EU.

- Tests not successful *in vitro*: tests which could not be successfully performed *in vitro* (giving unreliable data), had to be repeated *in vivo*. Even in 2014-2015, only a positive (i.e. leading to effects) *in vitro* test was accepted by the European authorities. If a test was negative, EU regulators rarely accepted negative (i.e. no effects, non-hazardous) *in vitro* findings even when *in vitro* methods had been validated both for positive and negative assessments. In these cases the *in vitro* test had to be confirmed by an *in vivo* test. Typical examples include eye and skin irritation, skin sensitization or genotoxicity studies.

OECD 413 / 436 (2018, 2019):
Tests necessary to prove the non-hazardous nature of SAS products were based on formal requests from regulatory bodies. For example, the subchronic inhalation toxicity studies according to OECD 413 were requested by ECHA under the substance evaluation process of REACH.

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Further tests performed since 2019, but not listed on the ECHA dissemination website:

OECD 408 / 452:
Tests required by EFSA: These studies had to be conducted due to a data request from EFSA (European Food Safety Agency), originating from the re-evaluation process for SAS as food-additive E 551.

Conclusion

ASASP and its member companies are fully committed to animal welfare and do not conduct or plan animal testing unless there is a regulatory necessity to ensure the safe use of our SAS in products placed on the market. Animal testing for cosmetic products will not be done, unless legally required.

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About ASASP

The Association of Synthetic Amorphous Silica Producers is a sector group of the European Chemical Industry Council (Cefic) and represents the major producers of synthetic amorphous silica (SAS) in Europe. ASASP is a non-profit organisation established in 1992 dedicated to promoting the safe use and benefits of SAS to society.

The health and safety of employees, consumers and the wider community are of the upmost importance to ASASP members. ASASP continues to be convinced that based on the available information, the use of SAS in consumer products is considered safe.

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