

## Statement regarding the Status of Synthetic Amorphous Silica under French Decree 2012-232<sup>1</sup> and the Ministerial Order<sup>2</sup> on the Declaration of “Substances at Nanoscale”

The purpose of this statement is to provide the position of the Association of Synthetic Amorphous Silica Producers (ASASP) with respect to the substance Synthetic Amorphous Silica (“SAS”) under French Decree 2012-232 and Ministerial Order of the 6 August 2012. In addition, this statement will provide general guidance to the customers of the member companies of ASASP.

### **Background:**

The French Ministry of Ecology and Sustainable Development is requiring annual mandatory reporting of “substances at nanoscale”. In summary, companies that manufacture, import, or distribute a “substance at nanoscale” in France, on its own or in a mixture, in an amount of at least 100 grams per year, are required to submit an annual declaration. This legal requirement entered into force on 1 January 2013. Annual reports are due by May 1st for the previous year’s information, with the first declarations due to the French Ministry by May 1, 2013 for 2012. Sanctions for non-compliance become effective 1 July 2013.

French Decree 2012-232 (“The Decree”) defines “substance at nanoscale” as, “intentionally produced at nanometric scale, containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for a minimum proportion of particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm”. Ministerial Order of the 6 August 2012 (“Ministerial Order”) defines the minimum proportion of particles with one or more external dimensions in the size range 1 nm - 100 nm, to be 50% of the number size distribution.

Further, concerning mixtures, the Decree defines “substance at nanoscale contained in a mixture without being linked to it”, as a “substance at nanoscale intentionally introduced in a mixture from which it is likely to be extracted or released under normal or reasonably foreseeable conditions of use”. Note, the terms “extracted” or “released” have not been defined.

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<sup>1</sup> Decree no. 2012-232 of 17 February 2012

<sup>2</sup> Ministerial Order of 6 August 2012

Additionally, the 41 Frequently Asked Questions are available in English language under the following website: <https://www.r-nano.fr/?locale=en>



### **Applicability of the Decree & Ministerial Order to SAS:**

Synthetic Amorphous Silica (SAS), EINECS No. 231-545-4, is a form of silicon dioxide (SiO<sub>2</sub>) that is intentionally manufactured. SAS has been produced and marketed for decades without significant changes in its physical-chemical properties. SAS is in the form of white dry powders, or dispersions of these powders in a liquid most commonly water. SAS is used in a multitude of industrial and consumer applications.

There is no harmonized definition of a “nanomaterial”; referred to by the French Ministry as a “substance at nanoscale”. Currently, within the European Union, the EU Commission has adopted a Recommendation definition for “nanomaterial” (2011/696/EU); in addition, “nanomaterials” are defined in application-specific regulations (e.g. EU Cosmetic Regulation 1223/2009).

Therefore, the status of a substance as a nanomaterial is dependent entirely on the reference definition. As such, a substance may be considered a nanomaterial under one definition but not under another definition. As an example, we cite SAS’s status under the Commission Recommendation 2011/696/EU under which SAS is considered a “nanomaterial” and SAS’s status under the EU Cosmetic Regulation under which SAS is **not** considered a nanomaterial<sup>3,4</sup>.

Given this, ASASP has carefully reviewed the “substance at nanoscale” definition and makes the following determinations:

- SAS falls under the scope of the Decree and the Ministerial Order. This conclusion is based on TEM image analyses.<sup>3</sup>
- Dispersions of SAS fall under the scope of the Decree and the Ministerial Order. This conclusion is based on the technically feasible filtration of SAS out of the liquid (water) phase.

Note: SAS is used e.g. in the thickening of dispersions of polymer particles (i.e. paints). Due to the fact that the terms “extracted” or “released” have not been defined by the French Authorities, ASASP is not in a position to give an interpretation on this application.

### **Recommendations to the Customers of ASASP:**

As ASASP has determined that SAS, and dispersions of SAS, fall under the scope of the Decree and the Ministerial Order, members of ASASP by way of this statement, inform their customers that they may have a reporting obligation in France. ASASP recommends each customer to review its own situation to determine if it has a reporting requirement.

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<sup>3</sup> Synthetic Amorphous Silica – ASASP’s current interpretation as a nanomaterial. October 2012.

<sup>4</sup> ASASP Statement for Synthetic Amorphous Silica regarding the definition of ‘nanomaterials’ for cosmetic use. April 2013.

Should a customer determine a declaration is required, contact your SAS supplier(s) immediately to discuss how the supplier(s) may assist.

Note: The legislation enables SAS manufacturers (outside of France) to submit a declaration - according to Ministerial Order, Appendix, Part II. In this case, an identification number is generated which may be passed on by the SAS manufacturer to its customers. The French customers/users of SAS may then include this identification number – as reference – in their own declaration. This way, the French Authorities can use the SAS manufacturer’s declaration to identify/link to the material in question.

**Legal disclaimer:**

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