

POSITION STATEMENT ON SVHC IN ARTICLES

To whom it may concern,

This document concerns SGS's approach for testing an 'article' for substances of very high concern (SVHCs) and the subsequent evaluation of results in the context of REACH.

Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is a system for the management of chemicals in the European Union (EU).

DEFINITION OF AN 'ARTICLE' (ARTICLE 3, REACH)

An 'article' is an object which **during production** is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition. This implies that the shape, surface or design must be determined and given during a production step. Articles themselves that are assembled or joined together remain articles, as long as they keep a special shape, surface or design.

DEFINITION OF SVHCS (ARTICLE 57, REACH)

SVHCs are:

- Substances meeting the criteria for classification as carcinogenic, mutagenic or reprotoxic (toxic to reproduction) (CMR) category 1A or 1B in accordance with Regulation (EC) 1272/2008 on the Classification, Labelling and Packaging of Substances and Mixtures (CLP Regulation)
- Substances which are persistent, bioaccumulative and toxic (PTB) or very persistent and very bioaccumulative (vPvB)

- Substances having endocrine disrupting properties or having PBT and vPvB properties, which although not fulfilling the criteria for being a Carcinogen, Mutagen, Reprotoxic (CMR), PBT or vPvB, there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern.

According to Article 33 of REACH 'Duty to communicate information on substances in articles', suppliers of an article containing a **Candidate List** SVHC for Authorisation in a concentration of more than 0.1% shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article, including, as a minimum, the name of the SVHC. On request this equivalent information should be provided to consumers free of charge within 45 days of receipt of the request.

In 2011, the European Chemicals Agency (ECHA) published a "Guidance on requirements for substances in articles" document specifying that obligations according to Article 33, and Article 7(2) 'Notification of substances in articles', for an SVHC in a concentration of more than 0.1% applies to an entire article; even as a complex product. This interpretation was not shared by Austria, Belgium, Denmark, Germany, France, Norway and Sweden.

In September 2015, a **press release**, based on the judgment dated 10 September 2015 (**Case C-106/14**), by the Court of Justice of the European Union (CJEU) clarified that there is no need to draw a distinction between the situation of articles incorporated as a component of a complex product and that of articles present in an isolated manner. The CJEU ruled that the duties to notify (Article

7(2)) and provide information (Article 33) for an 'article' containing an SVHC in a concentration of more than 0.1% apply to each article incorporated as a component in a complex product. This ruling is applicable to manufacturers and importers to provide information to recipients, consumers of an article and to all economic operators along the supply chain when the economic operator supplies an article to a third party.

In view of the CJEU judgment and communication by ECHA, SGS adopts the viewpoint from this ruling for its SVHC related services. We would like to point out that this position statement does not constitute a legal advice and SGS has no authority to decide on the appropriateness for the interpretation of Article 3(3). As an independent 3rd party provider SGS is committed to follow the interpretation of legal frameworks by authorities. Please contact reach@sgs.com for further information.

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SGS CONSUMER AND RETAIL

Global REACH and RSTS teams

The logo for SGS, consisting of the letters 'SGS' in a bold, sans-serif font. A vertical line is positioned to the right of the letters, and a horizontal line is positioned below the letters, forming an L-shaped frame around the text.