



SUBSTANCE / MIXTURE / ARTICLE STATUS IN EU REGULATION FOR HTIW PRODUCTS

1. INTRODUCTION

The REACH¹ process requires clear definitions of the object status (i.e. "substance / mixture / article") of products at several stages of manufacturing and downstream use. More specifically, the definition of the substance / article borderline drives registration and potential authorisation requirements since substances are affected while articles are usually not.²

As REACH is a chemicals Regulation, some materials such as high temperature insulation wools (HTIW) do not easily "fit" the definitions without additional interpretation. The scope of this paper is to define the object status of products based on HTIW. The acronym HTIW describes a group of synthetic fibre materials:

- ASW (Alumino-Silicate Wools), often also described as Refractory Ceramic Fibres (RCF),
- AES (Alkaline Earth Silicate Wools) and
- PCW (Polycrystalline Wools).

It should be noted that the object status is independent of the material's hazard profile. The applicable REACH guidance³ lists parameters such as function, shape, surface, design and chemistry – but not hazard classification – as key determinants for the substance or article status of an object.

1 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals

2 Articles might be affected in the case of the „intended release“ of a constituent substance.

3 See ECHA: Guidance on requirements for substances in articles

2. SUBSTANCE STATUS OF FIBRES

Article 3 of the REACH Regulation contains generic definitions as follows:

1. **substance:** means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
2. **preparation:** means a mixture or solution composed of two or more substances;
3. **article:** means 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;

The key function of HTIW can be generically described as “thermal insulation⁴ at elevated temperatures, typically above 600° C”. Following the REACH definitions it needs to be determined whether the fibrous shape or the chemistry is more important to achieve the desired function. By focussing on the functional aspect (rather than shape or chemical composition) it becomes obvious that a single fibre is not able to provide the desired function and therefore cannot be considered an article following the definition above – hence it is considered a substance even while it has been given a specific shape during production.

3. OBJECT STATUS OF HTIW PRODUCTS

HTIW fibres or wools⁵ are not sold in significant quantities to an industrial end user as such, but are typically converted into a range of product forms. A distinction can be made between three main categories of conversion processes: formulation, dry conversion and wet conversion. The conversion processes either take place at the primary HTIW manufacturing site or a limited number of specialised reprocessing sites.

3.1 MIXTURES

Mixtures can be formulated by mixing fibres and other ingredients to create a powder, paste or liquid which does not have a defined form or shape before it is applied in the “end use” application – it takes the shape of the container (bale, cartridge, drum etc.). Mixtures can be “ready for use” (wet mixtures) or be sold in the form of a powder to be mixed with water before use. Mixtures containing HTIW fibres are used as high temperature adhesives, coatings, castables or cements, predominantly in industrial process equipment. The use of HTIW in the formulation of mixtures is rather limited (low total tonnage).

4 While thermal insulation is very often the main function, other key functions such as e.g. filtration can also be important in specific high temperature applications.

5 Wool: randomly oriented, loose mass of fibres of different length and diameter – the result of the initial HTIW manufacturing step in contrast to drawn fibres or filaments (sometimes referred to as stack fibres).

3.2 ARTICLES

The REACH Guidance on substances in articles describes a process based on a series of indicative questions which is supposed to lead to a clear interpretation of the object status. Applied to HTIW products, the approach allows the conclusion that most common product forms are articles. However, as some of the indicative questions only make limited sense for HTIW products, the Guidance alone does in some instances not lead to a robust conclusion. This is particularly relevant in cases where the function of an object is related to physical aspects rather than chemical reactions (which is the case for HTIW products). Therefore we conclude that it is sensible to discuss the substance / article borderline for HTIW products with a stronger focus on the function(s) of those objects – this will help to extend or further differentiate the conclusions resulting from the “indicative questions” approach.

The key product design characteristics determining the functions of HTIW products are porosity (insulation, filtration) and resilience (sealant). None of these functions can be fulfilled by single fibres, hence fibres are considered substances. Assembling multiple fibres into any product form with sufficient mechanical integrity, results in an object with the desired porosity and resilience to provide the desired function(s) of the object. Therefore it follows that all “assembled” or “shaped” products such as blanket, textiles, board, paper, shapes should be considered articles.

4. CONSEQUENCES OF THE OBJECT STATUS

Based on the discussion above, the following sections will explore the legal consequences – with a specific focus on the REACH Regulation.

4.1 REACH REGISTRATIONS

HTIW fibres have been considered substances under REACH and were hence registered during the first “registration wave” in 2010.

To further evaluate the legal implications related to the object status, a distinction has to be made between “intended” and “unintended” release of the substance (fibre) as REACH registration requirements normally do not apply to articles, except in the case of “intended release” of the contained substances.

Any release of fibrous materials from finished products is not only unintended but rather “undesired” as it would ultimately lead to performance losses (e.g. a reduction of the thermal insulation performance of a HTIW based furnace lining) and hence applications are carefully designed to avoid any potential release “in situ”.

As a consequence of the above, there is normally no registration requirement for (imported) articles containing HTIW.

4.2 HAZARD COMMUNICATION

Following the requirements of the CLP Regulation (including hazard classifications carried over from Directive 67/548/EEC), common elements of hazard communication such as hazard warning labels and safety data sheets are only required for substances falling under a hazard classification and mixtures (previously referred to as preparations) containing such substances above defined threshold levels. It should, however, be noted that most common HTIW product forms (including articles) have the potential for “unintended” release of fibrous dust at various stages of their life cycle – namely in situations where the product is directly manipulated. Following the principles of good industrial hygiene and knowing that HTIW based products (including dry mixtures and most HTIW articles) can release fibrous dust at some stages of their life cycle, the HTIW industry has been promoting appropriate industrial hygiene and risk management practices through the use of labels and / or handling advice. All ASW / RCF based products have been labelled by ECFIA members on a voluntary basis since the 1980s independent of the substance / mixture / article status.

Safety data sheets are commonly provided for all HTIW types – independent from the object status and hence exceeding regulatory requirements.

Specific supply chain information requirements exist for SVHC (substances of very high concern) following REACH Art. 33. These requirements are independent from the object status, i.e. they also relate to mixtures and articles containing >0.1% (w/w) of a SVHC. In the case of HTIW, these specific requirements are applicable for ASW / RCF products and are typically fulfilled via customer information letters, user manuals, safety data sheets and other means of information exchange.

4.3 AUTHORISATION

By definition, the authorisation process will apply only to those SVHCs included on Annex XIV – the Authorisation List⁶. While the impact of the object status on REACH Registration and certain aspects of “Hazard Communication” is rather limited, the object status has a much bigger impact on the authorisation process. Interpreting and explaining REACH Art. 56, the applicable REACH Guidance⁷ contains the following statement related to the “substance use” description required as part of an application for authorisation:

⁶ In the case of HTIW it might potentially affect ASW/RCF. For the purpose of worker protection throughout the entire life cycle of ASW/RCF we, however, have demonstrated that the application of existing OSH Directives complemented by an EU-wide binding workplace exposure limit is a more effective regulatory option.

⁷ ECHA: Guidance on the preparation of an application for authorisation

“The use or uses should be described in the authorisation application in accordance with user manual(s) for authorisation applications made available on the Agency’s website. This section should be completed for all applications, irrespective of the basis on which the application is made.

This should also cover any use(s) of the substance(s) in mixtures and / or incorporation of the substance into articles, where this is relevant.

[...The] use of a mixture is described in a similar way to the use of a substance. Further information on the specific purpose of the substance in the mixture can be added if needed. Where the substance is used in production of articles, the use descriptor system will include the category of article into which the substance is incorporated **(it should be noted that the use of the articles themselves is not subject to authorisation).**” [Emphasis added]

Following the interpretation of the applicable object status for HTIW products in this paper, this will lead to two important consequences:

1. The “substance uses” requiring authorisation will be limited to the immediate use of the bulk fibres and could be described as
 - a. “substance use for production of articles ...” (possibly further differentiated into dry and wet conversion) and
 - b. “substance use for the formulation of or use as part of a mixture ...”
2. The use of HTIW articles (including those imported from outside the EU) will not be affected by a potential authorisation requirement.

In the case of an inclusion of ASW / RCF on REACH Annex XIV the application(s) for authorisation will hence be limited to the substance conversion steps described above. It follows that authorisations for the continued use of the substance would have to be requested by ECFIA’s member companies. Authorisations granted following these use descriptions will also cover downstream users including the independent reproducers (i.e. vacuum formers, paper producers).

5. CONCLUSION

HTIW fibres are considered substances following applicable legal definitions under REACH. Following the interpretation of REACH Article 3 briefly presented in this paper, HTIW based objects after formulation or further processing using the applicable reprocessing or conversion steps are either mixtures (cements, mastics, coatings, adhesives) or articles (all “shaped” product forms, including blanket, board, paper, felt, shapes, modules, textiles etc.).

This definition has implications in various areas of EU regulation. The interpretation of the applicable rules is reflected in the position of the HTIW industry as follows:

LEGAL ASPECT	HTIW INDUSTRY INTERPRETATION / POSITION
REGISTRATION:	While the registration requirement is usually related to substances on their own or as part of mixtures, a better reflection of the true market volume is possible through the inclusion of “articles” in the case of HTIW products. This approach is however only foreseen under specific circumstances (intended release or suspected release of hazardous substances). ECFIA members registered ASW/RCF (CAS N° 142844-00-6), AES (CAS N° 436083-99-7) and PCW (CAS N° 6575106-31-7) before the first deadline (December 2010).
HAZARD COMMUNICATION:	Specific regulatory requirements are defined for hazardous substances on their own or if these are contained in mixtures above certain weight thresholds. In line with REACH principles, ECFIA’s members support a much wider interpretation and will maintain hazard communication activities above and beyond the regulatory requirements (e.g. voluntary labelling of ASW/RCF based articles).
AUTHORISATION:	Authorisation might become mandatory for ASW/RCF. By legal definition authorisation is designed to cover “substance uses”. Applications for authorisation must hence be based on a “substance use” description. For ASW/RCF this description will follow the substance definition established in this position paper. It follows that the production of articles is the main “use” potentially falling under the authorisation requirement.