

Notification of substances of very high concern (SVHC) in articles Producers, importers and suppliers of articles, plan your notifications!

REACH

REACH* requires a notification of substances of very high concern (SVHC) in articles. This obligation affects producers, importers and suppliers of articles. The first deadline is 1 June 2011.

What is an "article"?

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 compositions". For instance, an article can be a finished object (clothing, furniture, building products...), a component (e-card, spare parts...) or even a packaging. The packaging must be evaluated separately from any object it contains.

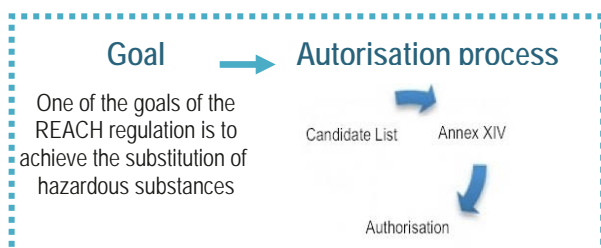
What is a chemical substance "SVHC"?

According to Article 57 REACH, a substance can be identified as substance of very high concern (SVHC) if it meets at least one of the following characteristics:

- Carcinogenic, mutagenic, or toxic for reproduction (CMR), category 1A or 1B according to the CLP regulation**,
- Persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) in accordance with the criteria set out in Annex XIII REACH,
- Scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern (e.g. endocrine disruptors).

What is the "Candidate List"?

The "**Candidate List**" includes all substances that have been officially identified as substances of very high concern (SVHC), i.e. they can be chosen for inclusion in Annex XIV REACH. Annex XIV is the list of substances that are subject to authorisation. They can no longer be placed on the market or used by any company without obtaining a prior authorisation from the European Commission.



The inclusion of a substance in the "Candidate List" triggers a number of obligations for companies (see next page).

* Regulation (EC) 1907/2006 for Registration, Evaluation, Authorisation and Restriction of Chemicals, so called REACH came into force on 1 June 2007.

** Regulation (EC) 1272/2008 on Classification, Labelling and Packaging of substances and mixtures, so called CLP came into force on 20 January 2009.

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What are the obligations related to "SVHC"?

A notification of a SVHC in articles is required when all the conditions of Article 7(2) REACH are met:

- the substance is included in the "Candidate List",
- the substance is present in those article above a concentration of 0,1% (weight/weight),
- the total amount of the substance present in all articles produced and/or imported, which contain more than 0.1% (w/w) of the substance, exceeds 1 tonne per year (see chapter 4.4 and 4.5 of the [Guidance on requirements for substances in articles](#)).

The threshold concentration of the substance of 0.1% (w/w) applies to the article as produced or imported.

Already the inclusion of a substance in the candidate list also raises some immediate obligations of communicating information by suppliers of chemical substances, mixtures and articles to their clients. It is also important to check if you are subject to those obligations that are already applicable (Article 33 REACH).

When do we have to notify SVHC substances?

As stated in Article 7(7) REACH, the notification of SVHC in articles shall be done within six months after the inclusion of the substance in the "Candidate List". For substances included before 1 December 2010, the notification must be submitted before 1 June 2011.

NOTIFICATION
BEFORE

1 JUNE 2011

of the 38 substances included in the "candidate list" before 1 December 2010.

NOTE: There is no fee linked to the notification of SVHC.

Are there exemptions?

The notification is not required if the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use (Article 7(3) REACH) or if the substance has already been registered for that use (Article 7(6) REACH).

To determine whether a substance has already been registered for a specific use, you must investigate in the supply chain of the object. A request may be made within the [SIEF](#) linked to concerned substance (see chapter 5 and 6 of the [Guidance on requirements for substances in articles](#)).

What information do we have to provide to ECHA?

The information to be notified to ECHA is listed in Article 7(4) REACH and includes, among others, the identity of the producer or importer, the identity and classification of the substance, and a brief description of the uses.

The notification must be submitted only electronically by the REACH-IT portal. This portal will only accept files created with the latest version of IUCLID 5.3 and the latest version of the bulk Excel 2.0 tool, provided by ECHA

To facilitate the submission of notifications, ECHA has made available pre-filled substance datasets in IUCLID format for substances on the Candidate List

Where to find further information?

Identity of the notifier	Download IUCLID 5 Create a LEO (Legal Entity Object) and import LEO XML (LEOX)
Download "Substance Dataset"	Available on ECHA's website, section "Candidate List"
Importing "Substance Dataset"	Import the information of the substance to IUCLID 5 (i5z files)
Complete the information	By the feature "update" of the IUCLID 5 programme
Create a dossier	Notification of a substance in an article dossier in IUCLID 5
Export the dossier	Export the notification dossier from IUCLID 5 to send it to ECHA by REACH-IT
Submit the dossier	Create an account in REACH-IT and Login by "Submit Dossier"

For further information:

[Data Submission Manual 20](#) «How to Prepare and Submit a Substance in Articles Notification using IUCLID».

[News alert from 13/04/2011](#) about the notification for SVHC in articles through REACH-IT.

These FAQs should help you!	8.2	Under what conditions and when do I have to notify substances of very high concern in articles?
	8.3	As Article 7(6) states "Paragraphs 1 to 5 shall not apply to substances that have already been registered for that use" does it refer to the same supply chain or to different supply chains?
	8.4	Can I already rely on the provisions of Article 7(6) when a substance in an article has been pre-registered?

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