

How do you know if your article contains a substance intended to be released?

Question 1: What is the function of your article? Is there a 'release' as a core part of its function?

The 'release' will almost certainly be part of the design specification for the article.

Examples of intended release:

Any article that is fragranced has an intention to release fragrance.

A welding rod is reduced in length and its material is released into the product as its core function.

A packing grease or stop-off compound is required to be removed. If the article changes ownership with the grease or stop-off compound in place, then the grease or stop-off is intended to be released.

Examples of not intended release: Wearing parts. Products of combustion as emissions from the article (in the case of engines etc.). Where the release is INEVITABLE, but NOT part of a function of the article. There is no added value from the release.

Question 2: 'Intentional release', or 'substance in a container?'

If there is a 'release', it could be that you have an article with intended release, or a substance within a container. The registration requirements will vary depending on what it is. To differentiate the two, answer the questions below.

If the answer to question 1 is unclear, try the following questions...

How does the function of the substance you are concerned about, relate to the article?

Question 2a: Will you dispose of the article separately from the substance?

If yes, it is likely that the substance is either 'intended to be released' or 'a substance within a container'. This is not always an indicator... you will dispose of packaging separately from the article, and some packaging is an article itself (such as a cardboard box).

Question 2b: Will the substance be part of the finished article or do you have to remove it before you can use the article?

Examples of intended release: Stop – off compounds, waxes used to stopper ends, packing grease for delivery purposes only, that will be removed on delivery.

Examples of not intended release: greases, lubricants, oils, coolant that are there to enable rotating / moving parts within the article to rotate / move during use.

Question 3: Is the "article" with intended release actually a substance within a container? Can you use the substance WITHOUT the article?

The substance thought to be released from the article could in some instances be 'substances within a container' according to REACH.

Examples of a substance in a container: Ink in a pen can be used (messily) without the need for a pen. The pen is just the 'delivery mechanism'. Screenwash in a bottle can be used without the bottle. The bottle is just the 'delivery mechanism'.

Examples of not a substance in a container: Fire extinguishants will not operate as intended (such as create a foam) without the appropriate nozzle end of the extinguisher.

ACTION if you have a substance intended to be released within your article:

1. Find out the CAS No. / EINECS or ELINCS number for the substance.
2. Identify how much substance is in a typical article (kg).
3. Identify how many articles are sold into the EU / Norway / Iceland region.
4. Estimate the total amount of substance sold into the EU as part of articles.
5. If the total amount is less than 1 Tonne, and is likely to remain less than 1 Tonne, you do not have to take any action.
6. If the total amount is more than 1 Tonne, and the substance has an ELINCS number, contact ECHA and ask if someone has registered the substance in relation to your use. If they have not, ECHA will advise you to register the substance. If you do this later than 1 June 2008, you may have to cease production until the registration process is completed – ECHA will advise.
7. If the total amount is more than 1 Tonne and the substance has an EINECS number, you need to pre-register the substance. You will need to identify the hazardous nature of the substance (if any) from the materials safety data sheet for the substance (contact the supplier). In particular, you need to know if the substance is classified as a 'substance of very high concern', or if it has the risk codes R50/53 on the materials safety data sheet. If the MSDS is from outside the EU it may not have this information. You can look the substance up on the EC classification and labelling website, and find out the information from there: <http://ecb.jrc.it/classification-labelling/>. You will need the CAS no. or the EINECS number to use this website to search 'classlab'.
8. Visit the ECHA website, which will have information about the IT systems that you will have to use to pre-register the substance (REACH IT and IUCLID5). Training courses on using these systems are available from REACHReady. Pre-registration using this software must be completed between 1 June 2008 and 30 November 2008.
9. Following pre-registration, your details will be shared in a Substance Information Exchange Forum (SIEF). In the SIEF, if any other company manufacturing the substance within Europe covers your use of the substance, you will not have to go through the full registration process. If no other manufacturer in Europe is covering your use, you will have to ensure that your use is covered in the registration dossier yourself. The deadline for compilation of the full registration dossier will depend on the tonnage band of the substance, and whether it is known to fulfil the definition of a 'Substance of Very High Concern' or not.

Tonnage band	Registration deadline
Greater than 1000 Tonnes or SVHCs (all tonnages)/yr Or R50/53 substances in quantities greater than 100 Tonnes/yr	1 December 2010
Greater than 100 Tonnes	1 December 2013
Greater than 1 Tonne	1 December 2018