

Application for an alternative chemical name Under EU safety data sheet legislation

Manufacturers, importers and downstream users who wish to produce or import a mixture – e.g. paints, cleaning agents, detergents etc – and place it on the European market, are obliged according to REACH and the CLP Regulation to inform a user of any relevant hazardous ingredient in the mixture by disclosing its chemical identity. Suppliers who are concerned about disclosing the full composition of a mixture on the product label or in the safety data sheet, can request the use of an alternative chemical name for a substance to protect the confidentiality of their formulation.

Procedure under DPD (until June 1 2015)

There is no fee for applications made for an alternative chemical name under the DPD.

Before 1 June 2015, if a mixture has not yet been classified, labelled and packaged according to the CLP Regulation, requests for an alternative chemical name (for a substance within the mixture) should be submitted to the Member State Competent Authority (i.e., the HSE in the UK) under Article 15 of the Dangerous Preparations Directive (DPD, Directive 1999/45/EC).

Under the DPD, it is only possible to apply for confidentiality for substances meeting certain criteria. These criteria are slightly different (and less restrictive) under the CLP Regulation, so substances that do not qualify for an alternative chemical name under the DPD may qualify for an alternative name under CLP. If the request is approved prior to 1 June 2015, the approved alternative name can continue to be used after this date.

Confidentiality requests should be prepared in accordance with Part A of Annex VI of the DPD and submitted to HSE (either hard copy or electronically). To make the system as flexible as possible HSE envisages two types of application for confidentiality:

1. Full Applications

There is no formal application form. However, applications must be as clear and concise as possible.

Each application must cover a request for confidentiality for a single substance and each substance for which confidentiality is being sought will require a Full Application of its own.

2. Update Applications

An Update Application builds upon a previous Full Application and extends it to cover additional preparations within the same group. As such only a minimal amount of extra information is required.

The applicant should provide the HSE reference number for the previous Full Application, the name of the new preparations and a statement that the new preparations are in the same group (ie they have similar composition, the same classification and labelling and use) as those listed in the Full Application. Provided that these conditions are met then the Update Application should be successful.

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The facility to apply for an alternative chemical name under the DPD applies to legal entities based within the EU - a non-EU company cannot apply. However, the UK authorities indicate that an OR is a suitable applicant under DPD rules.

Procedure under CLP

Under CLP rules, fees are to be paid for an application for an alternative chemical name and are given in Annex I of Regulation (EU) No 440/2010 to the CLP Regulation.

A request can be submitted for the use of an alternative chemical name to ECHA for a substance in mixtures which are classified, labelled and packaged according to CLP. The request needs to be prepared with the latest version of IUCLID 5 and it should be submitted using a specific web form found on the ECHA website. A REACH-IT account is necessary for invoicing and communication.

The following information is required to be included in the dossier:

- identity of the request submitter;
- the proposed alternative chemical name;
- identity and composition of the substance;
- information on the classification and labelling of the substance;
- the trade name(s) of the mixture(s) which contain the substance for which an alternative chemical name is requested;
- the SDS of the substance for which an alternative chemical name is requested;
- the SDS of the mixture(s) which contains the substance;
- a justification demonstrating that the request submitter has a commercial interest worthy of protection for non-disclosure of the actual substance name; and
- a justification demonstrating that the use of the alternative chemical name meets the need to provide enough information for necessary health and safety precautions to be taken in the workplace and the need to ensure that risks from handling the mixture can be controlled.

The IUCLID 5 file is submitted along with the required attachments via the web form.

Upon receiving the request, ECHA will perform a virus check and a 'Business Rules' check to verify that the dossier is complete and can be processed.

If the dossier passes the 'Business Rules' check, ECHA will send an invoice.

When ECHA has received the payment, a decision on the request for use of an alternative name will be communicated within six weeks.

For further information contact:

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