

Bundesanstalt für Arbeitsschutz und Arbeitsmedizin
Bundesstelle Chemikalien / Zulassung Biozide, Postf. 17 02 02, 44061 Dortmund

Request for confidentiality regarding the chemical identity of a substance in mixtures pursuant to Article 15 of Directive 1999/45/EC

Suppliers of mixtures may submit a request to use an alternative chemical name for a substance in a mixture if they can demonstrate that disclosure on the label or safety data sheet of the chemical identity of that substance will put at risk the confidential nature of his business, in particular his intellectual property rights. The request shall be submitted to the competent authority of the Member state (MSCA) where the mixture is intended to be placed on the market. Without a granted permission by the MSCA the use of the requested alternative chemical name is not permitted. In Germany the request shall be submitted to the “Federal Office for Chemicals“ established at the „Federal Institute for Occupational Safety and Health“ in Dortmund.

The substance for which the use of an alternative chemical name is requested shall meet the criteria set out in Article 15 and Annex VI of Directive 1999/45/EC.

The permission to use an alternative chemical name **may be granted only in case the substances are:**

- exclusively classified as irritant with the exception of those assigned R41 (Risk of serious damage to eyes)
- classified as irritant in combination with one or more of the properties as explosive, oxidising, extremely flammable, highly flammable, flammable or dangerous for the environment

or

- classified as harmful or harmful in combination with one or more of the properties explosive, oxidising, extremely flammable, highly flammable, flammable or dangerous for the environment presenting acute lethal effects alone

The procedure may *inter alia* not be applied if a substance:

- is classified as sensitising (R43)
- has been assigned a Community exposure limit

The procedure may not be applied for instance if the mixture:

- has been classified, labelled and packaged according to the CLP Regulation

Procedure and particular conditions in Germany:

- In Germany no fees are set for the request pursuant to Article 15 of Directive 1999/45/EC.

- In addition to the "Application form" both the safety data sheet of the mixture and the safety data sheet of the substance(s) shall be submitted.

- If the request/application is submitted by a representative on behalf of the supplier a written mandate has to be provided to the "Application form".

- The application form can be submitted either by mail or via e-mail.

- Should the request be approved before 1 June 2015, the use of the approved alternative chemical name on the label as well the safety data sheet can also continue after 1 June 2015. The approval will be provided in German as well as in English language.

- From 1 June 2015 the corresponding request shall meet the provisions under Article 24 of the CLP Regulation, and not the provisions of Directive 1999/45/EC. This includes the submission of the request to the Agency, and not to the MSCA.

- When the mixture is intended to be placed on the market in other EU member states, a copy of the approval has to be forwarded by the company to the respective

MSCA. Confidential information brought to the attention of the authorities of a Member State will kept confidential.