

From: ECHA Classification
Subject: D(2016)1695: Removal of a substance from an existing group entry in Annex VI, CLP

From: ECHA Classification
Sent: 16 May 2016 09:41
To: [REDACTED]@syngenta.com
Cc: [REDACTED]@echa.europa.eu>; KARHU Elina <Elina.KARHU@echa.europa.eu>; ECHA Classification <classification@echa.europa.eu>
Subject: D(2016)1695: Removal of a substance from an existing group entry in Annex VI, CLP

Dear Madam [REDACTED]

Thank you for your questions regarding the submission of a CLH dossier for 2,4,6-trichloroaniline (EC # 211-219-8, CAS # 634-93-5).

The substance is part of a group entry which includes at least fifteen mono-, di- and tri- chloroanilines. The entry was inserted in the 22nd ATP to DSD. It is indeed possible to extract from a group entry in Annex VI of CLP Regulation, a substance that, based on adequate evidence, does not share the classification(s) of the group and to create a new separate entry.

The way forward for the removal of the 2,4,6-trichloroaniline from the group entry is to submit a CLH proposal to a Member State Competent Authority (MSCA) in one of the Member States in which the substance is placed on the market. This is covered by Article 37(6) of CLP, i.e. that "*Manufacturers, importers and downstream users who have new information which may lead to a change of the harmonised classification and labelling elements of a substance in Part 3 of Annex VI shall submit a proposal in accordance with the second subparagraph of paragraph 2 [of Article 37] to the competent authority in one of the Member States in which the substance is placed on the market*".

Please find below some steps to follow:

1. Contact a MSCA in which the substance is placed on the market and agree with the MSCA upon their willingness to submit a CLH dossier to ECHA on your behalf, provided that it fulfils the requirements of the CLP Regulation in Art. 37(6).
2. When agreed, the MSCA will submit an intention to ECHA using the webpage tool at with an expected date of submission and additional information including the current classification in CLP and the proposed future entry. Please see at https://comments.echa.europa.eu/comments_cms/DossierIntentionCLHAuthority2010.aspx. The intentions is announced in the ECHA E-weekly letter which is sent out to stakeholders.
3. Prepare a CLH report in the format available at http://echa.europa.eu/documents/10162/13563/clh_report_template_en.doc. You will find some support, background information and guidance at <http://echa.europa.eu/support/clh>.
4. Send the CLH report to the MSCA which will review it and get back to you for any corrections or clarifications. When the CLH report is ready to be submitted to ECHA, the MSCA will submit it using the webpage tool at https://comments.echa.europa.eu/comments_clpproposalSubmission.aspx. Once submitted, registrants and notifiers will be notified. Please note that there is no obligation for a MSCA to submit the CLH dossier on your behalf if the proposal is not sufficiently justified.
5. Upon receiving the CLH dossier, ECHA will start an Accordance Check. ECHA will be in contact with the MSCA which will follow-up with you on any actions to take.

Please note that any of the existing hazard classes in the group entry that are not addressed in your CLH dossier will be transferred to the new entry without further scrutiny.

Your message below does not mention whether your proposal will also cover the removal or change for Acute Tox 3* classification by inhalation or for STOT RE 2. In addition, the C&L inventory reports a majority of notifiers with Acute Tox. 3 for the three routes of exposure. Some notifiers also report Skin

Irrit. 2 and Eye Irrit. 2. For efficiency, ECHA also suggests that you cover as many relevant endpoints as possible in your CLH report.

Do not hesitate to contact us if you need additional information.

Yours sincerely,
Fabrice Broeckaert

Fabrice Broeckaert, PhD, ERT

Senior Scientific Officer - Toxicology
Classification and Prioritisation Unit
European Chemicals Agency
Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland
Tel.: +358 [REDACTED]
fabrice.broeckaert@echa.europa.eu
echa.europa.eu

The above represents the opinion of the author and is not an official position of the European Chemicals Agency. This email, including any files attached to it, is intended for the use of the individual to whom it is addressed. If you have received this message in error, please notify the author as soon as possible and delete the message.