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Helsinki, 26 August 2020

Addressees
Registrants of JS_GUF-Me as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
18 December 2019

Registered substance subject to this decision ("the Substance")
Substance name: Urea, reaction products with formaldehyde, glyoxal and methanol
EC number: 296-665-1
CAS number: 92908-36-6

Decision number: Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/D)

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***5 March 2021***.

A. Requirements applicable to all the Registrants subject to Annex VI of REACH

1. Apply the harmonised classification and labelling on the Substance for carcinogenicity (Annex VI, Section 4.) or provide reasons for not classifying;

Reasons for the request is explained in the following appendix:

- Appendix entitled "Reasons for the requests to comply with Annex VI of REACH"

You must provide the information listed above independent from your tonnage band.

How to comply with your information requirements

To comply with your information requirements you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

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Appendix A: Reasons for the requests to comply with Annex VI of REACH

Under Article 10(a) of REACH, a technical dossier must contain information specified in Annex VI to REACH.

1. Apply the harmonised classification and labelling on the Substance for carcinogenicity (Annex VI, Section 4.)

Classification and labelling of the substance, resulting from the application of Title I, II and III of Regulation (EC) No 1272/2008 (CLP), is an information requirement as specified in Annex VI to REACH.

Your Substance is a UVCB, which contains formaldehyde (EC 200-001-8, CAS: 50-00-0) in its composition to which a harmonised classification applies.

According to ECHA's CLP Guidance[2] "*Substances may contain impurities, additives, or other constituents while still meeting the substance definition in CLP. This applies to both mono-constituent, multi-constituent (e.g. reaction masses) and UVCB substances. The classification of such impurities, additives or individual constituents may influence the classification of the substance, in addition to the other hazardous properties. If data on the substance with its components are not available (or for CMRs, see section 1.1.6.1), in principle, the same classification and labelling rules as for mixtures should apply also for such substances".*

Under Article 10(1) of CLP, "*Specific concentration limits and generic concentration limits are limits assigned to a substance indicating a threshold at or above which the presence of that substance in another substance or in a mixture as an identified impurity, additive or individual constituent leads to the classification of the substance or mixture as hazardous*".

Further, according to section 3.6.3.1.1. of Annex I to CLP a "*mixture will be classified as a carcinogen when at least one ingredient has been classified as a Category 1A, Category 1B or Category 2 carcinogen and is present at or above the appropriate generic concentration limit*" triggering classification. This concentration limit is ≥ 0,1 % for Category 1A/1B (Table 3.6.2. of Annex I to CLP).

Formaldehyde (EC 200-001-8, CAS: 50-00-0) is included in Annex VI to CLP as carcinogen, Category 1B (Carc 1B) (H350) with a statement "May cause cancer" (harmonised classification).

According to your registration dossier, your Substance is a UVCB, which contains formaldehyde (EC 200-001-8, CAS: 50-00-0) in its composition at a concentration of ≥ [redacted]%, but you have not classified the Substance as Carc 1B or provided any justification for the non-classification.

Based on the above, you are requested to classify your Substance as Carc 1B or to provide reasons for not classifying. These reasons should be scientifically justified.

[2] Guidance on the Application of the CLP Criteria, Section 1.1.7.2

Appendix B. Procedure

This decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 17 December 2019.

ECHA notified you of the draft decision and invited you to provide comments

ECHA did not receive any comments within the notification period.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix C: Addressees of this decision and the corresponding information requirements applicable to them

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.