EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114313754-52-01/F Helsinki, 09 March 2016

**DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006**

**For 4'-Methylenediphenyldiisocyanate, oligomeric reaction products with butane-1,3-diol, 2,4'-diisocyanatodiphenylmethane, 2,2'-oxydiethanol and propane-1,2-diol, EC No 500-415-1 (CAS No 158885-29-1), registration number: [redacted]**

**Addressee: [redacted]**

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

## I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for 4'-Methylenediphenyldiisocyanate, oligomeric reaction products with butane-1,3-diol, 2,4'-diisocyanatodiphenylmethane, 2,2'-oxydiethanol and propane-1,2-diol, CAS No 158885-29-1 (EC No 500-415-1), submitted by [redacted]

The scope of this compliance check is limited to the standard information requirements of Annex VI, Section 2 of the REACH Regulation.

This decision is based on the registration as submitted with submission number [redacted] for the tonnage band of 100 to 1000 tonnes per year. This decision does not take into account any updates submitted after the deadline for updating (19 March 2015) communicated to the Registrant by ECHA on 10 February 2015.

The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2016.

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

The compliance check was initiated on 10 June 2014.

On 13 November 2014 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted]

On 16 December 2014 ECHA received comments from the Registrant on the draft decision. On 13 February 2015 the Registrant updated his registration dossier with the submission number [redacted]

The ECHA Secretariat considered the Registrant's comments and update.

The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 29 October 2015 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

1. Name or other identifier of the substance (Annex VI, 2.1.);
2. Composition of the substance (Annex VI, 2.3.);

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **16 June 2016.**

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

1) Name or other identifier of the substance (Annex VI, 2.1. of the REACH Regulation.)

"Name or other identifier of the substance" is an information requirement as laid down in Annex VI, Section 2. 1. of the REACH Regulation. The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore fundamental for substance identification. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the Registrant identified the registered substance as a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). The naming of UVCB substances shall consist of two parts: the chemical name and a more detailed description of the manufacturing process, as described in chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014) - referred to as "the Guidance" thereinafter. ECHA observes that the Registrant did not provide sufficient and appropriate information on the naming of the registered substance, as explained thereinafter.

The Registrant received the draft decision requesting clarifications on the name of the registered substance and submitted an updated dossier. In the remarks field of section 1.1 of the updated dossier, the Registrant reported the chemical name for the registered substance:

"Reaction products of 4,4'-Methylenediphenyldiisocyanate, 2,4'-diisocyanatodiphenylmethane, 2,2'-diisocyanatodiphenylmethane and higher oligomers of MDI with a mixture of butane- 1,3-diol, 2,2'-oxydiethanol and propane-1,2-diol".

This name refers to the use of 2,2'-diisocyanatodiphenylmethane as starting material. However, ECHA notes that the description given for the manufacturing process of the registered substance specifies that the starting material used includes especially low relative amounts of 2,2'-diisocyanatodiphenylmethane. No explanation was given justifying why such reactant is considered relevant for deriving the name of the registered substance whilst the following other elements have not been taken into account:

- Other structures such as [redacted] MDI trimers (which are expected to contribute to an equivalent or higher extent to the composition of the registered substance, based on the information reported in IUCLID section 1.2) have not been specifically mentioned in the name;

- The oligomeric nature of the composition of the registered substance may be so limited that as much as [redacted] of the composition could consist of unreacted MDI starting materials (relying on the reported concentration ranges of the constituents in the registered substance and assuming that, where the content in e.g. unreacted 4,4'-MDI is the highest, the content in the other unreacted MDI (2,2'- , 2,4- or the oligomeric MDI) will also be the highest. This has not been reflected in the naming.

ECHA notes that the Registrant included also the name:

"4'-Methylenediphenyldiisocyanate, oligomeric reaction products with butane-1,3-diol, 2,4'-diisocyanatodiphenylmethane, 2,2'-oxydiethanol and propane-1,2-diol" in the IUPAC name field of section 1.1 of the IUCLID dossier. This name is not consistent with the above-mentioned name, proposed in the remarks field of section 1.1, that specifies the starting material as including also "higher oligomers of MDI".

ECHA also notes that the EC entry 500-415-1 specified for the registered substance is included in the No-Longer Polymer (NLP) list (available on esis.jrc.ec.europa.eu website). In such list, the EC entry 500-415-1 is actually linked to CAS entry 158885-29-1. The Registrant shall note, however, that as explained in the NLP list (page 8 of the document) "NLP-Nos and name descriptions take precedence. The CAS-RN given are to be treated as indicative and for a use as a searching tool". ECHA considers that the CAS information included in the registration dossier is generic and does not fully correspond to the registered substance.

Accordingly, the Registrant is required to provide the chemical name which reflects the actual oligomeric nature of the registered substance and includes the specific IUPAC names (or the specific chemical names derived according to the Guidance) of the starting materials used. The Registrant shall also delete the CAS entry with CAS number 158885-29-1 specified as CAS information for the registered substance.

ECHA notes that in the remarks field of section 1.1 of the updated dossier, the Registrant included the statement "The EC entry 500-415-1 currently assigned does not correspond to

the registered substance. This identifier cannot be modified or deleted at this stage in the present registration update for technical reasons. "

As explained in the draft decision, the Registrant should note that ECHA has established processes, subject to certain conditions, enabling registrants to adapt the EC identifier of an existing registration, while maintaining the regulatory rights already conferred to the substance concerned.

As for the reporting of the information in IUCLID, the chemical name and any available CAS entry for the registered substance shall be reported in the "IUPAC name" field and under the "CAS information" header of the reference substance in IUCLID section 1.1, respectively. Should this CAS number be related to the registered substance, it may be reported under the "Related CAS information" header in IUCLID section 1.1.

The Registrant shall ensure that appropriate and consistent identifiers are used throughout the registration whenever reference to the specific substance which is the subject of this registration is made.

2) Composition of the substance (Annex VI, 2.3. of the REACH Regulation)

The substance composition corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification and the cornerstone of all the REACH obligations.

ECHA notes that the registration does not contain sufficient and appropriate information for establishing the composition of the registered substance and therefore its identity, as required under Annex VI, section 2.3. of the REACH Regulation and explained thereinafter.

The draft decision communicated to the Registrant included a request for clarifying the composition of the registered substance and providing detailed information on the identity and concentration levels of the constituents and groups of constituents present in the registered substance.
The Registrant submitted an updated dossier after receiving the draft decision providing detailed information on the composition of the registered substance. However, ECHA notes that the analytical data (LC/MS) given indicate the presence of groups of constituents showing a polyol oligomeric structure that have not been reported in the composition section of the IUCLID dossier. Therefore the composition reported in the updated dossier is not consistent with the analytical data provided.

In section 1.4 of the IUCLID dossier, the Registrant provided an explanation for the above-mentioned inconsistency. More specifically, the Registrant explained that the presence of groups of constituents showing a polyol oligomeric structure in the sample, used for obtaining the provided analytical data, is due to an accidental addition of a polyol oligomeric reactant in the reaction vessel during manufacturing.

The Registrant also stated "*A new analysis will be submitted via an update of the registration IUCLID*".

In light of the statement included in the updated dossier, ECHA understands that the Registrant intends to submit new analytical data to support the identity of the registered substance and clarify the inconsistency observed with the composition information provided. As the registrant did not submit the new analytical data to support the composition reported in the updated dossier, ECHA is however currently not in a position to verify that the revised

compositional information describes the substance actually manufactured or imported. In the draft decision, the Registrant was explicitly requested to ensure that compositional information included in the dossier for the registered substance is consistent throughout the registration. The Registrant was also requested to ensure that the reported composition is verifiable and therefore supported by a description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported, as required under Annex VI section 2.3.7 of the REACH Regulation.

Accordingly, the Registrant is still requested in this decision to make any necessary revision of the composition currently reported in the dossier, should the results of the new analytical data, proposed by the Registrant, indicate that this composition is insufficiently detailed or inappropriate.

Further technical details on how to report the composition of UVCB substances in IUCLID are available in paragraphs 2.1 and 2.2.2 of the Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 2.0, July 2012).

## IV. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://www.echa.europa.eu/web/guest/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[1] by Claudio Carlon, Head of Unit, Evaluation E2

[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.