EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114292583-41-01/F Helsinki, 16 March 2015

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

For 4,4'-ethylidenediphenyl dicyanate, CAS No 47073-92-7 (EC No 405-740-1), 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 4,4'-ethylidenediphenyl dicyanate, CAS No 47073-92-7 (EC No 405-740-1), submitted by [redacted] (Registrant). The scope of this decision is limited to the standard information requirements of Annex VII, Section 8 'Toxicological information' of the REACH Regulation and Annex VI section 4.1 on 'Classification and labelling'.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1 to 10 tonnes per year. This decision does not take into account any updates submitted after 4 September 2014, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

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 1 October 2013.

On 28 February 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 24 March 2014 ECHA received comments from the Registrant on the draft decision.

On 28 March 2014 the Registrant updated his registration dossier with the submission number [redacted]

The ECHA Secretariat considered the Registrant's comments and update.
On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed to reflect the information.

On 4 September 2014 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.

Subsequently, proposals for amendment to the draft decision were submitted.

On 10 October 2014 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and amended the draft decision.

On 20 October 2014 ECHA referred the draft decision to the Member State Committee.

By 10 November 2014, in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments on the proposals for amendment of the Registrant into account.

After discussion in the Member State Committee meeting on 8-11 December 2014, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 10 December 2014.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 41(1), 41(3), 10(a)(vi), 12(1)(a), and Annex VII of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

A.1. Study summaries for the following studies

1. *In vivo* skin irritation according to test method: EU B.4 "Biodynamics Inc., East Millstone, New Jersey 08873, USA, 1991" for meeting the information requirement of Annex VII, 8.1. of the REACH Regulation.

2. Skin sensitisation according to test method OECD 406, "Inveresk Research International (I.R.1) Limited, Tranent, EH33 2NE, Scotland/UK, 1991"; for meeting the information requirements of Annex VII, 8.3. of the REACH Regulation.

3. *In vitro* gene mutation study in bacteria according to EU-testing method EU B.13/14. , "Inveresk Research International (I.R.1) Limited, Tranent, EH33 2NE, Scotland/UK, 1991", for meeting the information requirements of Annex VII, 8.4.1 of the REACH Regulation.

Note to the Registrant for consideration:
As an alternative to providing the study summaries referred to in points 1 and 3 above

1) the Registrant may decide to fulfil the information requirements of section 8.1 of Annex VII by conducting the assessments and in vitro studies as described in that section. He shall however not repeat the *in vivo* skin irritation test.

2) the Registrant may decide to fulfil the information requirement of section 8.4.1 in Annex VII by conducting a new *in vitro* gene mutation study in bacteria according to EU-testing method B13.14

In any case adequate information on these endpoints needs to be present in the technical dossier for the registered substance to meet these information requirements.

A.2. Available information for the following study:

4. Mutagenicity study *(In vivo* cytogenicity assay).

B. Information in the technical dossier related to the classification and labelling of the substance

Pursuant to Articles 41(1), 41(3), 10(a)(iv) and Annex VI, Section 4.1 first paragraph of the REACH Regulation in conjunction with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) the Registrant shall submit the following information for the registered substance subject to the present decision:

The harmonised classification and labelling as specified in Annex VI of the CLP Regulation under Index number 615-025-008 for this substance.

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 **23 September 2015**.

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.

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 10(a)(vi) and, 12(1)(a) of the REACH Regulation, a technical dossier for a non-phase-in substance substance manufactured or imported by the Registrant in quantities of 1 to 10 tonnes per year shall contain as a minimum the information specified in Annex VII, of the REACH Regulation.

A.1 Study summaries

Pursuant to Article 10(a)(vi) the the information set out in Annex VII must be provided in the form a of a study summary. Article 3(29) of the REACH Regulation defines a study summary as a summary of the objectives methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study. Guidance on the preparation of study summaries is provided in the Practical Guide 3: How to report robust study summaries", which is available on the ECHA website under the following link:
http://echa.europa.eu/documents/10162/13643/pg_report_robust_study_summaries_en.pdf

Article 25(3) of the REACH Regulation permits registrants to use for the purposes of their registration study summaries submitted in the framework of the REACH Regulation at least 12 years previously.

However, according to the ECHA "Guidance on data sharing", Version 2.0, April 2012, section 4.6.3 "It is always the responsibility of the inquirer to assess the quality and relevance of the information received by ECHA so that, as a registrant, he fulfils his registration obligations. When using study summaries submitted more than 12 years earlier (e.g. in a NONS notification), it may be that these study summaries are not of sufficient quality to meet the registration obligations under the REACH Regulation and the potential registrant may consider alternatives to ensure compliance of the registration dossier. Additionally the potential registrant is also advised to contact the previous registrant/ notifier to ensure full study summary is available." (see
http://echa.europa.eu/documents/10162/13631/guidance_on_data_sharing_en.pdf)

In other words, inadequacy of the quality of the study summaries submitted more than 12 years earlier cannot be used as a reason for not meeting the REACH information obligations.

In the present registration dossier the Registrant refers to studies that are more than 12 years old. However, the Registrant has not reported in the IUCLID format study summaries within the meaning of Article 3(29) of the REACH Regulation.

1. Skin irritation or skin corrosion (Annex VII, 8.1.)

"Skin irritation or corrosion" is a standard information requirement as laid down in Annex VII, Section 8.1. of the REACH Regulation: "The assessment of this endpoint shall comprise the following consecutive steps: (1) an assessment of the available human and animal alternative data, (2) an assessment of the acid or alkaline reserve, (3) *in vitro* study for skin corrosion, (4) *in vitro* study for skin irritation". Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant has not provided a complete assessment of skin irritation or corrosion in the dossier that would meet the information requirement of Annex VII, Section 8.1.

The dossier only contains a short summary of an *in vivo* skin irritation study according to EU test method B.5 that lacks i.a. the irritation/corrosion scores for each animal at all time points measured.

The Registrant stated in his comments that the *"inital robust summary was revised and completed; will be re-submitted as part of an updated dossier".* However the only relevant new information in the updated dossier concerns the form of the test material, "viscous". Other changes made are editorial revisions in the sections 'Reference' and 'results and discussion' and deletion of the sentence, with which he originally described the data as follows: "Only limited information available; test data from migrated ELINCS-notification dossier obtained from ECHA on 10-June-2010." He thus added no substantial new information to the endpoint summary.

Further, the Registrant does not give a valid reason for not providing a complete study summary as explained in the ECHA "Guidance on data sharing", Version 2.0, April 2012, section 4.6.3 (see above).

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently the Registrant is requested to upgrade the study summary for the endpoint.

Alternatively the registrant may decide to fulfil the information requirement by conducting the assessments and in vitro studies as described in Annex VII, 8.1. He shall however not repeat the in vivo skin irritation test.

Scientific guidance on integrated testing for skin irritation is available in the OECD Guidance Document No 203, ENV/JM/MONO (2014)/19 "New Guidance Document on an Integrated Approach on testing and assessment (IATA) for skin corrosion and irritation."

2. Skin sensitisation (Annex VII, 8.3.)

"Skin sensitisation" is a standard information requirement as laid down in Annex VII, Section 8.3. of the REACH Regulation: "The assessment of this endpoint shall comprise the following consecutive steps: (1) an assessment of the available human, animal and alternative data, (2) *In vivo* testing". Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier the Registrant has provided a study record for a Guinea pig maximisation test (skin sensitisation study according to EU-testing method B6 /OECD TG 406). However, this study does not provide the information required by Annex VII, Section 8.3., because the summary of the methods and results is inadequate. For example there is no information on positive controls or individual animal results. Some text is inconsistent: e.g. "Signs of irritation during induction: - moderate irritation in all test animals; slight irritation in all negative controls. Slight irritation in all test animals, no irritation in negative controls."

The Registrant stated in his comments that the *"inital robust summary was revised and completed; will be re-submitted as part of an updated dossier".* However the only relevant new information in the updated dossier concerns the form of the test material, "viscous". Other changes made are editorial revisions e.g. in the section 'Reference', some duplicate text was removed; under "Maximum concentration not causing irritating effects in preliminary test" the statement "test missing in ECHA document" was replaced by "no data". In the endpoint summary the sentence "Only limited information available; test data from migrated ELINCS-notification dossier obtained from ECHA on 10-June-2010." was deleted. Thus the Registrant did not add substantial new information. Further the Registrant does not give a valid reason for not providing a complete study summary as explained in the ECHA "Guidance on data sharing", Version 2.0, April 2012, section 4.6.3 (see above).

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement.

Consequently the Registrant is requested to upgrade the study summary for the endpoint. The Registrant shall pursuant to the process set out in Article 27 of the REACH Regulation make every effort to obtain the information from the former NONS registrant but he shall not repeat the *in vivo* study for skin sensitisation.

3. In vitro gene mutation study in bacteria (Annex VII, 8.4.1.)

An "*In vitro* gene mutation study in bacteria" is a standard information requirement as laid down in Annex VII, Section 8.4.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The dossier only contains a concise summary that the registrant originally described as follows: "Only limited information available; test data from migrated ELINCS-notification dossier obtained from ECHA on 10-June-2010."

The Registrant stated in his comments that the *"inital robust summaries for Ames- and CA-test were revised and completed; will be re-submitted as part of an updated dossier within this week"* . However the only relevant new information concerns the form of the test material, "viscous". Other changes made are editorial revisions in the sections 'Reference' and deletion of the sentence "Only limited information available; test data from migrated ELINCS-notification dossier obtained from ECHA on 10-June-2010." The Registrant thus did not add substantial new information to the endpoint summary.

Further the Registrant does not give a valid reason for not providing a complete study summary as explained in the ECHA "Guidance on data sharing", Version 2.0, April 2012, section 4.6.3 (see above).

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently the Registrant is requested to upgrade the study summary for the endpoint. Alternatively the Registrant may decide to fulfil the information requirement by conducting a new *in vitro* gene mutation study in bacteria according to EU-testing method B13.14

A.2. Any other relevant and available information

4. Further mutagenicity study *(In vivo* cytogenicity assay)

Pursuant to Article 12(1) as well as Annex VII of the REACH Regulation there is a requirement that "Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided".

The Registrant concludes in IUCLID Section 7.6. "Endpoint conclusion: Adverse effect observed (positive)."

In section 7.6.1 of the IUCLID dossier the Registrant refers to an *in vivo* test that had to be conducted by another Registrant for the same substance under the provisions of directive 67/548/EEC, "to investigate further the potential mutagenicity of the substance". He further states that "Remark: The data of the micronucleus test were not provided by ECHA."

In his comments the Registrant gives the following reasons for not providing the requested information; *"the mandatory genotoxicity test in-vitro (Ames test) required at Annex VII was negative - the chromosome abberation test in-vitro is an Annex VIII test and was submitted voluntarly for the 1-10 tpa registration as supplemental information - in the data set provided by ECHA (NONS data from 1st notifier) as a result of our inquiry, an in-vivo MNT is suggested to clarify the clastogenic effects of the CA-test; however this micronucleus test was not part of the data set from ECHA, therefore it was assumed that this test was finally not conducted* [redacted] *is of the opinion, that a micronucleus test in-vivo is not justified for a 1-10 tpa registration, where the mandatory endpoint (Ames test) showed a negative result."*

ECHA notes however that the content of the registration dossier is built on information that has been provided by ECHA in the inquiry process. In a second inquiry, inquiry number [redacted], the Registrant has been provided with the information of the SNIF (Structured Notification Interchange Format) file for the tonnage level 10-100t/a. This included SNIF information for *in vitro* and *in vivo* chromosome aberration studies.The information provided is older than 12 years and therefore can be used freely by the Registrant for registration purposes.

In his dossier the Registrant included the available information for the *in vitro* chromosome aberration study but not the results of the *in vivo* study.

ECHA notes that the information on the *in vivo* cytogenicity study is available to the Registrant as ECHA, as indicated above, has provided this information to the Registrant in response to his inquiry. The information is relevant for the registrant because it addresses the positive outcome of the *in vitro* chromosomal aberration assay which is included in the registration dossier.

Consequently the registrant is requested to include in his registration dossier all freely available information in relation to the *in vivo* cytogenicity study.

B. Information in the technical dossier related to the classification and labelling of the substance

Article 10(a)(iv) of the REACH Regulation requires that the technical dossier shall include the classification and labelling of the substance as specified Annex VI, Section 4 of the REACH Regulation. Section 4.1 first paragraph of Annex VI requires a registrant to provide the hazard classification of the substance resulting from the application of Title I and Title II of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation).

According to Annex VI of the CLP Regulation, Index number 615-025-008 the registered substance has a harmonised classification for the hazard class "Aquatic Chronic 1, H410". This harmonised classification and labelling is not applied correctly in the fields of section 2 of the technical dossier, where instead "Aquatic Chronic 2, H411" is given as classification for this hazard class.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the correct information on the harmonised classification and labelling of the registered substance subject to the present decision.

C. Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 3 months from the date of adoption of the decision. The proposal for amendment submitted by a Member State Competent Authority asked for the fulfilment of the information requirements for *in vitro* gene mutation in bacteria endpoint by testing. As this request was not addressed in the present decision and the Registrant is now requested in section III of the decision to "alternatively the Registrant may decide to fulfil the information requirement by conducting a new *in vitro* gene mutation study in bacteria according to EU-testing method B13.14" ECHA considers that a reasonable time period for providing the required information in the form of an updated IUCLID5 dossier is 6 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

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://echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

Leena Ylä-Mononen
Director of Evaluation