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Helsinki, 05 June 2024

Addressees
Registrants of JS_PTSI_REACH as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
23 May 2013

Registered substance subject to this decision ("the Substance")
Substance name: p-toluenesulphonyl isocyanate
EC/List number: 223-810-8

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***10 September 2026***.

Requested information must be generated using the Substance unless otherwise specified.

Information required from all the Registrants subject to Annex IX of REACH

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211) - test on an aqueous solution of the Substance aged for a period equal to at least 6 degradation half-lives.

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210) - test on an aqueous solution of the Substance aged for a period equal to at least 6 degradation half-lives.

The reasons for the request(s) are explained in Appendix 1.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

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.

You must follow the general requirements for testing and reporting new tests under

REACH, see Appendix 4.

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 Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the request(s)
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[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.

Appendix 1: Reasons for the request(s)

Reasons related to the information under Annex IX of REACH

1. Long-term toxicity testing on aquatic invertebrates

1 Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

1.1. Information provided

2 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided the following information:

(i) Justification: '*According to REACH Annex IX, column 2 long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. PTSI is extremely water-reactive. It will react immediately with moisture to form p-toluenesulfonyl amide (PTSA) and carbon dioxide. Therefore the chemical safety assessment is conducted for the decomposition product PTSA. Using the available (short-term) aquatic toxicity data for PTSA, the chemical safety assessment does not reveal a need for further investigation (the environmental risk assessment for all intended uses shows that the risk is controlled). The available data is also sufficient for the hazard assessment and PBT assessment. Therefore, a study on long-term toxicity to aquatic invertebrates is waived.*'.

1.2. Assessment of the information provided

1.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the study

3 Under Annex IX, Section 9.1., Column 2 is not a basis for omitting information on long-term toxicity to aquatic invertebrates referred to under Column 1, Section 9.1.5.

4 Your adaptation is therefore rejected.

5 Therefore, the information requirement is not fulfilled.

1.3. Study design

6 The Substance is difficult to test due to its hydrolysable properties (see below). OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your Substance. In all cases, the approach selected must be justified and documented.

7 First, OECD GD 23, section 7.3 recommends that "*if the test chemical is likely to be unstable, a decision to test the parent test chemical and/or its degradation products, if identified, should be based on a consideration of its half-life under test and real-world conditions*". The Substance is not stable in water. It contains a isocyanate group (-N=C=O). Isocyanate groups are intrinsically unstable and can hydrolyse very rapidly when in contact with water. You indicate in the dossier that: '*The Substance is extremely reactive with water/moisture. Primarily used as a moisture scavenger in sealants, coatings and adhesives, the molecule reacts instantaneously to create p-toluenesulfonyl amide (PTSA) and carbon dioxide.*'. Therefore, the Substance is unstable with a hydrolysis half-life of less than one hour (OECD GD 23, para. 82), and you must consider testing the hydrolysis products of the Substance.

8 Second, OECD GD 23, section 7.3 indicates that "*testing of degradation products will normally be required where the results of a preliminary range-finding experiment or a (Q)SAR analysis indicates that the degradants have significant toxicities or other relevant*

properties (e.g. low or no degradability)". The available information on toxicity to algae indicates that the hydrolysis product (PTSA) is potentially toxic to aquatic organisms. Therefore, testing of the hydrolysis products is required.

9 Third, OECD GD 23, section 7.3, point 86 specifies that: "*The aquatic toxicity of degradation products may be determined by allowing the parent compound to degrade and then exposing the test organisms to the resulting test solution. Leaving a stock or test solution of the parent test chemical for a period equal to 6 degradation half-lives of the test chemical will generally be sufficient to ensure that the test solution contains only degradation products*". Therefore, an aqueous solution of the Substance aged for a period equal to at least 6 degradation half-lives must be tested.

10 In accordance with OECD GD 23, section 7.3, point 88, you must monitor the test concentrations of the hydrolysis products and/or of the Substance in the test solution throughout the exposure duration, using an appropriate analytical method. You must express the effect concentration based on the measured values of the dissolved hydrolysis products and/or of the Substance.

2. Long-term toxicity testing on fish

11 Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

2.1. Information provided

12 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided the following information:

(i) Justification:'*According to REACH Annex IX, column 2 long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. PTSI is extremely water-reactive. It will react immediately with moisture to form p-toluenesulfonyl amide (PTSA) and carbon dioxide. Therefore the chemical safety assessment is conducted for the decomposition product PTSA. Using the available (short-term) aquatic toxicity data for PTSA, the chemical safety assessment does not reveal a need for further investigation (the environmental risk assessment for all intended uses shows that the risk is controlled). The available data is also sufficient for the hazard assessment and PBT assessment. Therefore, a study on long-term toxicity to fish is waived.*'.

2.2. Assessment of the information provided

2.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the study

13 Under Annex IX, Section 9.1., Column 2 is not a basis for omitting information on long-term toxicity to fish referred to under Column 1, Section 9.1.6.

14 Your adaptation is therefore rejected.

15 Therefore, the information requirement is not fulfilled.

2.3. Study design

16 To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (Guidance on IRs and CSA, Section R.7.8.2.).

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17 OECD TG 210 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in "Study design" under request 1.3.

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).
Guidance for monomers and polymers; ECHA (2023).
***Guidance on intermediates*;** ECHA (2010).
All guidance documents are available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF); ECHA (2017).
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs; ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: 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 04 August 2023.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

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

ECHA did not receive any comments within the commenting 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 3: Addressee(s) of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

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

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1 Test methods, GLP requirements and reporting

(1) Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.
(2) Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.
(3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries (https://echa.europa.eu/practical-guides).
(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2 Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

(1) Selection of the Test material(s)

The Test Material used to generate the new data must be selected taking into account the following:

- the variation in compositions reported by all members of the joint submission,
- the boundary composition(s) of the Substance,
- the impact of each constituent/impurity on the test results for the endpoint to be assessed. For example, if a constituent/impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/impurity.

(2) Information on the Test Material needed in the updated dossier

- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- The reported composition must include all constituents of each Test Material and their concentration values.

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers (https://echa.europa.eu/manuals).