~~Confidential~~

Helsinki, 27 May 2024

Addressee(s)
Registrant(s) of JS-TSCHLNA-100T as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
31 May 2018

Registered substance subject to this decision ("the Substance")
Substance name: tosylchloramide sodium
EC/List number: 204-854-7

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 ***4 December 2025***.

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

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

1. Growth inhibition study on aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3/OECD TG 201).

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

2. In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490)

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 addressee of the decision and its corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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 VII of REACH

1. Growth inhibition study aquatic plants

1 Growth inhibition study on aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2.).

1.1. Information provided

2 You have provided:

(i) Growth inhibition study on algae (1997) with the Substance.

1.2. Assessment of the information provided

3 To fulfil the information requirement, a study must comply with the OECD TG 201 (Article 13(3) of REACH). Therefore, the following specifications must be met:

Validity criteria

a) exponential growth in the control cultures is observed over the entire duration of the test;

b) at least 16-fold increase in biomass is observed in the control cultures by the end of the test;

c) the mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures is ≤ 35%;

d) the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is ≤ 7% in tests with *Pseudokirchneriella subcapitata*;

Technical specifications impacting the sensitivity/reliability of the test

e) the test duration is 72 hours. Shorter or longer test durations may be used provided that all validity criteria are met;

Characterisation of exposure

f) analytical monitoring must be conducted. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided;

g) the test media prepared specifically for analysis of exposure concentrations during the test is treated identically to those used for testing (i.e. inoculated with algae and incubated under identical conditions);

h) the results can be based on nominal or measured initial concentration only if the concentration of the test material has been maintained within ±20 % of the nominal or measured initial concentration throughout the test.

4 In study (i):

Validity criteria
You have provided no information on:

a) exponential growth in the control cultures over the entire duration of the test;

b) the biomass at the start and end of the test, respectively. You state that "*the increase of the extinction of the control over 72 h by a factor of 74.*" However,

the test duration was 96 hours and you do not provide information on the fold increase in biomass at the end of the test;

c) the mean coefficient of variation for section-by-section specific growth in the control in %;

d) the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures in %.

Technical specifications impacting the sensitivity/reliability of the test

e) the test duration was 96 h and you do not provide evidence that all validity criteria of the study were met;

Characterisation of exposure

f) no analytical monitoring of exposure was conducted. You refer to Kroon and Geurts (1997) "*in which the standard algal medium was modified by replacing the NH_4Cl as the sole source of nitrogen with $NaNO_3$ showed that Chloramine-T trihydrate concentrations remained stable after 72 hrs in the modified medium.*" You do not provide any further information to prove stability of the test material during the test;

g) in the above-mentioned publication, the test media prepared specifically for analysis of test material stability was not inoculated with algae;

h) you have expressed the effect values based on nominal concentrations without providing evidence that the test material was stable within ±20 % of the nominal or measured initial concentration during the study;

5 Based on the above,

- it cannot be confirmed whether the validity criteria of the OECD TG 201 are met (a) to (d))
- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, in the absence of analytical monitoring (f) it cannot be confirmed whether the test material was stable during the study. You have not provided evidence that the test material was stable during the study (g) and (h). Therefore, deriving effect concentration based on nominal concentrations could underestimate the hazard. In addition, the test duration exceeded 72 h, i.e. the test duration as specified by OECD TG 201 (e). According to paragraph 32 of OECD TG 201 the test duration can be shorter or longer provided that all validity criteria are met. As explained above, you have not provided sufficient information to allow conclusion on whether the validity criteria were met. You have not justified why extension of the test duration was necessary. This affects reliability of the study and might lead to biased hazard conclusion.

6 On this basis, the specifications of OECD TG 201 are not met.

7 Therefore, the information requirement is not fulfilled.

8 In your comments to the draft decision, you state that further information on the validity and performance criteria of study (i) are available and will be provided in a dossier update. Along with your comments to the draft decision you provide the following including tabulated data supporting your conclusions:

- *"The exponential growth in the control cultures over the entire duration of the test was followed. A growth rate of 0.06 h^{-1}, exponential increase by a factor of > 16 within 96 h (and 72h) is demonstrated"*

- *"biomass increased from start N0: 1x10^4 to N96: 3.2x10^6 at the end of the test"*
- *"the mean coefficient of variation for section-by-section specific growth in the control has been calculated and is below 35%"*
- *"the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is below 7%"*

9 You further provide a supporting study demonstrating that the test material is stable in the test medium, which you consider sufficient to justify the omission of the need for analytical monitoring of exposure concentrations during the study (i) itself.

10 In your comments to the draft decision, you address the study deficiencies identified above. However, as the information is currently not available in your registration dossier, the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set in the decision.

Reasons related to the information under Annex VIII of REACH

2. In vitro gene mutation study in mammalian cells

11 An *in vitro* gene mutation study in mammalian cells is an information requirement under Annex VIII, Section 8.4.3., in case of a negative results in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2.

2.1. Triggering of the information requirement

12 Your dossier contains negative results for both, Annex VII, Section 8.4.1. (Ames test) and Annex VIII, Section 8.4.2 (adaptation based on Annex VIII, Section 8.4., Column 2, first paragraph, first indent; negative *in vivo* cytogenicity study).

13 Therefore, the information requirement is triggered.

2.2. Information provided

14 You have provided:

(i) an *in vitro* gene mutation study in mammalian cells (1998) with the Substance.

2.3. Assessment of the information provided

15 To fulfil the information requirement, a study must comply with the OECD TG 476 or the OECD TG 490 (Guidance on IRs and CSA, Table.7.7-2) (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) the maximum concentration tested induces 80-90% of cytotoxicity compared to the negative control, or the precipitation of the tested substance. If no precipitate or limiting cytotoxicity is observed, the highest test concentration corresponds to 10 mM, 2 mg/mL or 2 µL/mL, whichever is the lowest;

b) data on the cytotoxicity and the mutation frequency for the treated and control cultures are reported.

16 In study (i):

a) the maximum tested concentration did not induce 80-90% of cytotoxicity compared to the negative control, or the precipitation of the tested substance, and it was less than 10 mM, 2 mg/mL or 2 µL/mL;

b) data on the cytotoxicity and the mutation frequency for the treated and control cultures were not reported.

17 The information provided does not cover the specification(s) required by the OECD TG 476.

18 In your comments to the draft decision, you state that study (i) is covering all the specification(s) required by OECD 476. You provide data on the cytotoxicity and the mutation frequency for the treated cultures and claim that the maximum concentration tested induces 80-90% of cytotoxicity.

19 However, the information in your comments is not sufficient for ECHA to make an assessment. In the experiments 1. and 2. with metabolic activation, concentrations up to 18.8 µg/ml and 25 µg/ml were used, respectively. Data provided do not indicate any cytotoxicity at the concentrations tested. In the dose range finding study with metabolic activation at the concentration of 100 µg/ml, the cells survival rate was still 39 % with cloning efficiency of 94 %. The results of the dose range finding study justify that higher

concentrations can be tested. Therefore, you have not demonstrated that the highest possible concentrations was tested in study (i).

20 You also claim that 2.9- fold increase in the mutant frequency without metabolic activation was within the historical control data range. However, data on the mutation frequency of the historical control cultures were not reported. You have not demonstrated that mutant frequencies are within the historical control data.

21 Therefore the information provided in your comments does not change the assessment and the data gap remains.

22 Therefore, the information requirement is not fulfilled.

2.4. Study design

23 To fulfil the information requirement for the Substance, either the *in vitro* mammalian cell gene mutation tests using the hprt and xprt genes (OECD TG 476) or the thymidine kinase gene (OECD TG 490) are considered suitable.

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 27 March 2023.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 6 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 took into account your comments and did not amend the request(s) or the deadline.

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]

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

(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 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.

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).