EUROPEAN CHEMICALS AGENCY

Helsinki, 10 February 2020

Addressees
Registrants of [redacted] listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
03/05/2019

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: cadmium telluride
EC number: 215-149-9
CAS number: 1306-25-8

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

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***17 February 2022***.

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

1. Composition (Annex VI, Section 2.3.) of the Substance: Nature of impurities

B. Requirements applicable to all the Registrants subject to Annex VII of REACH

1. Robust Study Summary for the existing OECD 29 studies or a new study on Water solubility (Annex VII, Section 7.7.; test method: OECD series on Testing and Assessment Number 29 - Guidance Document on Transformation/Dissolution of Metals and Metal Compounds in Aqueous media) with the Substance;

2. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method EU C.2./OECD TG 202) with the Substance as explained under General Considerations;

3. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method EU C.3./OECD TG 201) with the Substance as explained under General Considerations.

C. Requirements applicable to all the Registrants subject to Annex VIII of REACH

1. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method OECD TG 203) with the Substance as explained under General Considerations.

D. Requirements applicable to all the Registrants subject to Annex IX of REACH

1. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method OECD TG 414) in a first species (rat or rabbit), oral route with the Substance;

2. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method EU C.20./OECD TG 211) with the Substance as explained under General Considerations;

3. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method OECD TG 210) with the Substance as explained under General Considerations.

Conditions to comply with the requested information

You are bound by the requests for information corresponding to the REACH Annexes applicable to your own registered tonnage of the Substance at the time of evaluation.
To identify your legal obligations, please refer to the following:

- you have to comply with the requirements of Annexes VII, VIII and IX of REACH, if you have registered a substance at 100-1000 tpa;

The Appendix on general considerations addresses issues relevant for several requests while the other Appendices state the reasons for the requests for information to fulfil the requirements set out in the respective Annexes of REACH.

The Appendix entitled Observations and technical guidance addresses the generic approach for the selection and reporting of the test material used to perform the required studies and provides generic recommendations and references to ECHA guidance and other reference documents.

You must submit the information requested in this decision by the deadline indicated above in an updated registration dossier and also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information. The timeline has been set to allow for sequential testing where relevant

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Approved[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.

Appendix on general considerations

Test material for aquatic toxicity testing.

Testing for sparingly soluble inorganic compounds, such as the Substance (Sections B.1 and B.2), must be carried out with a representative test material, i.e. with a water soluble salt that readily releases the same species as obtained from a transformation/dissolution study on the Substance (CLP Guidance, Annex IV).

Advice on testing metals provided in the OECD TG and the OECD GD 23 should be followed. Aquatic studies should be performed at a pH that maximizes the concentration of dissolved ions in solution, within the pH range given in the specific OECD TGs.

You must perform analytical monitoring of the dissolved species in the test media. This allows a reliable comparison of the dissolved species found in the transformation/dissolution study (ECHA Guidance R.7b (v4.0, June 2017), Section 1 in Appendix A and Section 1 in Appendix B of this decision).

In order for the tests on the soluble salts to be relevant for the Substance in hazard assessment, including classification and labelling, and for risk assessment, you must include a scientifically valid justification on how the data generated relates to the whole Substance, including the impurities as far as possible, following the instructions given in RAAF and attach it under Section 13 in IUCLID (link to RAAF: https://echa.europa.eu/documents/10162/13628/raaf_en.pdf).

For classification purposes, you must use an appropriate approach: see the approach described in CLP Guidance and the requirement at Annex I, sections 3.2. For hazard and risk assessment, you must follow an appropriate approach: see the approach given for PNEC derivation and risk characterisation in ECHA Guidance R.10 and the requirement at Annex I, section 3.3 of the REACH Regulation. Any substance specific considerations you may use in your hazard and risk assessment must be fully justified, and it must cover the whole Substance as registered.

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

Under Article 10(a)(ii) of REACH, the technical dossier must containn as a minimum, the information specified under Annex VI of REACH.

1. Composition of the substance (Annex VI, Section 2.3.)

Composition of the Substance is a standard information requirement under Annex VI, Section 2 of REACH.

Annex VI, section 2.3. of REACH requires that information given on composition of each substance is sufficient to enable each substance to be identified. Section 4.2.1 of the 'Guidance for identification and naming of substances under REACH and CLP (Version: 1.4, June 2016)' defines a mono-constituent substance as a substance, defined by its quantitative composition, in which one main constituent is present to at least 80% (w/w). It further stipulates for the mono-constituent substances that the impurities present in a concentration > 1% should be specified by at least one of the following identifiers: chemical name (IUPAC and/or CAS name), CAS-number and EC-number and/or molecular formula. Impurities that are relevant for the classification and/or PBT assessment shall always be specified by the same identifiers, independently from their concentration. As a general rule, the compositional information should be completed up to 100%.

You have reported the degree of purity and the concentration range of the main constituent of the Substance to be [redacted] (w/w). You have not reported any impurities.

The minimum degree of purity and the minimum concentration of the main constituent of the Substance indicates that the Substance may contain up to [redacted] (w/w) of impurities. However, you have not reported these impurities.

You are requested to report in addition to the main constituent of the Substance each impurity present at concentration ≥ 1 %(w/w) or relevant for the classification and/or PBT assessment independent of the concentration.

You shall ensure that the composition is verifiable and therefore supported by a description of the analytical methods for the identification and quantification of the constituents required to be reported, as required under Annex VI.2.3.7. of the REACH Regulation. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

Regarding how to report the requested information in IUCLID, the following applies; Impurities of your substance shall be reported in section 1.2. Further technical details on how to report the compostion of a substance in IUCLID are available in the section 9.4.2 of ECHA manual "How to prepare registration and PPORD dossiers" (https://echa.europa.eu/manuals)

Appendix B: Reasons for the requests to comply with Annex VII of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 1 to 10 tonnes or more per year must contain, as a minimum, the information specified in Annex VII to REACH.

1. Water solubility (Annex VII, Section 7.7.);

Water solubility is a standard information requirement in Annex VII to REACH.

In the registration dossier you have provided study summaries for the following studies on the registered substance:

- Transformation/Dissolution test (OECD Series on Testing and Assessment No. 29) at a loading rate of 1mg/l of cadmium telluride for 7 days.
- Transformation/Dissolution test (OECD Series on Testing and Assessment No. 29) at a loading rate of 10mg/l of cadmium telluride for 7 days.
- Transformation/Dissolution test (OECD Series on Testing and Assessment No. 29) at a loading rate of 1mg/l of cadmium telluride for 28 days.
- Water solubility test (OECD guideline 105), as your key study.

We have assessed this information and identified the following deficiencies:

a. The Substance is a metal or an inorganic metal compound, and therefore, Water solubility is most appropriately tested according to the test method described in OECD series on Testing and Assessment Number 29 - Guidance Document on Transformation/Dissolution of Metals and Metal Compounds in Aqueous media. Therefore ECHA regards the Transformation/Dissolution tests as the key studies and the water solubility test (OECD guideline 105) as supporting evidence.
b. A robust study summary (RRS) must be provided for the study/ies giving rise to the highest concern (Articles 3(28) and 10(a)(vii) of REACH).

   A RSS must cover critical information and allow for an assessment of the validity and reliability of the study, including the following aspects of the Transformation/Dissolution tests (among others):

   - Powders should be tested at the smallest representative particle size as placed on the market. In addition, according to the OECD Guidance, measured specific surface area (m^2/g) should be reported on the sample tested because surface area has an important influence on the rate and extent of transformation/dissolution.
   - As pH has a significant influence on transformation/dissolution the tests should in principle be carried out at a pH that maximises the concentration of the dissolved metal ions in solution.
   - The concentration of dissolved substance should be analysed.

The registration dossier does not provide the above information. For example, the justification for testing at pH6 was not reported in the registration. The Substance contains both cadmium and tellurium. In the 7-day test at a loading rate of 10 mg/l, only the dissolved cadmium was reported, not dissolved tellurium.

Therefore the information provided is not compliant.

In order to allow an independent assessment of the study submitted, pursuant to Article 41(1) and (3) of the REACH Regulation you are requested to provide complete robust study summary (RRS) with the above missing elements for the study.

Alternatively, if you cannot submit a complete RSS or the RSS indicates that the study is not reliable as per the criteria indicated above and/or not adequate to fulfil the information requirement, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: OECD series on Testing and Assessment Number 29 Guidance Document on Transformation/Dissolution of Metals and Metal Compounds in Aqueous media).

2. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.);

Short-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex VII to REACH.

You have provided 5 study records based on OECD 202:

i. DAC 12 003 (2012),
ii. DAC 12 003 herhaling (2012),
iii. DAC 12 003 herhaling 2 (2012),
iv. DAC 12 003 herhaling 5 (2012), and
v. DAC 12 003 herhaling 3 (2012).

We have assessed this information and identified the following deficiencies:

A. For sparingly soluble metal compounds, testing must follow the approach explained under the Appendix on general considerations.

The studies that lead to hazard assessment, including classification and labelling, and risk assessment need to cover the whole Substance. That is, in this case each element obtained from the Transformation/Dissolution study.

In the dossier you have submitted studies performed with the Substance and for PNEC derivation you have used data on soluble Cd compounds, no information on Te has been provided.

While further information from the existing transformation dissolution study or a new study is requested (request 1, Appendix B), it is already clear that in aqueous media the Substance releases ions of Cd and Te in low concentrations. Your Substance is hence a sparingly soluble metal compound.

The studies used for hazard assessment, including classification and labelling, have not been conducted with the standard approach given in the Appendix on general considerations, and therefore are not acceptable.

Available data on soluble Cd compounds have already been used for risk assessment, and should be used for hazard assessment. Information on Te must be provided.

B. Additionally, the following deficiencies are found:

- you have not provided particle size to allow the comparison with Transformation/Dissolution studies (OECD GD 23 –since your Substance is sparingly soluble inorganic compound, it is difficult to test and OECD GD 23 applies-, OECD GD 29, CLP Guidance).
- you have not provided the effect concentrations based on the measured values, although the test concentrations are not maintained within the required 20% (OECD TG 202), and
- the analytical techniques used do not appear sufficiently sensitive as typical detection limits for Cd are much lower (OECD GD 23). For example, 0.1 µg/L in

water is indicated in a WHO report (https://www.who.int/water_sanitation_health/publications/cadmium/en/ or https://www.ncbi.nlm.nih.gov/books/NBK158833/).
- you have not provided any information on the concentrations of Te in the test solutions.

Therefore the information provided does not fulfil the information requirement.

As discussed above you need to provide the requested aquatic toxicity data generated with a test material representative of the Substance, i.e., with the dissolved ion(s) taken into account the relevant speciation.

3. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.);

Growth inhibition study aquatic plants is a standard information requirement in Annex VII to REACH.

You have provided 1 study record based on OECD 201: Vito (2012d).

The information provided does not fulfil the information requirement for the same reasons discussed under Section 2 above.

As disscused above (i.e. Appendix on general considerations and Appendix B) you need to provide the requested aquatic toxicity data generated with a test material representative of the Substance, i.e., with the dissolved ion(s) taken into account the relevant speciation.

Appendix C: Reasons for the requests to comply with Annex VIII of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 10 to 100 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII and VIII to REACH.

1. **Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.);**

Short-term toxicity testing on fish is a standard information requirement in Annex VIII to REACH.

You have provided one study record perfomed based on OECD TG 203: Lab Research (2010).

The information provided does not fulfil the information requirement for the same reasons discussed under Section 2 Appendix B, with the exception of the measurement deficiency. In the case of this study, no analytical measurement was provided at all.

Therefore the information provided does not fulfil the information requirement.

As disscused above you need to provide the requested aquatic toxicity data generated with a test material representative of the Substance, i.e., with the dissolved ion(s) taken into account the relevant speciation.

Appendix D: Reasons for the requests to comply with Annex IX of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 100 to 1000 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII to IX to REACH.

1. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species;**

A Pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is a standard information requirement in Annex IX to REACH.

You have provided a one-generation reproductive toxicity study.

In order to be considered compliant and enable assessing if the Substance is a developmental toxicant, information provided has to meet the requirements of OECD TG 414 on one species.

You have not provided information following OECD TG 414. Instead, you have provided a one-generation reproductive toxicity study (non-guideline, not GLP) in rat and conducted with the registered substance via oral route ([redacted] 1994). In this study, structural malformations and variations are not investigated as required in the PNDT study (OECD TG 414).

Therefore, this study does not fulfil the information requirement

A PNDT study according to the test method OECD TG 414 should be performed in rat or rabbit as preferred species with oral[2] administration of the Substance.

2. **Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.);**

Long-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex IX to REACH.

You have provided one study record performed following OECD TG 211: Vito (2012).

The information provided does not fulfil the information requirement for the same reasons discussed under Section 2 Appendix B above.

As disscused above (i.e. Appendix on general considerations and Appendix B) you need to provide the requested aquatic toxicity data generated with a test material representative of the Substance, i.e., with the dissolved ion(s) taken into account the relevant speciation.

According to ECHA Guidance on information requirements and chemical safety assessment (version 3.0, February 2016), Chapter R7b (Section R.7.8.5., including Figure R.7.8-4), if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. In such case, according to the integrated testing strategy, the Daphnia study is to be conducted first. If based on the results of the long-term Daphnia study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, the long-term fish study needs to be conducted.

[2] ECHA Guidance R.7a, Section R.7.6.2.3.2.

3. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.);

Long-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex IX to the REACH Regulation.

You have provided an adaptation based on short-term results which would indicate that fish are less sensitive than the other taxonomic groups.

In order to adapt the information requirement for long-term toxicity to fish based on Annex IX, Section 9.1, Column 2, the Chemical Safety Assessment (CSA) needs to demonstrate that risks towards the aquatic compartment arising from the use of the Substance are controlled (as per Annex I, section 0.1). The Chemical Safety Assessment (CSA) needs to assess and document that risks arising from the Substance are controlled and demonstrate that there is no need to conduct further testing (Annex I, Section 0.1; Annex IX, Section 9.1, Column 2).

In particular, you need to take into account of the following elements in your justification:
- all relevant hazard information from your registration dossier,
- the outcome of the exposure assessment in relation to the uses of the Substance,
- the outcome of the PBT/vPvB assessment including information on relevant degradation products and constituents present in concentration at or above 0.1% (w/w).

You did not submit in your dossier any specific justification as to why the risks of the substance are controlled. However, to reach the conclusion that the risks are controlled, we understand that you rely on the results on short term data and the long-term data on aquatic invertebrates.

As specified in requests 2 & 3 in Appendix B, 1 in Appendix C and 2 in this Appendix, the data on short term algae, Daphnia and fish, as well as long-term Daphnia is not compliant. Hence your dossier currently does not include adequate information to characterize the hazard property of the Substance.

Besides, in your adaptation justification, you only describe the toxicity of Cd ion while no information on Te toxicity is provided. No adequate and reliable information on Te toxicity profile is provided in the dossier. Since the substance is CdTe, this should have been considered.

Therefore your Chemical Safety Assessment does not demonstrate that the risks of the Substance are adequately controlled.

The information provided does not fulfil the information requirement.

As disscused above (i.e. Appendix on general considerations and Appendix B, Section 2) you need to provide the requested aquatic toxicity data generated with a test material representative of the Substance, i.e., with the dissolved ion(s) taken into account the relevant speciation.

According to ECHA Guidance on information requirements and chemical safety assessment (version 3.0, February 2016), Chapter R7b (Section R.7.8.5., including Figure R.7.8-4), if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. In such case, according to the integrated testing strategy, the Daphnia study is to be conducted first. If based on the results of the long-term Daphnia study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, the long-term fish study needs to be conducted.

Appendix E: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of the REACH Regulation.

The compliance check was initiated on 24 July 2018.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

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

ECHA did not receive any comments within the 30-day 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 F: Observations and technical guidance

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

2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of the Member States.

3. Test guidelines, GLP requirements and reporting

Under Article 13(3) of REACH, all new data generated as a result of this decision needs to be conducted according to the test methods laid down in a European Commission Regulation or according to international test methods recognised by the Commission or ECHA as being appropriate.

Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses shall be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

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: 'How to report robust study summaries'[3].

4. Test material

Selection of the test material(s)

The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

While selecting the test material you must take into account the impact of each constituent/impurity is known to have or could have 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.

Technical reporting of the test material

The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents and impurities (impurities must be reported to the same extent as required for the impurities of the Substance itself under Section 1 of Appendix A) of the test material and their concentration values and other parameters relevant for the property to be tested, in this case, e.g., particle size and measured specific surface area. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers" on the ECHA website (https://echa.europa.eu/manuals).

[3] https://echa.europa.eu/practical-guides

5. List of references of the ECHA Guidance and other guidance/ reference documents[4]

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 in this decision.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 in this decision.

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Guidance on Information requirements and chemical safety assessment, Chapter R.10 (May 2008), referred to as ECHA Guidance R.10 in this decision.

OECD Guidance documents[5]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD23.
Guidance Document on Mammalian Reproductive Toxicity Testing and Assessment – No 43, referred to as OECD GD43.

CLP Guidance:
Guidance on the Application of the CLP Criteria (v5.0, July 2017)) referred to as CLP Guidance in this decision

[4] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[5] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix G: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fufilled
[redacted]	[redacted]	[redacted]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.