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Helsinki, 17 November 2020

Addressees
Registrants of JS_DMPSA-K2_950-225-1 listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of a decision
23 October 2019

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Reaction mass of dipotassium 2-(3,4-dimethyl-1H-pyrazol-1-yl) succinate and dipotassium 2-(4,5-dimethy-1H-pyrazol-1-yl) succinate
EC number: 950-225-1
CAS number: NS

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

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by ***22 January 2022***.

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

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method OECD TG 408) in rats with the analogue substance Reaction mass of 2-(3,4-dimethyl-1H-pyrazol-1-yl)succinic acid and 2-(4,5-dimethyl-1H-pyrazol-1-yl)succinic acid (EC 940-877-5, CAS 2241455-89-8);

2. 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 analogue substance Reaction mass of 2-(3,4-dimethyl-1H-pyrazol-1-yl)succinic acid and 2-(4,5-dimethyl-1H-pyrazol-1-yl)succinic acid (EC 940-877-5, CAS 2241455-89-8)

Conditions to comply with the requests

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

Registrants are only required to share the costs of information they are required to submit to fulfil the information requirements for their registration.

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 studies listed in A.1. and A.2. have already been requested in another decision (TPE-D-2114495542-42-01/F) and the deadline has been aligned.

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 Reasons common to several requests

1. Assessment of your read-across approach under Annex XI, Section 1.5.

You propose to provide information on the standard information requirements of the Substance on

- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2), and
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2).

by testing the analogue substance Reaction mass of 2-(3,4-dimethyl-1H-pyrazol-1-yl)succinic acid and 2-(4,5-dimethyl-1H-pyrazol-1-yl)succinic acid (EC 940-877-5, CAS 2241455-89-8) (source substance) and using the results obtained in a grouping and read-across approach under Annex XI, Section 1.5.

Annex XI, Section 1.5 specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category (addressed under 'Scope of the grouping'). Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance[2] and related documents[3,4].

You have provided the following reasoning to justify testing on the source substance: "*The target and source substance are structurally very similar, i.e. both share the same anion species- succinate moiety connected to one of the nitrogen atoms of the pyrazole ring with two methyl groups attached. The difference between the target and the source substance is that the target is the dipotassium salt of the source substance. Both substances are well soluble, therefore once dissolved into water, the common anion species will be released from dissociation [pKa (source substance): 4.0 at 20 °C]. The non-common cation species, K+ or H+ are present in the target and source substances, respectively. Potassium ions are not considered to cause adverse effects in the human body and/or environmental species or to influence the suitability of the read-across, since potassium is an essential element abundantly present in nature*".

ECHA considers that in your read-across justification document you have established that the Substance and the source substance have a similar composition and differ only in the cation in the structure of the constituents. As indicated in your dossier, the toxicological properties of these substances are associated with common anions formed from the related constituents in the substances after administration of the substances. The structural differences between these constituents is not expected to affect the toxicological properties of the substances.

Therefore information obtained from the tests to be performed with the source substance (EC 940-877-5), as described in your read-across justification document, is considered appropriate to predict the properties under consideration of the Substance.

[2] ECHA Guidance R.6
[3] RAAF, March 2017
[4] RAAF UVCB, March 2017

Appendix A: Reasons for the requirements applicable to all the Registrants subject to Annex IX of REACH

This decision is based on the examination of the testing proposals you submitted.

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

A sub-chronic toxicity study (90 day) is a standard information requirement in Annex IX, Section 8.6.2. to REACH.

You have submitted a testing proposal for a sub-chronic toxicity study (90 day) in rats by the oral route according to OECD TG 408 with the analogue substance Reaction mass of 2-(3,4-dimethyl-1H-pyrazol-1-yl)succinic acid and 2-(4,5-dimethyl-1H-pyrazol-1-yl)succinic acid (EC 940-877-5, CAS 2241455-89-8).

ECHA notes that you provided your considerations and you applied read-across to fulfil the respective information requirement, and no other alternative methods were available. ECHA has taken these considerations into account.

ECHA accepts testing with the proposed analogue substance, for the reasons explained in the Appendix on reasons common to several requests.

According to OECD TG 408, the rat is the preferred species and the most appropriate route of administration is the oral route[5].

Under Article 40(3)(a) of REACH, you are requested to carry out the proposed test.

2. 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 under Annex IX, Section 8.7.2. to REACH.

You have submitted a testing proposal for a PNDT study according to OECD TG 414 with the analogue substance Reaction mass of 2-(3,4-dimethyl-1H-pyrazol-1-yl)succinic acid and 2-(4,5-dimethyl-1H-pyrazol-1-yl)succinic acid (EC 940-877-5, CAS 2241455-89-8), in the rat, by the oral route.

You provided your considerations and you applied read-across to fulfil the respective information requirement, and no other alternative methods were available. ECHA has taken these considerations into account.

ECHA accepts testing with the proposed analogue substance, for the reasons explained in the Appendix on reasons common to several requests.

The rat and the rabbit are the preferred species under the OECD TG 414[6]. The oral route is the most appropriate route of administration to investigate reproductive toxicity[7].

Under Article 40(3)(a) of REACH, you are requested to carry out the proposed test.

[5] ECHA Guidance R.7a, Section R.7.5.4.3
[6] ECHA Guidance R.7a, Section R.7.6.2.3.2.
[7] ECHA Guidance R.7a, Section R.7.6.2.3.2.

Appendix B: Procedural history

ECHA received your registration containing the testing proposals for examination on 7 November 2019.

ECHA held a third party consultation for the testing proposals from 17 December 2019 until 31 January 2020. ECHA did not receive information from third parties.

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 REACH.

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

ECHA did not receive any comments within the 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 C: Observations and technical guidance

1. This testing proposal examination decision does not prevent ECHA from initiating 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 your Member State(s).

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 must 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'[8].

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 of the test material and their concentration values. 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"[9].

[8] https://echa.europa.eu/practical-guides
[9] https://echa.europa.eu/manuals

5. List of references of the ECHA Guidance and other guidance/ reference documents[10]

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.

ECHA Read-across assessment framework (RAAF, March 2017)[11]

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.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

OECD Guidance documents
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

[10] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[11] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

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Appendix D: 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 fulfilled
[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.