EUROPEAN CHEMICALS AGENCY

Helsinki, 26 June 2020

Addressees
Registrant(s) of JS_65212-77-3_Azo as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
05/09/2019

Registered substance subject to this decision ("the Substance")
Substance name: Calcium 4,5-dichloro-2-[[4,5-dihydro-3-methyl-5-oxo-1-(3-sulphonatophenyl)-1H-pyrazol-4-yl]azo]benzenesulphonate
EC number: 265-634-4
CAS number: 65212-77-3

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

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadlines of ***5 July 2021*** for the information requested in point A.1 below, and ***3 January 2022*** for the information requested in point A.2 below.

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

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

1. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: OECD TG 413) by inhalation route, in rats. The study must include measurements of lung burden and bronchoalveolar lavage fluid (BALF) analysis as described in the current version (25 June 2018) of the OECD TG 413.

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) by oral route, in one species (rat or rabbit).

Reasons for the request(s) are explained in the appendix entitled "Reasons to request information required under Annex IX of REACH", respectively.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa.

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 testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

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.

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 A: Reasons to request information required under Annex IX of REACH

1. Sub-chronic toxicity study (90-day)

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

You have provided one study in your dossier:
Subacute 28-day oral study (OECD 407, 2001) with an analogue substance.

In addition you have provided an adaptation according to Column 2 of Annex IX, Section 8.6.2., fourth indent.

We have assessed this information and identified the following issues:

No study provided that meets the standard information requirement

To be considered compliant and enable concluding whether the Substance has dangerous properties and supports the determination of the No-Observed Adverse Effect Level (NOAEL), a study has to meet the requirements of OECD TG 408. The key parameters of this test guideline include, among others, at least 10 female and 10 male animals should be used at each dose level (including control group) and dosing of the Substance daily for a period of 90 days until the scheduled termination of the study.

The study you have provided was conducted with less than 10 animals per sex per test dose group. The statistical power of the information provided is not sufficient because it does not fulfil the criterion of 20 animals (10 males + 10 females) for each test group set in OECD TG 408. Furthermore, it does not have the required exposure duration of 90 days as required in OECD TG 408, because you indicated an exposure duration of 28 days.

Column 2 adaptation rejected

In your justification for your adaptation you explain that "*Administration of a structural analogue (disodium salt) for 28d did not induce any mortalities, signs of toxicity or abnormalities. There was also no evidence for absorption or systemic distribution*".

As provided in Annex IX, Section 8.6.2, Column 2, you may adapt the information requirement, provided you fulfil one of the identified criteria, including:

i. the Substance is not inhalable and
ii. no evidence of absorption,
iii. particularly if such a pattern is coupled with limited human exposure.

You have not demonstrated that all criteria are met:

(i) The data provided in your dossier indicate that the Substance is inhalable (as discussed further below) and uses are reported that include spray application.
(ii) You did not demonstrate that there is no evidence of absorption. More specifically, the results of the OECD TG 407 study cannot be considered as no evidence of absorption because the study did not investigate toxicokinetic properties such as absorption.
(iii) Human exposure cannot be considered as limited because widespread uses, including professional and consumer uses are reported.

Therefore, your adaptation is rejected.

Based on the above, the information you provided does not fulfil the information requirement.

Following the criteria provided in Annex IX, Section 8.6.2, Column 2, the inhalation route is the most appropriate route of administration to investigate repeated dose toxicity[2]. The information provided in the technical dossier and the chemical safety report on properties of the Substance and its uses (industrial, professional and consumer uses, including PROCs 7 and 11 industrial and non-industrial spraying) indicate that human exposure to the Substance by the inhalation route is likely. More specifically, the Substance is reported to occur as a dust with a significant proportion of particles of inhalable size (D10 = 46 µm).

Therefore the sub-chronic toxicity study must be performed according to the OECD TG 413, in rats and with inhalation administration of the Substance.

2. Pre-natal developmental toxicity study 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 one study in your dossier:
Screening study (OECD 421, 2011) with an analogue substance.

In addition you provided an adaptation according to Annex IX, Section 8.7., Column 2, third indent based on lack of toxicity, and no evidence of absorption or systemic distribution.

We have assessed this information and identified the following issues:

No study meeting the requirements of OECD TG 414

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 in one species.

You have not provided information following OECD TG 414. Instead, you have provided a "reproduction/ developmental toxicity screening test" (OECD TG 421). 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.

Column 2 adaptation rejected

In your justification for your adaptation you explain that "*Administration of the test item (analogue) for 28d did not induce any mortalities, signs of toxicity or abnormalities. There was also no evidence for absorption or systemic distribution. Furthermore, application of the test substance (analogue) to male and female rats in the course of a combined screening study for toxicity to reproduction and development (OECD 421) did not affect number of pubs, weight, sex ratio or viability. Malformations were also not observed*". On the basis of your justification we understand that you wish to adapt this information requirement according to Annex IX, Section 8.7., Column 2, third indent.

According to Annex IX, Section 8.7., Column 2, third indent, the study does not need to be conducted if the substance is of low toxicological activity. This needs to be demonstrated

[2] ECHA Guidance R.7a, Section R.7.5.4.3.

with three concomitant criteria, including:

i. that it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure; and
ii. that there is no or no significant human exposure.

You have not demonstrated that all criteria are met:

i. You have not provided any toxicokinetic data to prove that no systemic absorption occurs. The OECD TG 421 study study provided did not investigate toxicokinetic properties such as absorption.
ii. As discussed in section 1 of Appendix A above, the reported uses of the Substance indicate that there is possibility of significant human exposure.

Therefore, your adaptation is rejected.

Based on the above, the information you provided does not fulfil the information requirement.

A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral[3] administration of the Substance.

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

Appendix B: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. 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[4].

B. 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 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 and other parameters relevant for the property to be tested.

This information is needed to assess 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[5].

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

[5] https://echa.europa.eu/manuals

Appendix C: Procedure

The information requirement for an Extended one-generation reproductive toxicity study (EOGRTS; Annexes IX or X, Section 8.7.3.) is not addressed in this decision. This may be addressed in a separate decision once the information from the Sub-chronic toxicity study (90-day) requested in the present decision is provided; due to the fact that the results from the 90-day study is needed for the design of the EOGRTS.

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 9 July 2019.

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 took the decision according to Article 51(3) of the REACH Regulation.

Appendix D: List of references - ECHA Guidance[6] and other supporting documents

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 where relevant.

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 where relevant.

Read-across assessment framework (RAAF, March 2017)[7]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[7]

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.

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.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[8]

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[6] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

[7] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

[8] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

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

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

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

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

Appendix E: Addressees of this decision and the corresponding information requirements applicable to them

You must provide the information requested in this decision for all REACH Annexes applicable to you.

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.