~~Confidential~~

Helsinki, 18 August 2021

Addressees
Registrants of JS_2235-00-9 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
25/11/2019

Registered substance subject to this decision ("the Substance")
Substance name: 1-vinylhexahydro-2H-azepin-2-one
EC number: 218-787-6
CAS number: 2235-00-9

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 the deadline of ***23 November 2023***.

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

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

1. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) by oral route, in rats

B. Information required from 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) by oral route, in one species (rat or rabbit)

2. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)

3. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210)

Reasons for the request(s) are explained in the following appendices:

- Appendix entitled "Reasons common to several requests";
- Appendices entitled "Reasons to request information required under Annexes VIII to 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 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;

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". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations 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.

Authorised[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 seek to adapt the following standard information requirements by applying a read-across approach in accordance with Annex XI, Section 1.5:

- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

ECHA has considered the scientific and regulatory validity of your read-across approach(es) in general before assessing the specific standard information requirements in the following appendices.

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. 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 (addressed under 'Predictions for toxicological properties').

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6. and related documents[2,3].

A. Predictions for toxicological properties

You have provided a read-across justification document in IUCLID Section 13.2. for human health endpoints entitled "[redacted]".

You read-across between ε-Caprolactam (EC No. 203-313-2, CAS No. 105-60-2) as a source substance and the Substance as target substance.

You have provided the following reasoning for the prediction of toxicological properties:

- *"N-Vinylcaprolactam as well as ε-Caprolactam are structurally very similar, varying only in terms of a vinyl-group but both containing an intramolecular amide group."*
- Similarity in toxicological profile
    - *"In the acute oral toxicity studies both compounds indicated toxicity with LD50 values of 1114-1864 mg/kg bw."*
    - *"Both compounds were classified as irritating to the eyes"*
    - *"In the genetic toxicity test battery in vitro (Ames test, CA, HPRT), both compounds were negative."*
    - *"The NOAELs from the oral repeated dose studies are in a similar range."*

  "Therefore, the structural analogue approach between N-Vinylcaprolactam and ε-Caprolactam is justified."

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted to be quantitatively equal to those of the source

[2] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)

[3] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://doi.org/10.2823/794394

substance.

ECHA notes the following shortcomings with regards to predictions of toxicological properties:

a) *Read-across hypothesis*

According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled. 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. 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 (read-across approach).
A read-across hypothesis needs to be provided, establishing why a prediction for a toxicological or ecotoxicological property is reliable. This hypothesis should be based on recognition of the structural similarities and differences between the source substance(s) and your Substance (ECHA Guidance R.6). It should explain why the differences in the chemical structures should not influence the toxicological/ ecotoxicological properties or should do so in a regular pattern.

Your read-across hypothesis is that the similarity in chemical structure and in some of the physicochemical and toxicological properties between the source substance and your Substance is a sufficient basis for predicting the properties of your Substance for other endpoints.

However, similarity in chemical structure and similarity of some of the physicochemical and toxicological properties does not necessarily lead to predictable or similar human health properties in other endpoints. As described above, a well-founded hypothesis is needed to establish a reliable prediction for a toxicological property, based on recognition of the structural similarities and differences between the source substance and your Substance.

b) *Relevance of the supporting information*

According to the ECHA Guidance R.6.2.2.1.f "*it is important to provide supporting information to strengthen the rationale for the read-across approach. Thus, in addition to the property/endpoint being read-across, it is also useful to show that additional properties, relevant to the endpoint, are also (qualitatively or quantitatively) similar between the source and target chemicals*".

In order to support your claim that your Substance and source substance have similar properties for the endpoints under consideration in the read-across approach, you refer to their acute oral toxicity, eye irritation and *in vitro* genetic toxicity properties.

Whilst this data set suggests that the substances may have similar properties for acute toxicity, eye irritation (irritant) and *in vitro* genotoxicity (negative), these studies do not inform on the developmental and reproductive toxicity properties of the target and source substances. Accordingly, these information are not considered as relevant to support prediction of the endpoints under consideration.

c) *Read-across hypothesis contradicted by existing data*

Annex XI, Section 1.5. provides that "substances whose physicochemical, toxicological and eco-toxicological properties are likely to be similar or follow a regular pattern as

result of structural similarity may be considered as a group or 'category' of substances. The ECHA Guidance R.6.2.2.1.f indicates that "*it is important to provide supporting information to strengthen the rationale for the read-across*". The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance. The observation of differences in the toxicological properties between the source substance and the Substance would contradict the hypothesis that the properties of the Substance can be predicted from the data on the source substances. An explanation why such differences do not affect the read-across hypothesis needs to be provided and supported by scientific evidence.

As indicated above, your read-across hypothesis is based on the assumption that the structurally similar target and source substances cause the same type of effect(s).

The information on repeated dose toxicity obtained with the source and target substances indicates that the target substance may have higher potential for toxicity. Specifically, in a subchronic toxicity study via inhalation, LOAEC of 6 mg/m^3 was obtained with the target substance, whereas ten-fold higher NOAEC (66 mg/m^3) was obtained for the source substance. This is also supported by subchronic toxicity study via oral route, i.e. NOAEL 342 mg/kg bw (females) with the source substance and LOAEL 130 mg/kg bw with the target substance. Differences in the toxicological profile are seen also in lower tier endpoints. The target substance is a skin sensitizer whereas the source substance is not.

The available set of data on the target and source substances indicates differences in the toxicological properties of the substances. This contradicts your read-across hypothesis whereby the structurally similar target and source substances cause the same type of effect(s). Therefore you have not demonstrated and justified that the properties of the source substance and of the Substance are likely to be similar despite the observation of these differences.

d) Adequacy and reliability of the source studies

In addition, we have identified deficiencies with the source studies provided on the source substance. These deficiencies are addressed under the corresponding Appendix (Appendix B.1).

B. Conclusions on the read-across approach

As explained above, you have not established that relevant properties of the Substance can be predicted from data on the analogue substance. Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected.

2. Assessment of your substance-tailored exposure-driven testing adaptation under Annex XI, Section 3.

While an adaptation was not specifically indicated by you, ECHA has evaluated the information below under the rules set in Annex XI, Section 3. Substance-tailored exposure-driven testing for the following information requirements:

- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

In support of your adaptation, you provided the following statement: "*N-Vinylcaprolactam is used only in industrial settings. During manufacture and processing of N-Vinylcaprolactam, worker exposure is controlled by the use of closed systems, industrial hygiene controls, and personal protective equipment. For worker exposure, toxicity to respiratory tract and liver has been identified as the key toxicological concern for N-Vinylcaprolactam. Thus, the parameters with the highest sensitivity (cell proliferation of liver and respiratory tract) were investigated in a repeated dose inhalation toxicity study with rats ([redacted], 2013). The NOAECs were determined to be 0.2 ppm (1 mg/m3) and 10 ppm (58 mg/m3) for toxic effects on respiratory tract and liver, respectively. The lowest NOAEC (0.2 ppm) was considered for risk assessment. Therefore, it is unlikely that the NOAEC observed in further reproductive toxicity studies would be lower than the NOAEC from the repeated dose inhalation toxicity study. The observed NOAEL/NOAEC from a reproductive toxicity study would most probably not contribute to the overall risk assessment. From a scientifically point of view including animal welfare reasons, it is not justified to conduct a reproductive toxicity study.*"

We have assessed this information and identified the following issue:

a) *Exposure based adaptation*

Under Annex XI, Section 3, testing in accordance with Sections 8.6 and 8.7 of Annex VIII and in accordance with Annexes IX and X may be omitted based on the exposure scenario(s) developed in the Chemical Safety Report (CSR). The justification must be based on rigorous exposure assessment in accordance with Annex I, Section 5 and, for an adaptation under Annex XI, Section 3.2 (a) or (b), it must meet, among others, the following criteria:

- 3.2 (a) the manufacturer or importer demontrates and documents that all of the following conditions are fulfilled,
    i. the results of the exposure assessment covering all relevant exposures throughout the life cycle of the substance demonstrate the absence of or no significant exposure in all scenarios of the manufacture and all identified uses as referred to in Annex VI section 3.5.;
    ii. a suitable DNEL or a PNEC can be derived from results of available test data for the Substance taking full account of the increased uncertainty resulting from the omission of the information requirement, and that DNEL or PNEC is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes;
- 3.2 (b) where the substance is not incorporated in an article the manufacturer or the importer demonstrates and documents for all relevant scenarios that throughout the life cycle strictly controlled conditions as set out in Art 18(4)(a) to (f) apply.

However, you did not provide adequate and reliable documentation demonstrating the "*absence of or no significant exposure in all scenarios of the manufacture and all identified uses*" as required in the criterion 3.2(a)(i). Several PROCs (e.g. 4, 5, 10, 15, 20 and 28) indicate potential for exposure in your provided exposure scenarios. For example, for the combined routes, the systemic long-term RCRs can be as high as [redacted] for PROC 4 in exposure scenario 6 (industrial workers) or [redacted] for PROC 4 in exposure scenario 8 (professional workers).

The criterion 3.2(a)(ii) requires that "a DNEL can be derived from results of available data" and that "DNEL is relevant and appropriate". However, the worker long-term systemic DNEL for inhalation, which you dervided in your CSR, is based on a short-term repeated dose toxicity study with the Substance. ECHA notes that

such DNEL is not relevant nor appropriate for the information requirements to be omitted and for risk assessment purposes. A short-term repeated dose toxicity study does not investigate effects on mating, fertility, pregnancy, lactation and postnatal development as an screening study (OECD TG 421 or 422) or effects on prenatal development as a prenatal developmental toxicity study (OECD TG 414).

The criterion 3.2(b) requires a demonstration that "*throughout the life cycle strictly controlled conditions as set out in Article 18(4)(a) to (f)*" apply. As mentioned above, in several exposure scenarios for the combined routes, systemic long-term, the RCRs do not demonstrate strictly controlled conditions as per Annex XI, section 3.2(b) and therefore criterion 3.2(b) for exposure-based adaptation is not satisfied. In particular, condition (a) as set out in Article 18(4) does not appear to be fulfilled because it has not been demonstrated that the substance is rigorously contained by technical means during its whole lifecycle.

The adaptation you provided is not in line with the conditions specified in Annex XI, Section 3.2 (a) and (b).

Therefore your adaptation is rejected.

Appendix A: Reasons to request information required under Annex VIII of REACH

1. Screening for reproductive/developmental toxicity

A Screening for reproductive/developmental toxicity study (test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) is an information requirement under Annex VIII to REACH (Section 8.7.1.), if there is no evidence from analogue substances, QSAR or *in vitro* methods that the Substance may be a developmental toxicant. There is no information available in your dossier indicating that your Substance may be a developmental toxicant.

You have adapted this information requirement under Annex XI, Section 1.5. (Grouping of substances and read-across approach). In support of your adaptation you provided the following information on analogue substance:

i. A study similar to OECD TG 416 via oral route in rats with an analogue substance, ε-caprolactam, EC 203-313-2 ([redacted] 1981)

As explained in section 2 in the Appendix on reasons common to several requests, the statement you provided does not explicitly claim an adaptation. However, ECHA understands that the statement provided was submitted as a justification to omit the information requirement under Annex XI, Section 3 (Substance-tailored exposure-driven testing).

We have assessed this information and identified the following issues:

a) Read-across adaptation

As explained in the Appendix on Reasons common to several requests your read-across adaptation under Annex XI, Section 1.5. is rejected.

b) Exposure based adaptation

As explained in the Appendix on reasons common to several requests you exposure based adaptation under Annex XI, Section 3 is rejected.

On this basis, the information requirement is not fulfilled.

Study design

A study according to the test method EU B.63/OECD TG 421 or EU B.64/OECD TG 422 must be performed in rats with oral administration of the Substance (ECHA Guidance R.7.6.2.3.2).

In your comments on the draft decision, you agreed to perform the requested study.

Appendix B: Reasons to request information required under Annex IX of REACH

1. Pre-natal developmental toxicity study in one species

A Pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is an information requirement under Annex IX to REACH (Section 8.7.2.).

You have adapted this information requirement under Annex XI, Section 1.5 ('Grouping of substances and read-across approach'). In support of your adaptation, you provided the following information:

i. A study similar to OECD 414 via oral route in rats with an analogue substance, ε-caprolactam, EC 203-313-2 ([redacted] 1980)
ii. A study similar to OECD 414 via oral route in rabbits with an analogue substance, ε-caprolactam, EC 203-313-2 ([redacted] 1983)
iii. A study according to Guidelines for reproduction studies for safety evalutation of drugs for human use (FDA 1966) and Guidance on reproduction studies from the Association of the British Pharmaceutical Industry (1975) via oral route in rats with an analogue substance, ε-caprolactam, EC 203-313-2 ([redacted] 1978)

As explained in section 2 in the Appendix on reasons common to several requests, The statement you provided does not explicitly claim an adaptation. Nevetrheless, ECHA understands that the statement provided was submitted as a justification to omit the information requirement under Annex XI, Section 3 (Substance-tailored exposure-driven testing).

We have assessed this information and identified the following issues:

a) Read-across adaptation

As explained in the Appendix on Reasons common to several requests your read-across adaptation under Annex XI, Section 1.5. is rejected.

b) Adequacy and reliability of the source study

Under Annex XI, Section 1.5., the results to be read across must provide adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case OECD TG 414. Therefore, the following specifications must be met:

- testing of at least three dose levels and a concurrent control
- highest dose level should aim to induce some developmental and/or maternal toxicity
- dosing of the Substance from implantation until the day prior to scheduled caesarean section

In the study (i.), the animals were exposed on gestation days 6-15 and sacrificied on gestation day 20. The study (i.) does not have a required exposure duration because the exposure duration is not from implantation until the day prior to scheduled caesarean section as specified in OECD TG 414. The study (iii.) was conducted only with one dose level (0 and 166 mg/kg bw/d) and it did not induce any developmental and/or maternal toxicity. You have not shown that the aim was to induce toxicity. The study (iii.) does not fulfil the criterion of at three dose levels and the dose level selection was too low set, therefore it does not fulfil the criterion set in OECD TG 414.

Therefore, studies (i.) and (iii.) do not have adequate and reliable coverage of the key parameters of the OECD TG 414.

c) *Exposure based adaptation*

As explained in the Appendix on reasons common to several requests your exposure based adaptation under Annex XI, Section 3. is rejected.

On this basis, the information requirement is not fulfilled.

Study design

A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral administration of the Substance (ECHA Guidance R.7.6.2.3.2).

In your comments on the draft decision, you agreed to perform the requested study.

2. Long-term toxicity testing on aquatic invertebrates

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

You have provided a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2.

We have assessed this information and identified the following issue:

Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to aquatic invertebrates under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

In your comments on the draft decision you provided a QSAR estimate of long-term Daphnia toxicity and updated your dossier. The information you have provided in your comments addresses the incompliances identified in this decision for this information requirement. 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 out in the decision.

Your adaptation is therefore rejected.

3. Long-term toxicity testing on fish

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

You have provided a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2.

We have assessed this information and identified the following issue:

Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing

further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

In your comments on the draft decision, while you recognize the reasons for the rejection of the adaptation of the information requirement, you also specify that you intend to adapt this information requirement under Annex XI, Section 1.2. ('Weight of evidence'). You provide the following justification:

i. The structure as well as the physico-chemical properties of the Substance are clearly identified. The Substance is inherently biodegradable;
ii. The substance does not produce an alert for protein binding in the scheme OASIS but it is a base surface narcotic ([redacted], 2020). According to the protein binding scheme of OECD, an acylation mechanism has been suggested for chemicals of this type of substance ([redacted], 2020). The modified classification scheme of Verhaar is not suitable to classify the substance. Overall you conclude that long-term effects are not to be expected;
iii. You specify that no information on long-term toxicity to fish is available for the Substance and that no reliable QSAR predictions or *in vitro* results for long-term toxicity to fish are available;
iv. You argue that fish are not the most sensitive aquatic trophic level;
v. The Substance is neither acutely nor chronically hazardous to the aquatic environment according to the CLP-Regulation (EC) No 1272/2008.
vi. You use the acute-to-chronic ratio (ACR) approach to predict a NOEC of 3.2mg/l using an ACR of 100;
vii. You further consider that this information is not needed for the PBT assessment of the Substance as it is concluded not B/vB based on low logKow;
viii. You refer to Article 25 to REACH to specify that vertebrate animal testing should be undertaken as a last resort.

Relevant information that can be used to support weight of evidence adaptation for long-term toxicity to fish includes similar information that is produced by the OECD TG 210. The following aspects need to be covered: Parameters related to the survival and development of fish in early life stages from the stage of fertilized egg until the juvenile life-stage following exposure to the test substance are measured, including:

1) the stage of embryonic development at the start of the test, and
2) hatching of fertilized eggs and survival of embryos, larvae and juvenile fish, and
3) the appearance and behaviour of larvae and juvenile fish, and
4) the weight and length of fish at the end of the test.

As you did not submit such information, ECHA concludes that there is, in the justification provided in your comments, no weight of evidence adaptation to be assessed. Furthermore, the use of the acute-to chronic ratio concept on its own is not regarded as providing sufficient weight of evidence to conclude on chronic toxicity (ECHA Guidance R.7.8.5.).

On this basis, the information requirement is not fulfilled.

Appendix C: 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 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 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 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[5].

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

Appendix D: 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 08 May 2020.

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

ECHA took into account your comments and did not amend the requests but amended the deadline.

The timeline indicated in the draft decision to provide the information requested is 18 months from the date of adoption of the decision. In your comments to the draft decision, you requested an extension of the timeline to 30 months. You justified your request with following statement "*To perform both studies (OECD 422 and 414) in a step wise approach, [redacted] laboratory would schedule a time period of 30 months. This is especially true in the current situation due to the COVID 19 pandemic. To protect our staff, specific safety measures in our lab facility are needed which reduce the capacity. The capacity of the [redacted] laboratory is booked for at least 6 months in advance, which means that an initial planning phase of 6 months is needed as soon as the test order is definitive. This time schedule is based on the laboratories experience with other substances. We consider facing a comparable situation in external labs (CROs). We have seen lead-times of 3-6 months to get the work at CROs initiated for other studies in the past few months*.".

In addition, you provided documentary evidence from the contract research organisation to support your request to extend the deadline. ECHA notes that requested OECD 422 and 414 studies can be performed partially concurrently. On this basis and due to laboratory overload, we have updated the deadline to submit the requested information to 24 months.

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

[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 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 F: Addressees of this decision and their corresponding information requirements

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]
[redacted]	[redacted]	[redacted]
[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.