ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 06 February 2020

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

Date of submission for the jointly submitted dossier subject of this decision
23 August 2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Acrylic acid
EC number: 201-177-9
CAS number: 79-10-7

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 deadlines provided.

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

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

B. 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;

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

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

2. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: OECD TG 443) in rats, oral route, specified as follows:
   - Ten weeks premating exposure duration for the parental (P0) generation;
   - Dose level setting shall aim to induce systemic toxicity at the highest dose level;
   - Cohort 1A (Reproductive toxicity);
   - Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation with the Substance.

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 X of REACH, if you have registered a substance at above 1000 tpa.

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

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 points B.1 and C.1-2 above in an updated registration dossier by ***13 August 2020***, and the information requested in point A.1 above by ***13 November 2020***.

You must 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.

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Appendix on general considerations

(i) Assessment of adaptations under Annex XI

Exposure-based adaptation

You seek to adapt the following standard information requirements:

- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)
- Pre-natal developmental toxicity study in a second species (Annex X, Section 8.7.2.)

For both endpoints, you have provided an adaption in Section 5.9.2.1 of your Chemical Safety Report (CSR), and you conclude that *"the study does not need to be conducted because human exposure can be excluded as demonstrated in the relevant exposure assessment"*.

We have evaluated the above information under the rules set in Annex XI, Section 3. Substance-tailored exposure-driven testing. As stated in Annex XI, Section 3, you may adapt the information requirement, if the information provided in your dossier fulfils all the identified criteria in paragraphs 3.2(a)(i) to (iii). You also must provide an adequate and scientifically supported justification, based on a thorough and rigorous exposure assessment, in accordance with Section 5 of Annex I, in particular:

(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.; and
(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; and
(iii) the comparison of the derived DNEL or PNEC with the results of the exposure assessment shows that exposures are always well below the derived DNEL or PNEC."

We have assessed the provided information and identified the following issue(s).

You have considered two uses for the Substance: a) use as a monomer in polymer production and b) use as an intermediate. You have described the operational conditions and risk management measures in the related exposure scenarios. For the exposure estimates you have concluded that worker exposure should be minimised through engineering/process controls, work practises and personal protection equipment. You also state that skin contact is not to be expected since the substance is corrosive to skin and the measured air concentrations are maintained below the DMEL of [redacted] mg/m^3. However, you have not included any documented exposure estimates of the Substance for supporting your statement e.g. measured data in your CSR.

You have not described the derivation of the provided DMEL (which should be DNEL). The only information is that it is based on irritation in the respiratory tract. No results from test data on developmental toxicity are available to allow the derivation of a DNEL for this specific hazard and for risk assessment purposes. Therefore, the criterion on the possibility to derive a DNEL from available test data, which must be appropriate both to the information requirement to be omitted and for risk assessment purposes, is not fulfilled.

In particular, the CSR does not contain any chemical risk assessment covering the entire life-cycle of monomer substance subject to this decision because the presence of unreacted monomer in the polymer has not been considered. In addition, the unreacted monomer might

be released from the polymer or the polymer might be decomposed to the monomer during its lifetime and result in exposure to man. In this respect, you are also referred to the ECHA Guidance for monomers and polymers (April 2012, Version 2.0), in particular Sections 2.2, 3.2.1 and 4.2, and the judgement of the European Court of Justice in EU Case C 558/07 of 7 July 2009, paragraph 51.

Therefore, reliable documentation and justification for the premise that there is no exposure to the Substance is currently missing. In particular, the following requirements of Annex XI, Section 3 of the REACH Regulation are not fulfilled:

a) no rigorous exposure assessment in accordance with Annex I, Section 5 of the REACH Regulation has been developed (cf. Annex XI, Section 3.2, 2nd sentence of the REACH Regulation); and
b) you have not provided relevant life-cycle information and exposure scenarios relating to the unreacted monomer (cf. Annex XI, Section 3.2.(a)(i) of the REACH Regulation); and
c) you have not derived the provided DNEL from an appropriate toxicological study (cf. Annex XI, Section 3.2.(a)(ii) of the REACH Regulation).

Therefore, the adaptations of the information requirements under Annex IX and X, 8.7.2 (pre-natal developmental toxicity; first and second species) of the REACH Regulation provided by you cannot be accepted because several requirements of Annex XI, Section 3 of the REACH Regulation are not fulfilled, as explained above.

Appendix A: 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. 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 a study ("other information") according to ISO 8692 (Water Quality - Fresh Water Algal Growth Inhibition Test with *Scenedesmus subspicatus* and *Selenastrum capricornutum*) (Radix P et al., 2000), conducted with the Substance.

We have identified the following deficiency with the study report.

A robust study summary must be provided for all key data used in the hazard assessment (Articles 3(28) and 10(a)(vii) and Annex I, Section 3.1.5 of REACH). A robust study summary must cover critical information and allow an assessment of the validity and reliability of the study. A robust study summary of a Growth inhibition study aquatic plants must include (among others) the following information:[2]

- initial cell concentration;
- test conditions (temperature, lighting, test medium, test system, etc.);
- test design (e.g. test concentrations, number of controls, number of replicates);
- adequate raw data relative to cell density determination to allow a verification that the validity criteria of the method were fulfilled;
- growth curves (evidence of exponential growth in the controls, growth rate evolution throughout the test in the test vessels, etc.);
- EC50, EC10 at 24h intervals or NOEC and LOEC for both growth rate and biomass, dose-response relationships, description of statistical analysis performed.

The robust study summary you provided does not cover the critical information listed above to make an independent assessment of the validity and reliability of this study and its results for use in hazard assessment.

Therefore, the information requirement is not fulfilled.

We consider the OECD TG 201 an appropriate guideline to fulfil this information requirement.[3]

Possibility for data sharing for studies not involving vertebrate animals

The jointly submitted registration for the Substance contains data which is relevant for this endpoint. In accordance with Title III of the REACH Regulation, you may request it from the other registrant(s) and then make every effort to reach an agreement on the sharing of data and costs.

[2] ECHA Practical Guide 3 (How to report robust study summaries)
[3] Section R.7.8.4.1 and Appendix R.7.8-2 of ECHA Guidance R.7b.

Appendix B: 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 an adaptation in Section 5.9.2.1 of your Chemical Safety Report (CSR), and you conclude that "the study does not need to be conducted because relevant human exposure can be excluded".

As explained in the Appendix on General considerations, your adaptation is rejected.

A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral[4] administration of the Substance.

Information on data sharing for studies involving vertebrate animals
The jointly submitted registration for the Substance contains data which is relevant for this endpoint. In accordance with Title III of the REACH Regulation, you must request it from the other registrant(s) and then make every effort to reach an agreement on the sharing of data and costs.

ECHA considers six months as sufficiently reasonable time for the registrant to seek permission to refer to the other registrants' full study report.

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

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

Under Articles 10(a) and 12(1) of REACH, a technical dossier at a tonnage abve 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X to REACH.

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.) in a second species

Pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is a standard information requirement in Annex X to REACH.

You have provided adaptations in Section 5.9.2.1 of your Chemical Safety Report (CSR), and you conclude that "the study does not need to be conducted because relevant human exposure can be excluded".

As explained in the Appendix on General considerations, your adaptation is rejected.

In order to be compliant and enable concluding if the Substance is a developmental toxicant, the information provided has to meet the requirements of OECD TG 414 in two species.

A PNDT study according to the OECD TG 414 should be performed in rabbit or rat as the preferred second species, depending on the species tested in the PNDT study in the first species (request B.1. in this decision). The study must be performed with oral[4] administration of the Substance.

Information on data sharing for studies involving vertebrate animals
The jointly submitted registration for the Substance contains data which is relevant for this endpoint. In accordance with Title III of the REACH Regulation, you must request it from the other registrant(s) and then make every effort to reach an agreement on the sharing of data and costs.

ECHA considers six months as sufficiently reasonable time for the registrant to seek permission to refer to the other registrants' full study report.

2. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.)

The basic test design of an Extended one-generation reproductive toxicity (EOGRT) study (OECD TG 443) is a standard information requirement in Annex X to REACH. Furthermore Column 2 of Section 8.7.3. defines when the study design needs to be expanded.

You have provided the following study in your IUCLID dossier:

- One-generation reproductive toxicity, OECD TG 415, DePass L. R. et al., 1983.

We have assessed this information and identified the following issue(s):

To be considered compliant and enable concluding if the Substance is a reproductive toxicant, the study has to meet the requirements of OECD TG 443 as specified in REACH.

The study you provided does not cover all relevant life stages required in OECD TG 443, as the extensive postnatal investigations of the fully exposed F1 generation up to the adulthood are not included.

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

The specifications for the study design

Premating exposure duration and dose-level setting

The length of premating exposure period must be ten weeks to cover the full spermatogenesis and folliculogenesis before the mating, allowing meaningful assessment of the effects on fertility. Ten weeks premating exposure duration is required to obtain results adequate for classification and labelling and/or risk assessment. There is also no substance specific information in the dossier supporting shorter premating exposure duration.[5]

The study must be performed in rats with oral[4] administration.

In order to be compliant and not to be rejected due to too low dose levels, the highest dose level shall aim to induce systemic toxicity, but not death or severe suffering of the animals, to allow comparison of reproductive toxicity and systemic toxicity. The dose level selection should be based upon the fertility effects. A descending sequence of dose levels should be selected in order to demonstrate any dose-related effect and to establish NOAELs.

If there is no relevant data to be used for dose level setting, it is recommended that range-finding results are reported with the main study.

You have to provide a justification with your study results that demonstrates that the dose level selection meets the conditions described above.

Cohorts 1A and 1B belong to the basic study design and must be included.

Information on data sharing for studies involving vertebrate animals

The jointly submitted registration for the Substance contains data which is relevant for this endpoint. In accordance with Title III of the REACH Regulation, you must request it from the other registrant(s) and then make every effort to reach an agreement on the sharing of data and costs.

ECHA considers six months as sufficiently reasonable time for the registrant to seek permission to refer to the other registrants' full study report.

[5] ECHA Guidance R.7a, Section R.7.6.

Appendix D: 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 REACH.

The compliance check was initiated on 29 January 2019.

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 within 30 days of the notification.

ECHA did not receive any comments within the 30 days.

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: 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'[6].

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 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 [and other parameters relevant for the property to be tested, in this case...]. 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.

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

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"[7].

5. List of references of the ECHA Guidance and other guidance/ reference documents[8]

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.

ECHA Read-across assessment framework (RAAF, March 2017)[9]

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.

OECD Guidance documents[10]
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.

[7] https://echa.europa.eu/manuals
[8] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[9] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[10] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix F: 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]