Helsinki, 13 December 2019

Addressee
Registrant of 2-bromo-3,3,3-trifluoroprop-1-ene as listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
16/02/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: 2-bromo-3,3,3-trifluoroprop-1-ene
EC number: 627-872-0
CAS number: 1514-82-5

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

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***22 June 2020***.

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

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

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

Conditions to comply with the requested information

You are bound by the requests for information corresponding to the REACH Annexes applicable to your own registered tonnage of the Substance at the time of evaluation.

You have to comply with the requirements of Annex VII and VIII of REACH, if you have registered a substance at 10-100 tpa.

Appendix A states the reasons for the requests for information to fulfil the requirements set out in Annex VII of REACH.

The test material used to perform the required studies must be selected and reported in accordance with the specifications prescribed in the Appendix entitled "Observations and technical guidance".

You must submit the information requested in this decision by the deadline indicated above in an updated registration dossier and also update the chemical safety report, where relevant,

including any changes to classification and labelling, based on the newly generated information. The timeline has been set to allow for sequential testing where relevant.

Appeal

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

Approved[1] under the authority of Christel Schillinger-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 for the requests to comply with Annex VII of REACH

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, 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 the REACH Regulation.

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

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

You have provided a key study based on OECD TG 202 (2013).

Tests on substances must be conducted in accordance with OECD test guidelines or another recognised international test method (Article 13(3) of REACH). OECD TG 202 in combination with the revised OECD Guidance 23, ENV/JM/MONO(2000)6/REV1 require that the following conditions are met (among others):

- analytical monitoring of exposure concentrations. For difficult to test substances, including highly volatile substances, a sufficiently sensitive analytical method is necessary for the analysis of the test substance in the test solution. The possibility of losses during sampling, sample treatment and analysis must be considered and documented
- appropriate reporting of the test results. If the test concentrations are not maintained within the required 20% of the measured initial concentrations throughout testing, the effect concentrations based on the measured values must be reported (see ECHA Guidance R7B (section R.7.8.4.1)

The Substance is highly volatile. In your CSR section 7.6 you state that: *'The calculated Henry's law constant (H) for BTP is [redacted] Pa. m^3/mol; on the basis that H is greater than 100 Pa. m^3/mol it is expected that more than 50% of the substance will be lost from the water phase between 3 and 4 hours.'*

Therefore it is expected that considerable losses will occur during the exposure period, as confirmed in the algal growth inhibition study, where it is reported that: *'After 96 hours, the measured concentrations had decreased to values ranging from below the limit of quantitation of the analytical method (0.8 mg/L) to 4% of nominal.'*

You did not provide any analytical monitoring of exposure concentrations and did not demonstrate that the test substance concentration during the test was maintained within the required 20% of the measured initial concentrations.

Consequently, the aforementioned conditions of the guidelines are not met, therefore the information provided does not fulfil the information requirement.

2. **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 key study based on OECD TG 201 (2013).

Tests on substances must be conducted in accordance with OECD test guidelines or another

recognised international test method (Article 13(3) of REACH). OECD TG 201 in combination with the revised OECD Guidance 23, ENV/JM/MONO(2000)6/REV1 require that the following condition is met (among others):

- appropriate reporting of the test results. If the test concentrations are not maintained within the required 20% of the measured initial concentrations throughout testing, the effect concentrations based on the measured values must be reported (see ECHA Guidance R7B (section R.7.8.4.1)

The Substance is highly volatile. In your CSR section 7.6 you state that: *'The calculated Henry's law constant (H) for BTP is [redacted] Pa. m^3/mol; on the basis that H is greater than 100 Pa. m^3/mol it is expected that more than 50% of the substance will be lost from the water phase between 3 and 4 hours.'*

There is also evidence that the Substance was not maintained in the test solutions with virtually complete loss of the substance during the exposure period, i.e. it is reported that: *'After 96 hours, the measured concentrations had decreased to values ranging from below the limit of quantitation of the analytical method (0.8 mg/L) to 4% of nominal.'*

The test concentrations are not maintained within the required 20% of the measured initial concentrations throughout testing and you have expressed the effect values as initial concentrations rather than on measured values taken during the conduct of the test.

Consequenlty, the aforementioned condition is not met, therefore the information provided does not fulfil information requirement.

Appendix B: Procedural history

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

The compliance check was initiated on 08 November 2018.

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 C: Observations and technical guidance

1. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for the start of substance evaluation in 2019.

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

3. 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.

4. Test guidelines, GLP requirements and reporting

   Under Article 13(3) of REACH, all data, including the tests 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 data, including the tests 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[2]'.

5. 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. 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.

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

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

6. List of references for the Guidance documents[3] referred to 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.

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

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 fufilled
[redacted]	[redacted]	[redacted]