ECHA
EUROPEAN CHEMICALS AGENCY

~~Confidential~~

Helsinki, 20 May 2021

Addressees
Registrant(s) of 1,1-difluoroethane-CAS_75-37-6 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
26/11/2019

Registered substance subject to this decision ("the Substance")
Substance name: 1,1-difluoroethane
EC number: 200-866-1
CAS number: 75-37-6

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 ***25 August 2022***.

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

2. 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 appendix:

- Appendix entitled "Reasons to request information required under Annex IX of REACH".

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

1. **Long-term toxicity testing on aquatic invertebrates**

   and

2. **Long-term toxicity testing on fish**

Long-term toxicity testing on aquatic invertebrates and long-term toxicity testing on fish are information requirements under Annex IX to REACH (Section 9.1.5. and Section 9.1.6.).

You have provided the following information:

- a justification to omit the study, which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you provided the following justification:

"*In accordance with Column 2 adaptation statement of REACH Annex IX, information requirement section 9.1.6, this study does not need to be conducted because the substance is a gas with a low log Kow, a high vapour pressure, and limited or no potential for long term chronic exposure to invertebrates/fish. The estimated log Kow is 1.13 and the vapour pressure is 514624 Pa at 25°C. These physicochemical properties in conjunction with limited or no aqueous exposure indicate the potential for long-term toxicity to invertebrates/fish is low*".

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 and 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).

Your adaptation is therefore rejected.

In your comments to the draft decision, you have provided the following information:

A. an adaptation based on Annex XI Section 2;
B. your intention to provide an adaptation based on Annex XI Section 3.

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

A. As stated in Annex XI, Section 2, testing for a specific endpoint may be omitted if it is technically not possible to conduct the study as a consequence of the properties of the substance. The guidance given in the test methods referred to in Article 13(3), more specifically on the technical limitations of a specific method, must always be respected. Any technical difficulties to perform the test and the proposed solutions must be clearly documented.

If a substance is difficult to test, an aquatic toxicity study must follow the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) to fulfil the information requirements (Article 13(3) of REACH). For volatile test chemicals (e.g. Henry's law constant >0.1 Pa.m3/mol), appropriate exposure systems must be selected to maintain analytically quantifiable test chemical concentrations throughout the test, such as using closed systems and reducing head-space.

In your comments to the draft decision, you have provided the following justification for your adaptation based on Annex XI Section 2:

"*The challenges foreseen in attempting to test HFC 152a using the proposed study methods*

include:

- *The physical properties of HFC-152a (gas at ambient conditions) mean that it is very difficult to maintain a saturated aqueous solution and the necessary dilutions over the period of time of the test (21 days in the case of Daphnia), the half-life of HFC 152a in aqueous systems is expected to be of the order of a few days. In effect, the test system would need to be maintained under conditions that are far from representative of those that will ever occur in the natural environment. Laboratories are not expected to conduct tests under these conditions and are unlikely to have equipment available.*
- *HFC-152a is an extremely flammable gas which presents technical difficulties in performing the test safely, particularly as the laboratory would need to make and control a gas mixture comprising 5 bar HFC -152a in addition to sufficient oxygen to maintain aerobic conditions for the organism concerned. Whilst this mixture itself will not be flammable, leakage of this artificial atmosphere into the laboratory would result in flammable conditions. Laboratories are not expected to conduct tests under these conditions.*
- *Based on inquiries to date, we have not identified a suitable testing facility. Lack of equipment and experience could well lead to producing erroneous and non-reproducible results."*

The Substance is difficult to test due to the volatility (Henry's law constant 2 060 Pa.m³/mol > 0.1 Pa.m³/mol).

In your justification, you have indicated technical difficulties in maintaining exposure concentrations due to the volatility of the Substance. You consider that this would require laboratories to conduct the studies under conditions that are not environmentally relevant, and you also expect that they are unlikely to have the equipment available. However, your justification is not acceptable due to the following. Firstly, you have not described any possible solution to reduce the expected losses for volatile substances, such as conducting the aquatic toxicity studies with appropriate exposure systems as given in OECD GD 23. Secondly, for the purpose of REACH information on intrinsic properties of the Substance is needed as determined in standard tests (Article 13(3)). Since aquatic toxicity tests must be performed following the conditions specified in the standard guidelines and in OECD GD 23 for difficult to test substances, your claim that test conditions would not be environmentally realistic is not a valid reason to adapt these studies under Section 2 of Annex XI.

Furthermore, you have indicated technical difficulties in performing the test safely due to the properties of the Substance because a leakage of the testing mixture into the laboratory would lead to flammable conditions. While a study can be considered unfeasible when mixing of the substance with water may cause danger of fire or explosion (Annex XI Section 2), flammability per se is not a reason that would make the study not feasible. Moreover, laboratory testing of the Substance in water is possible in safe conditions, as demonstrated by the water solubility test ([redacted] 2009) provided in the registration dossier.

Finally, while you claim that you have not found a suitable testing facility to conduct these studies, you have not provided any documented evidence from the laboratories that the studies conducted with appropriate exposure systems for volatile substances would not be feasible, nor regarding concern for safety conditions when using a flammable gas such as the Substance.

Therefore, you have not demonstrated that the study is technically not possible to conduct and your adaptation is rejected.

B. Under Annex XI, Section 3, this information may be omitted based on the exposure scenario(s) developed in the Chemical Safety Report. The justification must be based on a rigorous exposure assessment in accordance with Annex I, Section 5 and must meet any one of the following criteria set out under section 3.2 of Annex XI:

(a) It can be demonstrated that all the following conditions are met:
   i. the absence or no significant exposure in all scenarios of the manufacture and all identified uses referred to in Annex VI, Section 3.5., and
   ii. a PNEC can be derived from available data, which:
      - must be relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes and therefore must be based on reliable information on the hazardous properties of the substance on at least three trophic levels;
      - must take into account the increased uncertainty resulting from the omission of the information requirement, in this case by selecting an appropriate assessment factor (AF) as described in ECHA Guidance R.10.3.
   iii. the ratio between the results of the exposure assessment (PECs) and the PNEC are always well below 1

(b) For substances that are not included in articles, it must be demonstrated for all relevant scenarios that strictly controlled conditions as set out in Article 18(4)(a) to (f) apply throughout the life cycle.

In all cases, adequate justification and documentation must be provided when testing is omitted.

In your comments to the draft decision, you have indicated your intention to provide an adaptation based on Annex XI Section 3 with the following justification: "*Further exposure-based arguments to waive testing in accordance with Annex XI.3 can also be prepared based on available evidence including the known physicochemical properties of HFC-152a (Ecotox JACC-045 report).The JACC report notes that HFC-152a has already been evaluated, based on an existing ECOSAR approach, and indicates a low order of toxicity to aquatic organisms.*"

Firstly, in your justification, you have mentioned only physico-chemical and hazard information to support your adaptation, which do not correspond to any of the criteria listed under Annex XI Section 3.

Secondly, in Section 3.5 of your registration dossier you report consumer uses (e.g. in Aerosol and MDI Propellant) and wide-spread professional uses (e.g. as foaming agent) with ERC9a: Widespread use of functional fluid (indoor) and ERC9b: Widespread use of functional fluid (outdoor)).

The requirements described above (based on Annex XI section 3.2(a)) must be met for all uses throughout the life-cycle including waste stage (ECHA Guidance R.5). The uses reported by you for the Substance include 'consumer use' and 'widespread use by professional workers'. These uses are, by definition, considered as widespread (ECHA Guidance R.12) and indicate a potential for significant release (ECHA Guidance R.16). Hence, you have not demonstrated that environmental exposure throughout the life-cycle including waste stage of the Substance is absent or no significant.

Furthermore, the justification based on Annex XI section 3.2(b) must include a qualitative assessment including three elements: the description of operational conditions and risk management measures in all related exposure scenarios; the quantification of the resulting release/exposure for all routes; and a qualitative statement why the release is low enough (ECHA Guidance R.5.1.3). In your exposure assessment, for all uses you report no local release of the Substance to waste-water. However, you do not provide justification including

description of operational conditions and risk management measures, nor the quantification of the resulting release/exposure for all routes. Therefore, you have not documented that strictly controlled conditions throughout the life-cycle including waste stage of the Substance apply.

Therefore, on the basis of the information provided with your comment your adaptation would be rejected.

On this basis, the information requirements are not fulfilled.

Study design

To fulfil the information requirement of long-term toxicity testing on fish for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (ECHA Guidance R.7.8.2.).

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[2].

B. Test material

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 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.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[3].

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

Appendix C: 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 07 July 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 request(s).

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 D: List of references - ECHA Guidance[4] 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)[5]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[5]

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[6]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

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

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.