~~Confidential~~

Helsinki, 14 July 2022

Addressee
Registrant of JS_Perfluorotripropylamine as listed in the last Appendix of this decision

Date of submission for the submitted dossier subject to this decision
9 October 2020

Registered substance subject to this decision ("the Substance")
Substance name: Perfluamine
EC number: 206-420-2

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

DECISION TAKEN UNDER ARTICLE 42(1) OF THE REACH REGULATION

By the decision of 19 July 2017 ("the original decision") ECHA requested you to submit information by 27 January 2020 in an update of your registration dossier.

Based on Article 42(1) of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA examined the information you submitted with the registration dossier specified in the header above, and concludes that

Your registration still does not comply with the following information requirement(s):

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: Daphnia magna reproduction test, EU C.20./OECD TG 211) with the FZ-7941 (cell crude of FC-3283) composition of the registered substance

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the FZ-7941 (cell crude of FC-3283) composition of the registered substance.

You are therefore still required to provide this information requested in the original decision.

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

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

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

The respective Member State competent authority (MSCA) and National enforcement authority (NEA) will be informed of this decision. They may consider enforcement actions to secure the implementation of the original decision and exercise the powers reserved to them under Article 126 of Regulation No 1907/2006 (penalties for non-compliance)[1].

Authorised[2] under the authority of Mike Rasenberg, Director of Hazard Assessment

[1] See paragraphs 61 and 114 of the judgment of 8 May of the General Court of the European Court of Justice in Case T-283/15 Esso Raffinage v. ECHA

[2] 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 (Annex IX, Section 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20./OECD TG 211) with the FZ-7941 (cell crude of FC-3283) composition of the registered substance**

You were requested to submit information on Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20./OECD TG 211) with the FZ-7941 (cell crude of FC-3283) composition of the registered substance.

You have provided an adaptation to the standard information requirement according to Annex XI, Section 3.2 (b) Substance-tailored exposure-driven testing. You have provided the following justification for the adaptation:

'[…] FZ-7941 is essentially a manufacturing intermediate used under strictly controlled conditions as set out in Article 18(4)(a) - 18(4)(f) of REACH […] *the hydride content is eliminated during processing, leaving only perfluorinated materials. Therefore, as per Annex XI, section 3.2(b), testing is not required.'*

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

As stated in 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 CSR, by providing an adequate and scientifically-supported justification based on a thorough and rigorous exposure assessment in accordance with Section 5 of Annex I and by communicating the specific conditions of use through the supply chain. Any one of the criteria 3.2.(a),(b) or (c) shall be met. In particular

- 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 (section 3.2(b));

Art 18(4)(a) states '*the substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage';*

Art 18(4)(e) states '*in cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures'*;

In your exposure assessment for the Substance, you report the following emission from the process to wastewater: water from periodical cleaning of the electrochemical vessels, scrubber water from the building ventilation, and washing water from the stabilization process. You report that residual material present in the wastewater influent is treated in the wastewater treatment (WWT) process and that the WWT effluent is monitored for the presence of organic and inorganic fluorides.

However, you do not demonstrate strictly controlled conditions as per Annex XI, section 3.2(b). In particular, condition (a) as set out in Article 18(4) is not fulfilled, because you have not demonstrated that the Substance is rigorously contained by technical means during its whole lifecycle. The reported exposure assessment shows that residual emissions are possible

during accidental events, sampling and analysis, cleaning and maintenance, and processing of waste. In addition, condition (e) as set out in Article 18(4) is not fulfilled. You do not specify to which extent the WWT process minimises emissions of the Substance and therefore, the absence of significant exposure is not demonstrated. In conclusion, the requirements of criterion 3.2(b) for an exposure-based adaptation are not met.

In your comments to the draft decision, you provided an amended exposure assessment with further details on the cleaning operations, maintenance, sampling, and accidental events.

However, the information confirms the possibility of emissions to the WWT. You did not provide further information on removal efficiency of the WWT. Therefore, you did not demonstrate that the substance is totally removed from the WWT. In conclusion, you have not demonstrated strictly controlled conditions for all processes as requested and testing cannot be omitted based on absence of significant exposure.

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

In your comments on the draft decision, you explain that conducting a study under flow-through conditions is not appropriate. In support of your claim, you refer to the results of a study conducted according to OECD TG 305 on FC-770 and to the difficulties in maintaining stable exposure concentrations. You further state that this study was "*done on a much simpler substance with two major constituents that were simple structural isomers, and which had a far higher water solubility (66 µg/L v. 0.381 µg/L). In comparison,* [the Substance] *is far more complex, with the solubility of the constituents potentially varying over an order of magnitude*". Therefore, you propose to conduct a preliminary OECD TG 211 study "*using a static-renewal method without removal of test material, in a sealed test system, using a suitable loading rate for a long-term toxicity test (e.g., 10 mg/L)*". You state that if effects are observed in this preliminary test, "a dilution series using an appropriate solvent will be attempted or a flow through design will be explored".

ECHA notes that based on results from an OECD TG 305 test with a different substance, you anticipate difficulties in maintaining stable exposure to the Substance in the conditions specified in the OECD TG 211. However, you have not provided any supporting information to demonstrate that adequate exposure cannot be maintained in a test according to OECD TG 211 with the Substance.

OECD TG 211 specifies that for difficult to dissolve substances, the OECD Guidance 23 is to be followed. To get reliable results, the substance properties need to be considered when performing the test, in particular with regard to the test design; including exposure system, test solution preparation, and sampling. OECD GD 23 (Table 1) describes testing difficulties related to a specific property of the substance. You may use the approaches described in OECD GD 23 or other approaches if more appropriate for your substance. The approach selected must be justified and documented. Due to the substance properties, it may be difficult to achieve and maintain the exposure concentrations. Therefore, you have to demonstrate that the concentration of the substance is stable throughout the test (i.e., measured concentrations remains within 80-120% of the nominal concentration). If it is not possible to demonstrate the stability, you must express the effect concentration based on measured values as described in the applicable test guideline. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the test solution preparation method applied was sufficient to maximise the concentration of the Substance in the test solution.

You are still required to provide the following information derived with the FZ-7941 (cell crude of FC-3283) composition of the registered substance subject to the present decision: *Daphnia magna* reproduction test (test method: EU C.20./OECD TG 211).

2. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the FZ-7941 (cell crude of FC-3283) composition of the registered substance.**

You were requested to submit information on Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the FZ-7941 (cell crude of FC-3283) composition of the registered substance.

You have provided an adaptation to the standard information requirement according to Annex XI, Section 3.2 (b) Substance-tailored exposure-driven testing. You have provided the following justification for the adaptation:

'[…] FZ-7941 is essentially a manufacturing intermediate used under strictly controlled conditions as set out in Article 18(4)(a) - 18(4)(f) of REACH […] *the hydride content is eliminated during processing, leaving only perfluorinated materials. Therefore, as per Annex XI, section 3.2(b), testing is not required.'*

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

As stated in 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 CSR, by providing an adequate and scientifically-supported justification based on a thorough and rigorous exposure assessment in accordance with Section 5 of Annex I and by communicating the specific conditions of use through the supply chain. Any one of the criteria 3.2.(a),(b) or (c) shall be met. In particular

- 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 (section 3.2(b));

Art 18(4)(a) states '*the substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage';*

Art 18(4)(e) states '*in cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures'*;

In your exposure assessment for the Substance, you report the following emission from the process to wastewater: water from periodical cleaning of the electrochemical vessels, scrubber water from the building ventilation, and washing water from the stabilization process. You report that residual material present in the wastewater influent is treated in the wastewater treatment (WWT) process and that the WWT effluent is monitored for the presence of organic and inorganic fluorides.

However, you do not demonstrate strictly controlled conditions as per Annex XI, section 3.2(b). In particular, condition (a) as set out in Article 18(4) is not fulfilled because you have not demonstrated that the Substance is rigorously contained by technical means during its

whole lifecycle. The reported exposure assessment shows that residual emissions are possible during accidental events, sampling and analysis, cleaning and maintenance, and processing of waste. In addition, condition (e) as set out in Article 18(4) is not fulfilled. You do not specify to which extent the WWT process minimises emissions of the Substance and therefore, the absence of significant exposure is not demonstrated. In conclusion, the requirements of criterion 3.2(b) for an exposure-based adaptation are not met.

In your comments to the draft decision, you provided an amended exposure assessment with further details on the cleaning operations, maintenance, sampling, and accidental events.

However, the information confirms the possibility of emissions to the WWT. You did not provide further information on removal efficiency of the WWT. Therefore, you did not demonstrate that the substance is totally removed from the WWT. In conclusion, you have not demonstrated strictly controlled conditions for all processes as requested and testing cannot be omitted based on absence of significant exposure.

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

In your further comments to the draft decision, and as already mentioned under Appendix A.1. above, you explain that conducting a study under flow-through conditions is not appropriate. You state that the OECD TG 210 "*is not suitable for this substance*". Instead, you propose to conduct a study according to OECD TG 212 as "*method uses a smaller number of fish in smaller volume, and it is therefore more readily adapted to the entirely closed conditions needed to maintain the presence of dissolved material*". You also state that "[…] *the test is also of shorter duration, reducing the risk to study integrity due to instabilities in test substance concentration"*. You conclude that "[…] *while TG212 is less preferred to the TG210 for long-term testing, the higher priority would be to have a valid, interpretable result from long- testing. The probability of success for a study under TG212 is much greater for the aforementioned reasons*".

ECHA has assessed the information from your comments on the draft decision and identified the following issues:

A. The adequacy of OECD TG 212 to meet the information requirement is not demonstrated.

The proposed OECD TG 212 study is considerably shorter and less sensitive than OECD TG 210 study for the purpose of addressing the information requirement of long-term toxicity to fish (ECHA Guidance R.7b, Section R.7.8.4.1). Furthermore, the OECD TG 212 specifies that the test is less sensitive than OECD TG 210, particularly with respect to chemicals with log Kow > 4.

In section 4,7 of your technical dossier, you report a log Kow for the Substance ranging from 5.3 to 6.1, based on internal studies conducted on similar substances. You have not provided any justification as to why the proposed study would provide equivalent sensitivity to the OECD TG 210.

The information currently available on the substance indicates that the OECD TG 212 would likely have lower sensitivity to the requested OECD TG 210 study. Therefore, you have not demonstrated that this test method would provide adequate information for the purpose of classification and labelling and risk assessment.

B. The OECD TG 212 should no longer be used due to animal welfare reasons.

ECHA points out that in the FISH TOXICITY TESTING FRAMEWORK (OECD Series on Testing and Assessment, No. 171)[3] the use of the OECD TG 212 is not advised due to animal welfare issues and the guideline is proposed to be deleted (section 11.2 of the framework). Firstly, the larvae used in the study could be subject to pain as the guideline recommends that larvae with severe deformities should be terminated to avoid suffering. Secondly, the test is performed without external food supply and lack of feeding could be considered unacceptably distressful for the test organisms. The test should be terminated just before the yolk sac of any larvae has been completely absorbed or before mortality by starvation starts in the controls, however the exact point at which this occurs may be difficult to define in practice. In the context of animal welfare considerations the OECD FISH TOXICITY TESTING FRAMEWORK in Section 5.5.1 therefore highlights that the TG 212 has been described as the "fish starvation test". This further highlights the animal welfare issues.

C. Your justification does not provide any supporting evidence that an OECD TG 210 is not technically feasible.

While you emphasizes the difficulties in maintaining stable exposure to the Substance in the conditions specified in the OECD TG 212 in conjunction with the OECD GD 23, you have provided no supporting information to demonstrate that adequate exposure cannot be maintained in such test.

In conclusion, ECHA maintains that the OECD TG 210 study is the most appropriate test method to fulfill the information requirement of long-term toxicity to fish.

You are still required to provide the following information derived with the FZ-7941 (cell crude of FC-3283) composition of the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

[3] The document is for example available at https://www.oecd-ilibrary.org/docserver/9789264221437-en.pdf?expires=1571648956&id=id&accname=guest&checksum=56A906873CF171D1C405D5C920E79C98

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

A. Test methods, GLP requirements and reporting

1. Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

2. Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

3. Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[4].

B. Test material

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[5].

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

Appendix C: Procedure

For this Substance the process of substance evaluation started in 2020.

In accordance with Article 42(1) of the REACH Regulation, the Agency examined the information submitted by you in consequence of decision of 19 July 2017 ("the original decision"). Agency considered that this information did not meet one or more of the requests contained in that decision. Therefore, a new decision-making process was initiated under Article 41 of the REACH Regulation.

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, as described below

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[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)[8]

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[9]

[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] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[9] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

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

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

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

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

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

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

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.