RISK MANAGEMENT OPTION ANALYSIS

CONCLUSION DOCUMENT

for

Substance name: 2,4,6-trimethyl-2,4,6-tris(3,3,3-trifluoropropyl)cyclotrisiloxane, F-D3
EC number: 219-154-7
CAS number: 2374-14-3

Member State(s): The Netherlands

Dated: 10 June 2015

Disclaimer: Please note that this RMOA conclusion was compiled on the basis of available information and may change in the light of new information or further assessment.

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Not applicable. There are no current measures for risk reduction for F-D3. With respect to classification and labelling, there is no harmonised classification for F-D3.

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

For each conclusion selected in the table below a justification is provided in section 3 of this document. Reasons outlining why a particular risk management option was not considered appropriate are also included in the relevant section.

Conclusions	**Tick box**
Need for follow up regulatory action at EU level	X
Harmonised classification and labelling	X
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action	

3. FOLLOW-UP OF REGULATORY RISK MANAGEMENT ACTION AT EU LEVEL

3.1 Need for follow-up regulatory action at EU level

Based on the available data and assessments the following concerns are identified that need further clarification:

- There is a concern related to the possible hazards for human health. F-D3 is self-classified as STOT RE1 for toxicity to myocytes of skeletal and cardiac muscle and effects have been observed at a low dose, with the NOAEL of 0.8 mg/kg bw/day.
- There is a concern for the environment. F-D3 is considered as a potential PBT substance. A valid study on bioaccumulation is needed to confirm the bioaccumulation property.
- There is a concern related to the possible exposure of workers, consumers and the environment. At present, there is uncertainty on the professional and consumer uses as well as on environmental concentrations of F-D3. Should professional and consumer use occur, widespread use would be of concern.
- There is also a concern for workers as from the CSR (Chemical Safety Report) the RCR is close to one.
- There is a lack of data identified (Compliance issue):
  - Developmental toxicity tests are missing. The applied waiving statement does not apply (This statement would apply only if F-D3 would have been classified as Repro Cat 1A and 1B, which is currently not the case). A concern for Reprotoxicity does exist though as F-D3 is self-classified as Repro Cat 2.

The following possible risk management options are identified:

a. Workers legislation
b. REACH Annex XVII (restriction):
    - Setting conditions on the manufacture and use
    - Restricting the manufacture or the placing on the market
    - Other (specific restriction)
c. Harmonised C&L
d. REACH Annex XIV (authorisation)
e. CoRAP entry and substance evaluation and Compliance Check (CCH)

a. Worker legislation (setting an OEL)

For substances for which exposure in the workplace is expected, risks can be controlled by setting a European Occupational Exposure Limit (OEL) under Directive 89/24/EC. Currently, there is no OEL available for F-D3. It is possible to set an OEL for F-D3 because there is a threshold for the effects of concern. As there is very limited information on the (industrial and laboratory) use of F-D3, at present the impact of setting an OEL is uncertain (information suggests only one site where workers may handle F-D3 in a monomer form). However, current RCRs are close to one and there exists some uncertainty on the derivation of the DNEL. Setting an OEL can be an appropriate and effective way of safeguarding occupational health effects for F-D3.

b. REACH Annex XVII (restriction)

A restriction as a risk management option may be appropriate when an immediate concern for workers, professional users, consumers or the environment is apparent. The registration dossier does not show any clear indication for such a concern and the additional information from the EU registrants further supports the absence of a need for urgent action stating that F-D3 is mainly imported in a polymer (only one company in Europe actually polymerizes the monomer themselves), and that F-D3 is not used as such by consumers. Based on the current knowledge therefore restriction of F-D3 may seem superfluous.

In principle, a total ban on the manufacture and use of F-D3 would prevent all (potential) health risks (including both worker exposure and potential exposure via environmental routes) and the environmental risks. However, like is indicated above, at this moment there is no information available that would support such measure. A total ban would be effective though to address the concern related to the potential PBT properties of F-D3. This may however also be regulated via Authorization, provided that imported articles are not the subject of concern.

Alternatively, one could follow a more targeted approach. For example, by setting a “condition” to the manufacture or use of F-D3. To address risks arising from the exposure of workers, one could consider formulating a mandatory DNEL. However, data are lacking to motivate the need for a mandatory DNEL. This also holds for a more targeted restriction related to the placing on the market of consumer products. Furthermore, a more targeted restriction may also not address the concern related to the potential PBT properties of F-D3.

c. Harmonised C&L

This substance is self-classified as follows:
Classification:
Repr. 2
STOT RE 1(cause damage to heart and skeletal muscle, oral)
STOT RE 2 (may cause damage to liver, dermal)
Hazard Statement:
H361: May damage fertility or the unborn child.

H372: Causes damage to organs (heart and skeletal muscle, oral) through prolonged or repeated exposure.
H373: May cause damage to organs (liver, dermal) through prolonged or repeated exposure.

It is noted that in the self-classification notified by manufacturers and importers, the classifications differ among notifiers. For example, for H361 Cat.2, H372 Cat.1, and H373 Cat.2, some notifiers apply a classification and some apply no classification. Considering the severe effects of F-D3 on human health and the environment and the absence of consensus between notifiers, harmonization of classification would be an appropriate option for F-D3. Due to the fact that some data are absent, e.g. aquatic toxicity, it may not be possible to harmonize classification for all endpoints. But it would be possible to harmonise classification for targeted endpoints like myotoxicity of H372 Cat.1. A harmonised classification is required prior to SVHC identification based on article 57f: equivalent level of concern based on STOT RE properties; or based on article 57d: PBT, in which the T can be based on Repro Cat. 2 or STOT RE, in absence of aquatic toxicity data.

Furthermore, harmonised C&L will ensure that the hazards of F-D3 are communicated in a consistent manner.

Harmonised C&L is therefore concluded as a possible next risk management measure for F-D3.

d. REACH Annex XIV (authorisation)

Once F-D3 obtains a harmonized classification for STOT RE1, authorization may be an appropriate route to further regulate this substance under art 57(f). The type of effect leading to STOT RE classification of F-D3 is toxicity to myocytes from skeletal and cardiac muscle. This effect is dose and exposure duration dependent where myocytes degenerate until necrosis resulting in a heart function failure. In the case of the skeletal muscle, the adverse effect in myocytes results in loss of behavioral and motor control. Due to the severity of the effect, the potential irreversibility of the lesions after a repeated exposure period as well as the societal impact, this substance can be considered to be of high concern under those conditions. Based on the available information, the type of effects observed after exposure to F-D3 may be of 'Equivalent level of Concern' in view of the current Article 57(f), assuming that the observed effects in rats are relevant to humans. After harmonized classification and labelling as STOT RE1, F-D3 could therefore be proposed for SVHC via the equivalent level of concern route under Article 57(f). However, since there are no human health cases available to support the Equivalent Level of Concern (ELoC) and since a DNEL can be derived allowing for safe use, there might be some reservation regarding an eventual case for ELoC.

F-D3 also meets the screening criteria for PBT and may therefore be proposed as SVHC under art 57(d). Currently though, data like bioaccumulation testing information are lacking for confirming possible PBT/vPvB properties. This information should be obtained via Substance evaluation. Once the information is available and would confirm that F-D3 is a PBT substance, F-D3 could also be included in the Candidate list based on article 57(d) with the eventual aim of Annex XIV inclusion.

In summary, F-D3 could meet the SVHC Roadmap criteria (either via art 57(d) or (57f)) as shown in the table below. In the absence of data on alternatives and in the absence of quantitative information on exposure and risks, authorization could be a good way to further regulate F-D3, which would force industry to actively look for substitutes and phase out the use of F-D3.

SVHC Roadmap 2020

Criteria	YES	NO
a) Art 57 criteria fulfilled?	Possibly 57f or 57d	
b) Registrations in accordance with Article 10?	x	
c) Registrations include uses within scope of authorization?	x	
d) Known uses not already regulated by specific EU legislation that provides a pressure for substitution?	x	

e. Screening of registration dossiers, CoRAP entry and substance evaluation and Compliance check (CCH)

Substance evaluation seems to be the most appropriate measure to address and clarify the concern of possible reproductive and myocyte effects as well as the PBT properties of F-D3. First of all substance evaluation would be an effective step to target the information required to evaluate P and B properties of F-D3. Before actually formulating a substance evaluation, it could be considered to present F-D3 to the PBT-expert group to discuss and obtain further feedback on the likeliness that F-D3 could be PBT/vPvB. Alternatively compliance check (CCH) could be considered. However, it is not expected that CCH will result in sufficient information to draw conclusions upon the PBT/vPvB properties as the information required goes beyond the standard information requirements of REACH (Annexes VII to X).

When substance evaluation is considered to resolve the current uncertainty related to PBT/vPvB, it could be considered to address reprotoxicity also since there is an alert for reproductive toxicity based on a one generation study that is reflected by a self-classification (H361: Suspected of damaging fertility or the unborn child). This important endpoint could be investigated in more detail via substance evaluation where the missing developmental toxicity studies could be included in the substance evaluation requirements, but may alternatively be addressed via CCH. This could already be tackled by the CCH initiated by ECHA, prior to substance evaluation.

In addition, substance evaluation could also clarify the potential risks arising from exposure and the use of F-D3 for workers, for professional and consumer uses and for the environment.

Conclusions on the set of risk management options

From the evaluation of different risk management options described in section 5, authorization may eventually be an appropriate risk management route for F-D3. However, before the appropriateness of this route can be established, Harmonized Classification and Labelling (on STOT RE1) and Substance Evaluation (on P and B, and on exposure and uses) should preferably be conducted first.

Harmonising the classification and labelling is effective to ensure that the message on the hazards of F-D3 is communicated in a consistent manner. Harmonising the classification and labelling can also provide for the “T” in the PBT assessment.

Without the information and further insights on exposure and uses, the current data on F-D3 may be too weak to complete the ELoC case for SVHC under art 57(f). It is therefore concluded that Harmonized Classification and Labelling (on STOT RE1) only is

probably insufficient to continue on the SVHC route. F-D3 is not produced in Europe and is used in Europe primarily in the form of a polymer. Main exposure to humans or the environment may therefore occur through contact with any residual F-D3 monomer (concentration in the polymer is in the order of 0.5-1%). Exposure of workers and emission to the environment may be expected during manufacturing of the polymer, but this only occurs in a single plant in Europe. F-D3 therefore may eventually not meet the prioritization criteria for Annex XIV of wide dispersive use and consequently, after Candidate listing, the priority to select F-D3 for Annex XIV may be low. However, when F-D3 is shown to be a PBT substance, this will add to the concern for F-D3. If F-D3 is a PBT substance, the fact that emission to the environment is to be expected (via leaching from the polymer) a priority for Authorisation can be concluded.

Restriction seems a less appropriate regulation route because the data do not show an immediate reason for action, nor do the data indicate particular uses of high concern.

The following steps are proposed:

1. ***Harmonized Classification and Labelling for STOT RE1:*** The available information in the registration dossier is sufficient to establish harmonised classification with respect to STOT RE 1 (myotoxicity). Harmonised classification as STOT RE 1 can be used to motivate the Toxic (T) criterion for an eventual PBT assessment.
2. ***Substance evaluation to clarify P and B and the concern for reprotoxicity:*** Based on the current data, F-D3 fulfils the screening criteria for persistency and bioaccumulation. However, there are no data available to actually identify either P or B. These data have to be generated first through substance evaluation. With a harmonised classification for STOT RE 1, this substance may then meet the art. 57(d) criteria for PBT. The substance evaluation should then also further look at possible exposure and uses to clarify these issues in any further evaluation of the appropriateness of proposing authorization in a follow-up process. Finally, substance evaluation should address reprotoxicity as far as possible via the CCH initiated by ECHA prior to substance evaluation and possibly by asking for additional information.
3. ***Annex XV for Candidate listing and Authorization based on 57(d) or art 57(f):*** Harmonised classification as STOT RE 1 could be followed by Annex XV for SVHC according to art 57(d) after substance evaluation, or may be on art 57(f) though the ELoC support is considered rather weak. If substance evaluation results in the appropriate data to propose classification as Repro Tox Cat 1B, this could be taken up in the Annex XV also. However, the most appropriate follow-up should be evaluated again when substance evaluation and CLH are concluded.

In order to make the time frame of the overall process as short as possible, it is concluded to start the substance evaluation and the harmonized classification and labelling activities in parallel. Harmonised classification and labelling should preferably also address the end-point of reprotoxicity, if the concern appears justified. The timing is therefore crucial. It is expected that it will take some years before any data on reprotoxicity will be generated. It is therefore concluded to first address the STOT RE and to continue with an update of the harmonised classification and labelling for reprotoxicity, when appropriate, after the substance evaluation is concluded and data become available.