ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 21 April 2016

Addressee: [redacted]

Decision number: CCH-D-2114328256-51-01/F
Substance name: 2,4,6-trimethyl-2,4,6-tris(3,3,3-trifluoropropyl)cyclotrisiloxane
EC number: 219-154-7
CAS number: 2374-14-3
Registration number: [redacted]
Submission number: [redacted]
Submission date: 26.04.2013
Registered tonnage band: 100-1000 t/a

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on

1. **Updating of the CSR with available information on the modified OECD TG 111 (Hydrolysis as a Function of pH) study from the SIDS report (CoCAM 6, 30 - 03 October 2014) and/or the hydrolysis study [redacted] mentioned in the technical dossier (Annex I, Section 0.5.;**

2. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a first species (rats or rabbits), oral route with the registered substance;**

3. **Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24./OECD TG 308) at a temperature of 12 °C with the registered substance;**

4. **Soil simulation testing (Annex IX, Section 9.2.1.3.; test method: Aerobic and anaerobic transformation in soil, EU C.23./OECD TG 307) at a temperature of 12 °C with the registered substance**

5. **Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method with the registered substance;**

6. **Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous and dietary exposure, EU.C.13/OECD TG 305, dietary exposure) with the registered substance and/or its degradation products as relevant;**

7. **Revision of the PBT and vPvB assessment of the registered substance including the PBT and vPvB assessment of the relevant transformation and/or degradation products (Annex I, Section 4.0);**

8. Revision of the life-cycle of the registered substance, exposure assessment and risk characterization (Annex VI, Section 3.5. and Annex I, Sections 5.0. and 6.0.) - Considering all stages of the life-cycle of the registered substance.

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **28 January 2019**. **You shall also update the chemical safety report, where relevant.** The timeline has been set to allow for sequential testing.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

Appeal

[Applicable only for the final decision: 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, shall 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.]

[Applicable only for the final decision: Authorised[1] by Guilhem de Seze, Head of Unit, Evaluation E1**]**

[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 1: Reasons

1. **Updating of the CSR with available information on the modified OECD TG 111 (Hydrolysis as a Function of pH) study from the SIDS report (CoCAM 6, 30 - 03 October 2014) and/or the hydrolysis study [redacted] mentioned in the technical dossier (Annex I, Section 0.5.)**

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation, the registration shall contain a chemical safety report (CSR) which shall document the chemical safety assessment (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

Annex I Section 0.5. lays down that "*The chemical safety assessment shall be based on the information on the substance contained in the technical dossier and on other available and relevant information. ...Available information from assessments carried out under other international and national programmes shall be included.*"

ECHA notes that you have provided preliminary results from a Hydrolysis study [redacted] in section 5.1.2 of the technical dossier. In your dossier, you indicated that the study was *ongoing*. ECHA notes that since 2013 some time has passed and that at the time of this evaluation (autumn 2015) the study should have been completed. At the same time, ECHA notes that there is publicly available a summary SIDS report (CoCAM 6, 30 – 03 October 2014) referring to a study apparently identical to the study you refer to in your dossier.

Furthermore, Article 22(1)(e) REACH obliges registrants to update their registration without undue delay with relevant new information, amongst others, when new knowledge of the risks of the substance to human health and/or the environment of which he may reasonably be expected to have become aware which leads to changes in the safety data sheet or the chemical safety report. ECHA notes that the rate of hydrolysis and the formation of relevant degradation products is relevant for the assessment of exposure of the environment as well as the PBT and vPvB-assessment in the CSR. Also, Annex XIII fifth paragraph indicates that: "*The identification shall also take into account the PBT/vPvB-properties of relevant ... degradation products.*" However, ECHA notes that your dossier has not been updated with relevant information from these studies.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information: To update the CSR with available information from assessments carried out under international programmes, *i.e.* OECD SIDS (CoCAM 6, 30 – 03 October 2014) for the modified OECD TG 111 (Hydrolysis as a Function of pH) study and/or the hydrolysis study [redacted] mentioned in the technical dossier.

Note to your attention:

Information on hydrolysis is also a pre-requisite for the testing according to EU.C.13/OECD TG 305 for bioaccumulation in fish as requested under section 6 of this decision.

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

A "pre-natal developmental toxicity study" (test method EU B.31./OECD TG 414) for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of a pre-natal developmental toxicity study in the dossier that would meet the information requirement of Annex IX, Section 8.7.2.

You have sought to adapt this information requirement according to Annex IX, Section 8.7.2., column 2. You provided the following justification for the adaptation "*in accordance with Column 2 of REACH Annex IX, the pre-natal developmental toxicity study (required in Section 8.7.2), does not need to be conducted as the evidence available from an existing 1-generation reproductive toxicity indicates that the substance requires classification for developmental effects according to Regulation (EC) No 1272/2008*".

You have supported your justification with the study summary of a one generation reproductive toxicity study (Study report, 2001) resulting in the classification of the substance as toxic to reproduction category 2: Suspected of damaging fertility and the unborn child (H361).

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 8.7.2., column 2, because the column 2 of Annex IX, Section 8.7 state that "*If a substance is known to cause developmental toxicity, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered*". Hence, the classification from the one generation reproductive toxicity study, toxic to reproduction category 2, do not correspond to the column 2 rules of adaptation of Annex IX to omit the information requirements of Annex IX, Section 8.7.

Therefore, your adaptation of the information requirement is rejected.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to the test method EU B.31./OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default assumption ECHA considers testing should be performed with rats or rabbits as a first species.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.1, October 2015) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD TG 414) in a first species (rats or rabbits) by the oral route.

3. Sediment simulation testing (Annex IX, Section 9.2.1.4.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"Sediment simulation testing" is a standard information requirement as laid down in Annex IX, section 9.2.1.4. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the registered substance has low water solubility (1.3E-06 mg/l), high partition coefficient (log K_{ow} 9) and high adsorption coefficient (log K_{oc} 6), indicating the substance has a high potential for adsorption to sediment.

You have sought to adapt this information requirement according to Annex IX, Section 9.2.1.4., column 2. You provided the following justification for the adaptation: "*In accordance with Column 2 of REACH Annex IX, the simulation test on ultimate degradation in surface water and the sediment simulation test do not need to be conducted as the chemical safety assessment according to Annex I indicates that these are not necessary. The chemical safety assessment also indicates that identification of degradation products is not necessary*".

And further:

"*The chemical safety assessment according to REACH Annex I indicates that it is not necessary to conduct the simulation test on ultimate degradation in surface water and the sediment simulation test, or to identify degradation products. Simulation tests (water and sediments) are not considered necessary because exposure of the aquatic and sediment compartments is unlikely because:*
- The substance is classified for severe human health effects therefore measures are in place to minimise exposure.
- The physicochemical properties and high value of Koc means that if the substance could enter a wastewater treatment plant in influent waste waters, it would partition entirely to sludge (a small proportion may be volatilised), with a negligible amount passing to water. The result is that exposure of freshwater or marine aquatic compartments is negligible".

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.2., column 2, because a) there is no evidence that the exposure to aquatic compartment, and thus to sediment, through the wastewater treatment plant will be unlikely, and b) there is no evidence in the dossier that the substance does not leach from the polymer during downstream and end uses:

a) The registered substance is very volatile. As described in your qualitative exposure estimation of the submitted CSR, "the substance may be volatilised" from the wastewater stream and/or the treatment plant (in particular during the aeration step) due to the value for the vapour pressure of 88 Pa. According to information you provided in the dossier, the half-life of the substance in air is 3.6 days. The registered substance has therefore potential for long-range transport. The registered substance or its degradation products could thus reach surface water, sediment and soil.

b) The dossier does not provide any information on the end use of the substance. The dossier indicates that the substance is used as monomer to manufacture polymers, but it is neither clear what the downstream uses/end uses are nor whether unreacted substance could be released from the polymer or the final product, *i.e.* article.

Hence, ECHA believes that you have not demonstrated the exposure to sediment to be unlikely.

According to the information you provided in the dossier on screening for biodegradation in water (0% degradation in 28 days), the substance is not readily biodegradable.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 2.0, November 2014) Aerobic and anaerobic transformation in aquatic sediment systems (test method EU C.24./OECD TG 308) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.4.

One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of REACH regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*". The Guidance on information requirements and chemical safety assessment R.7b (version 2.0, November 2014) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-9 (version 2.1 October 2012) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD TG 308. Therefore, the test should be performed at the temperature of 12°C.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision

Aerobic and anaerobic transformation in aquatic sediment systems (test method: EU C.24./OECD TG 308).

Notes for your consideration

Before conducting the requested simulation tests (sections 3 and 4) you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.7b, Sections R.7.9.4 and R.7.9.6 (version 2.0, November 2014) and Chapter R.11, Section R.11.4.1.1 (version 2.0, November 2014) on PBT assessment to determine the sequence in which the simulation tests are to be conducted and the necessity to conduct all of them. The order in which the simulation biodegradation tests are performed needs to take into account the intrinsic properties of the registered substance and the identified use and release patterns which could significantly influence the environmental fate of the registered substance.

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the tests required by this decision are available. You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R.11, Section R.11.4.1.1. and Figure R. 11-3 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

4. Soil simulation testing (Annex IX, Section 9.2.1.3.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"Soil simulation testing" is a standard information requirement as laid down in Annex IX, section 9.2.1.3. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the registered substance has low water solubility (1.3E-06 mg/L), high partition coefficient (log Kow 9) and high adsorption coefficient (log Koc 6), indicating the substance has a high potential for adsorption to soil.

You have sought to adapt this information requirement according to Annex IX, Section 9.2., column 2 using the same justification as for sediment simulation testing above. You conclude that "*WWTP sludges are incinerated, therefore the result is that exposure of the terrestrial compartment is negligible.*"

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.2., column 2, because as discussed above, there is no evidence that the exposure to soil compartment through a wastewater treatment plant will be unlikely, and there is no evidence in the dossier that the substance does not leach from the polymer during downstream and end uses as already explained under section 3 above. Hence, ECHA therefore considers that you have not demonstrated that soil exposure is unlikely.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 2.0, November 2014) Aerobic and anaerobic transformation in soil (test method EU C.23. / OECD TG 307) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.3.

One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of REACH Regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*". The Guidance on information requirements and chemical safety assessment R.7b (version 2.0, November 2014) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-9 (version 2.1 October 2012) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD TG 307. Therefore, the test should be performed at the temperature of 12°C.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Aerobic and anaerobic transformation in soil (test method: EU C.23./OECD TG 307).

Notes for your consideration

Before conducting the requested simulation tests (sections 3 and 4), you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.7b, Sections R.7.9.4 and R.7.9.6 (version 2.0, November 2014) and Chapter R.11, Section R.11.4.1.1 (version 2.0, November 2014) on PBT assessment to determine the sequence in which the simulation tests are to be conducted and the necessity to conduct all of them. The order in which the simulation biodegradation tests are performed needs to take into account the intrinsic properties of the registered substance and the identified use and release patterns which could significantly influence the environmental fate of the registered substance.

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the tests detailed above is available. You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R.11, Section R.11.4.1.1. and Figure R. 11-3 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

5. Identification of degradation products (Annex IX, 9.2.3.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

The identification of the degradation products is a standard information requirement according to column 1, Section 9.2.3. of Annex IX of the REACH Regulation. Column 2 of Section 9.2.3. of Annex IX further states that the information does not need to be provided, if the substance is readily biodegradable.

You have sought to adapt this information requirement according to Annex IX, Section 9.2., column 2 using the same justification as for sediment simulation testing above. You state that "*The chemical safety assessment according to REACH Annex I indicates that it is not necessary to conduct the simulation test on ultimate degradation in surface water and the sediment simulation test, or to identify degradation products.*"

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.2.3, column 2, because the substance is not readily biodegradable.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance decision in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Regarding appropriate and suitable test method, the methods will have to be substance specific. When analytically possible, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound should be evaluated. In addition degradation half-life, log Kow and potential toxicity of the metabolite may be investigated.

Therefore, pursuant to Article 41(1)(a) and(b) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision:

Identification of the degradation products using an appropriate and suitable test method, as explained above in this section.

6. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.) with the registered substance and/or its degradation products if relevant

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"Bioaccumulation in aquatic species, preferably fish" is a standard information requirement as laid down in Annex IX, Section 9.3.2.of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance and/or its degradation products if relevant to meet this information requirement.

You have sought to adapt this information requirement according to Annex IX, column 2. You provided the following justification for the adaptation:

"*Exposure of the aquatic compartment is unlikely because:*

1. *The substance is classified for severe human health effects therefore measures are in place to minimise exposure*
2. *The physicochemical properties and very high value of Koc means that if the substance could enter a wastewater treatment plant in influent waste waters, it would partition entirely to sludges (see Section 9 of the CSR).*

Therefore, in accordance with Column 2 of REACH Annex IX, the bioaccumulation in aquatic species study does not need to be conducted".

You further noted in the CSR that "*The wider literature, e.g. BCFBAF (EPA, 2000), indicates that substances with very high log Kow values (>8), such as F-D3, do not bioaccumulate.*"

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.3.2., column 2 because:

1. Toxicity is not an adaptation possibility of Annex IX, Section 9.3.2., column 2.
2. As explained above (Appendix 1, Section 3; sediment simulation testing) you have not demonstrated the exposure to the environment to be unlikely (e.g. wastewater).

ECHA concludes that the condition of the specific rule of column 2 that "*direct and indirect exposure to the aquatic environment is unlikely*" is not met.

3. The Log Kow criterion, which would determine a substance to potentially fulfil the B/vB criteria, is based on that the uptake of an organic substance is driven by its hydrophobicity (ECHA Guidance R.7c, Section R.7.10.3.2). It cannot be used in case a substance is known to bioaccumulate by a mechanism other than passive diffusion driven by hydrophobicity (e.g. protein binding of fluorinated compounds). ECHA considers that there is not enough information about the bioaccumulation behaviour of the registered substance, to determine bioaccumulation potential based solely on Kow values.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7c* (version 2.0, November 2014) bioaccumulation in fish: aqueous or dietary exposure (test method EU C.13. / OECD TG 305) is the preferred test to cover the standard information requirement of Annex IX, Section 9.3.2.

According to ECHA guidance R.7c, chapter R.7.10.3.4, where the hydrolysis half-life is less than 12 hours at environmentally relevant pH values (4-9) and temperature, it can be assumed that the rate of hydrolysis is greater than that for uptake by the exposed organisms. Hence, in such cases it may be appropriate to perform a BCF test on the hydrolysis products, instead of the parent substance. However, because of uncertainties on whether hydrolysis actually occurs for the registered substance and on how fast it is, it is not possible to judge at this stage, whether the bioaccumulation study should be performed on the parent substance or on the potential hydrolysis products.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance and/or its degradation products if relevant subject to the present decision:

Bioaccumulation in fish: aqueous and dietary bioaccumulation fish test (test method: EU.C.13/OECD TG 305).

Notes for your consideration

You are advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R.11.4. and Figure R.11—4 on the PBT/vPvB assessment for further information on the integrated testing strategy for the bioaccumulation assessment of the registered substance. The bioaccumulation or bioconcentration potential of degradation products shall also be investigated when conducting the required test to be used for the PBT/vPvB assessment. You shall revise the PBT/vPvB assessment when information on bioaccumulation is available as part of revising the chemical safety report.

7. Revision of the PBT and vPvB assessment of the registered substance including the PBT and vPvB assessment of the relevant transformation and/or degradation products (Annex I, Section 4.0);

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation, the registration shall contain a chemical safety report (CSR) which shall document the chemical safety assessment (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation

Pursuant to Article 14(3)(d) and Section 4 of Annex I of the REACH Regulation a chemical safety assessment (CSA) performed by a Registrant shall include the PBT and vPvB assessment. Section 4.0.1. of Annex I notes that "*the objective of the PBT and vPvB assessment shall be to determine if the substance fulfils the criteria given in Annex XIII and if so, to characterise the potential emissions of the substance*". Annex XIII of the REACH Regulation lays down the criteria for the identification of persistent, bioaccumulative and toxic substances (PBT substances), and very persistent and very bioaccumulative substances (vPvB substances) as well as the information that must be considered for the purpose of assessing the P, B, and T properties of a substance.
Pursuant to the fifth introductory paragraph of Annex XIII, the identification of PBT/vPvB substances shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products.
ECHA acknowledges that you have summarised the outcome of the PBT and vPvB assessment of the registered substance in the CSR (Section 8) attached to the technical dossier, as well as in Section 2.3 of IUCLID. You have concluded that the registered substance is not persistent (not P) nor bioaccumulative (not B) but it is toxic (T), and therefore that the substance is not PBT/vPvB. However, ECHA notes, as already explained in Appendix 1 Section 3, that according to the screening biodegradation in water information you provided on the dossier, 0% degradation in 28 days, the substance is not readily biodegradable, and thus it fulfils the screening P or vP criteria. Besides, you conclude that the substance is T. According to Article 14(3)(d), PBT and vPvB assessment is required.

Also, ECHA notes that there is no indication in the CSR or in the technical dossier that the PBT/vPvB properties of any relevant degradation products were considered in the PBT and vPvB assessment. The information on degradation products is incomplete (see Appendix 1 Sections 1, 3-5). ECHA concludes that the consideration of degradation products of the registered substance in the PBT and vPvB assessment is missing.

Therefore, pursuant to Article 41(1), 41(3) and Annex XIII of the REACH Regulation, you are requested to revise the PBT and vPvB assessment of the registered substance and take into account of the PBT/vPvB-properties of the relevant transformation and/or degradation products.

8. Revision of the life-cycle of the registered substance, exposure assessment and risk characterization (Annex VI, Section 3.5. and Annex I, Sections 5.0. and 6.0.) - Considering all stages of the life-cycle of the registered substance

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation the registration shall contain a chemical safety report which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

According to Article 14(4), the CSR must include an exposure assessment and risk characterisation in the chemical safety assessment if the substance is assessed to be a PBT or vPvB or fulfils the criteria for any of the enumerated hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008. You classified the substance as toxic for reproduction in category 2, specific target organ toxic after repeated dose in category 1 (Oral, organs: heart, skeletal muscle) and specific target organ toxic after repeated dose in category 2 (Dermal, organs: liver) and therefore an exposure assessment and a risk characterization need to be included in the CSR.

Pursuant to Article 10(a)(iii) of the REACH Regulation the technical dossier shall contain information on the manufacture and use(s) of the substance representing all the registrant's identified uses, as specified in Annex VI, Section 3 of the REACH Regulation. In addition, pursuant to Annex I, Section 5, exposure assessment, which is a part of the chemical safety assessment (CSA), shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses. Pursuant to Annex I, Section 5.2.4., any required exposure estimation should take account of e.g. the activities of workers related to the processes. This information is required in the CSR, or a justification and documentation for its omission.

ECHA observes that in Section 3.5 of the technical IUCLID dossier, relating to the industrial use of the substance, you have identified that a use is as a monomer prepared from the substance to produce a polymer product. It should be noted that you have no identified uses in the section 3.5 of the technical IUCLID dossier for professional workers or consumers. ECHA notes that based on information you have provided in the technical registration dossier and in the CSR, uncertainty about a full life-cycle of the substance remains. ECHA notes that it can be anticipated the final polymer product has some uses, meaning that further life-cycle steps of the substance may exist. In the environmental exposure assessment, you have added the environmental release category, ERC 6c, with a text "industrial use of monomers for manufacture of thermoplastics". You have also added several sectors of use (SU3, 8, 9 and 10).

Further, in the CSR you state that "*typical wastes that may contain the substance during its use as a chemical intermediate are filter cake and filter plates*". The exposure assessment for human health contains two exposure scenarios covering assessment for the manufacture and uses of the registered substance to produce a polymeric product, both under closed conditions (PROC 1 only), with a third exposure scenario related to laboratory use (PROC 15). There is a concern that there may be potential for exposure beyond the description of PROC 1 to include e.g. handling of waste as well as maintenance and cleaning. Concern is increased by the low values of the DNELs you have provided for inhalation and dermal exposure for workers, and the low value provided for DNEL oral exposure for the general population, which is relevant to consumers who may be in contact to polymer products or articles. The assessment shall also include the exposure during the end use, e.g. evidence of the absence of exposure to residual monomer in the polymer, if that is the case.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to revise the life-cycle of the registered substance considering all stages of the life-cycle of the registered substance and to revise the exposure assessment and risk characterisation accordingly. If no further relevant stages of the life-cycle are identified and no uses are to be considered, an adequate justification for such a conclusion shall be given. The chemical safety report and section 3.5 of the technical IUCLID dossier shall be amended accordingly.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 19 November 2015.

[Applicable only for the final decision: The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation:**]**

ECHA notified you of the draft decision and invited you to provide comments. ECHA did not receive any comments by the end of the commenting period.

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) for amendment(s).
As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

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

2. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

3. In relation to the information required by the present decision, the sample of the substance used for the new test(s) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new test(s) is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new test(s) must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the test(s) to be assessed.