EUROPEAN CHEMICALS AGENCY

Helsinki, 23 November 2016

Addressee: [redacted]

Decision number: CCH-D-2114347550-54-01/F
Substance name: P-tert-butylstyrene
EC number: 217-126-9
CAS number: 1746-23-2
Registration number: [redacted]
Submission number: [redacted]
Submission date: 08.07.2014
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. ***In vitro*** **gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: Bacterial reverse mutation test, EU B.13/14. /OECD 471) with the registered substance;**

2. ***In vitro*** **cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2, test method: EU B.10/OECD 473) or *in vitro* micronucleus study (Annex VIII, Section 8.4.2, test method: OECD 487) with the registered substance;**

3. ***In vitro*** **gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD 476 or OECD 490), provided that both studies requested under 1. and 2. have negative results, with the registered substance;**

4. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2; test method: EU B.26/OECD 408) in rats with the registered substance;**

5. **Screening study for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: OECD 421 *or* 422) in rats, oral route with the registered substance;**

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

7. **Ready biodegradability (Annex VII, Section 9.2.1.1; test method: Ready biodegradability – CO_2 in sealed vessels (headspace test), OECD 310 or Closed bottle test EU C.4-E/OECD 301D) with the registered substance;**

8. **Identification of degradation products (Annex IX, Section 9.2.3.);**

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9. **Bioaccumulation in aquatic species (Annex IX, Section 9.3.2; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD 305, aqueous exposure) with the registered substance;**

10. **Short-term toxicity testing on fish (Annex VIII, Section 9.1.3; test method: Fish, acute toxicity test, OECD 203) with the registered substance;**

11. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1; test method: Fish, early-life stage (FELS) toxicity test, OECD 210) with the registered substance;**

12. **Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1; test method: *Daphnia sp*. Acute immobilisation test, EU C.2/OECD 202) with the registered substance;**

13. **Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211) with the registered substance;**

14. **with the registered substance; Growth inhibition study aquatic plants (Annex VII, Section 9.1.2; test method: Algae, growth inhibition test, EU C.3/OECD 201)**

15. **Activated sludge respiration inhibition test (Annex VIII, Section 9.1.4; test method: Activated Sludge, Respiration Inhibition Test (Carbon and Ammonium Oxidation), OECD 209) with the registered substance;**

16. **Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for environment: revise the environmental exposure assessment for all uses and revise the risk characterisation accordingly, as follows:**

    - use default release factors and other recommendations of ECHA Guidance R.16 and revise the risk characterisation accordingly or provide a detailed justification for not using the recommendations of ECHA Guidance R.16 for estimation of environmental exposure

    - use the default number of release days in accordance with the recommendations of ECHA Guidance R.16 or provide a detailed justification for not using the recommendations of ECHA Guidance R.16 for estimation of environmental exposure;

    - apply the "fraction of the main source" for exposure scenarios ES1, ES2, ES3 and ES4 in accordance with the recommendations of ECHA Guidance R.16 or provide a detailed justification for not using the recommendations of ECHA Guidance R.16 for estimation of environmental exposure;

17. **Exposure assessment (Annex I, Section 5.1.1) for human health: further specify the type of glove material, thickness and breakthrough times**

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You may adapt the testing requested above according to the specific rules outlined in Annexes VII to IX 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 **30 May 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

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.

Authorised[1] by Claudio Carlon, Head of Unit, Evaluation E2

[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.

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Appendix 1: Reasons

0. General rules for adaptation of the standard testing regime (Annex XI)

a) Grouping of substances and read-across approach (Annex XI, Section 1.5.)

Article 13(1) of the REACH Regulation provides that information on intrinsic properties of substances may be generated by means other than tests, "*provided that the conditions set out in Annex XI are met*". Annex XI of the REACH Regulation proposes some general rules for adapting the standard information requirements set out in Annexes VII to X of the REACH Regulation. In particular, Annex XI, Section 1.5. of the REACH Regulation introduces the concept of read-across. This concept is based on the identification of similar compounds. Information for one or more *source substances* or *reference substances* may be used to make a prediction for the *target substance* (i.e. the registered substance). According to that annex, the similarities between the source substance(s) and the target substance may be based on:

(1) "a common functional group;
(2) the common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals; or
(3) a constant pattern in the changing of the potency of the properties across the category".

That annex also specifies that in order to be acceptable, the results derived from a read-across approach should:

- *"be adequate for the purpose of classification and labelling and/or risk assessment,*
- *have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3),*
- *cover an exposure duration comparable to or longer than the corresponding test method referred to in Article 13(3) if exposure duration is a relevant parameter, and*
- *adequate and reliable documentation of the applied method shall be provided".*

In the registration dossier subject to this decision, you have provided a read-across approach using vinyl toluene (CAS: 25013-15-4) or para-methylstyrene (CAS: 622-97-9) as source substances[2] for the following endpoints:

1. *In vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.)
2. *In vitro* cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)
3. *In vitro* gene mutation study in mammalian cells, if negative results in Annex VII, Section 8.4.1. and in Annex VIII, Section 8.4.2. (Annex VIII, Section 8.4.3.)
4. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.)
5. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)
6. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)
7. Biodegradation in water and sediment (Annex VII, Section 9.2.1.1.)
9. Bioaccumulation (Annex IX, Section 9.3.2.)
10. Short-term toxicity to fish (Annex VIII, Section 9.1.3.)
12. Short-term toxicity to aquatic invertebrates (Annex VII, Section 9.1.1.)
14. Toxicity to aquatic algae and cyanobacteria (Annex VII, Section 9.1.2.)
15. Toxicity to aquatic microorganisms (Annex VIII, Section 9.1.4.)

[2] Vinyl toluene (CAS: 25013-15-4) is a generic name for different isomers. Para-methylstyrene (CAS: 622-97-9) is one of these isomers.

ECHA observes that you did not provide documentation establishing a basis whereby those endpoints for the registered substance may be predicted from data for the source substances. In the absence of any documentation supporting the proposed read-across approach, ECHA considers that you have failed to provide an adequate and reliable documentation of the applied method as required by Annex XI, Section 1.5 of the REACH Regulation. Therefore, ECHA is not in a position to evaluate your read-across approach and whether it could allow establishing that relevant properties of the registered substance can be predicted from those of the source substance.

The proposed read-across is therefore rejected. Accordingly, it is necessary to provide information on the registered substance.

b) Qualitative or Quantitative Structure-Activity Relationship ((Q)SAR) (Annex XI, Section 1.3.)

Annex XI, Section 1.3. of the REACH Regulation introduces the concept of Qualitative or Quantitative Structure-Activity Relationship ((Q)SAR) as another possible general rule for adapting the standard information requirements set out in Annexes VII to X of the REACH Regulation. Annex XI, Section 1.3. of the REACH Regulation specifies that (Q)SAR results may be used instead of testing if the following conditions are met:

- "*results are derived from a (Q)SAR model whose scientific validity has been established,*
- *the substance falls within the applicability domain of the (Q)SAR model,*
- *results are adequate for the purpose of classification and labelling and/or risk assessment, and,*
- *adequate and reliable documentation of the applied method is provided*".

In addition, the OECD Member Countries and the European Commission have adopted a set of five principles that should be considered when evaluating a (Q)SAR model for regulatory purposes[3]:

1. "*a defined endpoint;*
2. *an unambiguous algorithm;*
3. *a defined domain of applicability;*
4. *appropriate measures of goodness-of-fit, robustness and predictivity;*
5. *a mechanistic interpretation, if possible*".

In the registration subject to this decision, you have intended to cover by using (Q)SAR models the information requirements for the following endpoints:

1. *In vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.)
3. *In vitro* gene mutation study in mammalian cells, if negative results in Annex VII, Section 8.4.1. and in Annex VIII, Section 8.4.2. (Annex VIII, Section 8.4.3.)
6. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)
7. Biodegradation in water and sediment (Annex VII, Section 9.2.1.1.)
9. Bioaccumulation (Annex IX, Section 9.3.2.)
10. Short-term toxicity to fish (Annex VIII, Section 9.1.3.)
11. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)
12. Short-term toxicity to aquatic invertebrates (Annex VII, Section 9.1.1.)
13. Long-term toxicity to aquatic invertebrates (Annex IX, Section 9.1.5.)

[3] See ECHA Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of chemicals (May 2008)

The assessment of these (Q)SAR models is detailed for each of these endpoints in the respective sections below.

1. *In vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, your 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.

An "*In vitro* gene mutation study in bacteria" is a standard information requirement as laid down in Annex VII, Section 8.4.1. 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 sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a study record for a pre-guideline Bacterial reverse mutation test with the read-across substance vinyl toluene.

However, as explained above in Appendix 1, section 0(a) of this decision, your adaptation of the information requirement is rejected due to missing documentation and justification of your read-across approach. ECHA further notes that the use of non-GLP studies was not supported by adequate and reliable documentation.

You have also sought to adapt this information requirement according to Annex XI, Section 1.3. of the REACH Regulation by providing (Q)SAR prediction reports for "Mutagenicity model" (CAESAR), "Benigni-Bossa Mutagenicity" (TOXTREE) and "Mutagenicity SarPy model".

However, you have not discussed the validity of your conclusion and also you have not indicated whether the predicted results are derived from (Q)SAR models whose scientific validity has been established, and are adequate for the purpose of classification and labelling and/or risk assessment. Furthermore, you have not provided adequate and reliable documentation of the applied methods. Specifically, you have not indicated the training set used for the models. Hence, the information based on those (Q)SAR models does not meet the criteria listed under Annex XI, Section 1.3, and your adaptation of the information requirement of Annex VII, Section 8.4.1. 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.

ECHA considers that the bacterial reverse mutation test (test method EU B.13/14./OECD 471) is appropriate to address the standard information requirement of Annex VII, Section 8.4.1. of the REACH Regulation.

In your comments to the draft decision, you indicated your agreement to perform the requested study on the registered substance.

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: Bacterial reverse mutation test (test method: EU B.13./B.14./OECD 471).

2. *In vitro* cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, your 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.

An "*In vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study" is a standard information requirement as laid down in Annex VIII, Section 8.4.2. 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 sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing, e.g., pre-guideline study records for an *in vivo* mammalian erythrocyte micronucleus test and an *in vivo* mammalian bone marrow chromosome aberration test with the read-across substance vinyl toluene.

However, as explained above in Appendix 1, section 0(a) of this decision, your adaptation of the information requirement is rejected due to missing documentation and justification of your read-across approach.

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.

ECHA considers that the *in vitro* mammalian chromosome aberration test (test method EU B.10./OECD 473) and the *in vitro* micronucleus test (OECD 487) are appropriate to address the standard information requirement of Annex VIII, Section 8.4.2. of the REACH Regulation.

In your comments to the draft decision, you indicated your agreement to perform the requested study on the registered substance.

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: *In vitro* cytogenicity study in mammalian cells (test method: EU B.10./OECD 473) or *in vitro* mammalian cell micronucleus study (test method: OECD 487).

3. *In vitro* gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, your 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.

An "*In vitro* gene mutation study in mammalian cells" is an information requirement as laid down in Annex VIII, Section 8.4.3. of the REACH Regulation, "if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2." is obtained.
You have not provided any study record of an *in vitro* gene mutation study in mammalian cells in the dossier that would meet the information requirement of Annex VIII, Section 8.4.3.

Instead, you have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a study record for a pre-guideline *in vitro* mammalian cell gene mutation test with the read-across substance vinyl toluene.

However, as explained above in Appendix 1, section 0(a) of this decision, your adaptation of the information requirement is rejected due to missing documentation and justification of your read-across approach.

You have also sought to adapt this information requirement according to Annex XI, Section 1.3. of the REACH Regulation by providing (Q)SAR prediction reports for "Mutagenicity model" (CAESAR), "Benigni-Bossa Mutagenicity" (TOXTREE) and "Mutagenicity SarPy model". You have concluded that the (Q)SAR models assessments have predicted the registered substance as "non mutagen".

As discussed under section 1 of this decision, the information based on those (Q)SAR models does not meet the criteria listed under Annex XI, Section 1.3, and your adaptation of the information requirement of Annex IX, Section 8.4.3., 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.

ECHA considers that the *in vitro* mammalian cell gene mutation test – *hprt* test (OECD 476) and the *in vitro* mammalian cell gene mutation test – Mouse lymphoma assay (OECD 490) are appropriate to address the standard information requirement of Annex VIII, Section 8.4.3.

In your comments to the draft decision, you indicated your agreement to perform the requested study on the registered substance.

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: *In vitro* mammalian cell gene mutation test (test method: OECD 476 *or* OECD 490) provided that both studies requested under sections 1. and 2. of the present decision have negative results.

4. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, your 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 "sub-chronic toxicity study (90 day)" is a standard information requirement as laid down in Annex IX, Section 8.6.2. 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 sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study records, e.g. for two pre-guideline sub-chronic toxicity studies in rats by the oral route and two pre-guideline sub-chronic toxicity studies in rats by the inhalation route with the source substance vinyl toluene.

Pursuant to Annex XI, Section 1.5 of the REACH Regulation, information supporting a read-across approach must be appropriate for the purpose of classification and/or risk assessment. However, ECHA notes that none of the studies provides a "no observed effect level" (NOAEL), which renders the studies invalid for the risk assessment or for classification.

Furthermore, as explained above in Appendix 1, section 0(a) of this decision, your adaptation of the information requirement is rejected due to missing documentation and justification of your read-across approach.

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.

ECHA has evaluated the most appropriate route of administration for the study. Based on the information provided in the technical dossier and/or in the chemical safety report, ECHA considers that the oral route - which is the preferred one as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.1, October 2015) Chapter R.7a, section R.7.5.4.3 - is the most appropriate route of administration. More specifically, even though the information indicates that human exposure to the registered substance by the inhalation route is likely and the substance could be expected to lead to respiratory tract irritation following inhalation exposure, performance of an oral study is considered more appropriate in the absence of any repeated dose toxicity study by the oral route. Hence, the test shall be performed by the oral route using the test method EU B.26./OECD TG 408.

In your comments to the draft decision, you indicated that you would still intend to use a read-across approach but that you considered the timeframe set out in the draft decision too short for that purpose. Furthermore, you stated that ECHA had no right to request studies listed in Annex IX or X of the REACH Regulation in a compliance check and that those studies could only be requested after a registrant had submitted testing proposals.

ECHA acknowledges that the requested information might be adapted as long as the proposed adaptations meet the requirements of Annex XI of the REACH Regulation or of column 2 of Annex IX of the REACH Regulation. However, ECHA notes that you have not provided further details on the read-across approach you intend to apply, and so ECHA cannot assess the validity of this approach.

ECHA further notes that you did not provide a reasoned justification (with documentation of the timeline required) for why you considered the timeframe set out in the decision to be too short, and so ECHA cannot accept your proposal for an extension of the deadline for testing.

Finally, ECHA disagrees with your interpretation that studies listed in Annex IX of the REACH Regulation cannot be requested during a compliance check. There is no provision in the REACH Regulation that states that compliance check cannot address information requirements of Annexes IX and X of the REACH Regulation. On the contrary, Article 41(1)(a) and (1)(b) of the REACH Regulation indicates that ECHA may check the compliance, respectively, of the information provided in the registration dossier with the requirements of Articles 10, 12 and 13 of the REACH Regulation and with Annexes III and VI to X of the REACH Regulation, and of the adaptations provided in the registration dossier with the requirements of Annexes VII to X of the REACH Regulation and with the general rules set out in Annex XI of the REACH Regulation. As explained above, ECHA considers that the adaptations you proposed are not valid and ECHA notes that you did not make testing proposals when you submitted your dossier. There is therefore a data gap for the endpoint, and pursuant to Article 41 of the REACH Regulation, ECHA is entitled to request the missing information in a compliance check.

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: Repeated dose 90-day oral toxicity study (test method: EU B.26./OECD 408) in rats.

5. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, your 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.

"Screening for reproductive/developmental toxicity" (test method OECD 421 or 422) is a standard information requirement as laid down in Annex VIII, Section 8.7.1. of the REACH Regulation if there is no evidence from available information on structurally related substances, from (Q)SAR estimates or from *in vitro* methods that the substance may be a developmental toxicant. As explained further below, no such evidence is presented in the dossier. Therefore, adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a study record for a pre-guideline "Two generation reproductive toxicity study" (OECD 416) with the source substance vinyl toluene. You have further provided the following justification: "*Existence of 2-generation study known. Data access to be obtained. 'Reproductive Effects of p-Methylstyrene Administered Orally via Gavage to Crl:COBSCD(SD) BR Rats for Two Generations. Argus Research Laboratories, Report No. 2161-80, September 22, 1982.' Cannot justify use of addtional animals if this data is avialable.*"

ECHA notes that no data on reproductive/developmental toxicity, either on the registered substance or the source substance, is available in the technical dossier.

Furthermore as explained above in Appendix 1, section 0(a) of this decision, your adaptation of the information requirement is rejected due to missing documentation and justification of your read-across approach.

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 methods OECD 421 and OECD 422, the test is designed for use with rats. On the basis of this default assumption ECHA considers testing should be performed with rats.

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.

In your comments to the draft decision, you indicated your agreement to perform the requested study on the registered substance.

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: Reproductive/developmental toxicity screening test (test method: OECD 421) *or* Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (test method: OECD 422) in rats by the oral route.

Note for your consideration:

For the selection of the appropriate test, please consult ECHA *Guidance on information requirements and chemical safety assessment*, Chapter R.7a, section R.7.5 and 7.6 (version 4.1, October 2015). You are also reminded to carefully consider the order of testing.

6. 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, your 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 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 sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study records, e.g. pre-guideline developmental toxicity studies, three in rat and two in rabbit, with the read-across substances vinyl toluene.

However, as explained above in Appendix 1, section 0(a) of this decision, your adaptation of the information requirement is rejected due to missing documentation and justification of your read-across approach.

You have further sought to adapt this information requirement according to Annex XI, Section 1.3. of the REACH Regulation by providing (Q)SAR prediction reports for "Developmental Toxicity model (CAESAR)". You concluded that the (Q)SAR model assessments have predicted the registered substance as "*not be a developmental toxicant however, p-tert-butylstyrene maybe out of the model applicability domain*".

ECHA takes note of your statement that the registered substance may be out of the applicability domain of the model. However, according to Annex XI, Section 1.3, the results of a (Q)SAR prediction may be used only if the substance falls within the applicability domain.

Furthermore, you have not indicated whether the predicted results are derived from (Q)SAR models whose scientific validity has been established, and are adequate for the purpose of classification and labelling and/or risk assessment. You have not provided adequate and reliable documentation of the applied methods either. Specifically, you have not indicated the training set used for the models.

Hence, the information based on those (Q)SAR models does not meet the list of criteria listed under Annex XI, Section 1.3., and your adaptation of the information requirement of Annex IX, Section 8.7.2. 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 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.

In your comments to the draft decision, you indicated that you would still intend to use a read-across approach but that you considered the timeframe set out in the draft decision too short for that purpose. Furthermore, you stated that ECHA had no right to request studies listed in Annex IX or X of the REACH Regulation in a compliance check and that those studies could only be requested after a registrant had submitted testing proposals.

ECHA acknowledges that the requested information might be adapted as long as the proposed adaptations meet the requirements of Annex XI of the REACH Regulation or of column 2 of Annex IX of the REACH Regulation. However, ECHA notes that you have not provided further details on the read-across approach you intend to apply, and so ECHA cannot assess the validity of this approach.

ECHA further notes that you did not provide a reasoned justification (with documentation of the timeline required) for why you considered the timeframe set out in the decision to be too short, and so ECHA cannot accept your proposal for an extension of the deadline for testing.

Finally, ECHA disagrees with your interpretation that studies listed in Annex IX of the REACH Regulation cannot be requested during a compliance check. There is no provision in the REACH Regulation that states that compliance check cannot address information requirements of Annexes IX and X of the REACH Regulation. On the contrary, Article 41(1)(a) and (1)(b) of the REACH Regulation indicates that ECHA may check the compliance, respectively, of the information provided in the registration dossier with the requirements of Articles 10, 12 and 13 of the REACH Regulation and with Annexes III and VI to X of the REACH Regulation, and of the adaptations provided in the registration dossier with the requirements of Annexes VII to X of the REACH Regulation and with the general rules set out in Annex XI of the REACH Regulation. As explained above, ECHA considers that the adaptations you proposed are not valid and ECHA notes that you did not make testing proposals when you submitted your dossier. There is therefore a data gap for the endpoint, and pursuant to Article 41 of the REACH Regulation, ECHA is entitled to request the missing information in a compliance check.

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 414) in a first species (rats or rabbits) by the oral route.

7. Ready biodegradability (Annex VII, Section 9.2.1.1.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, your 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.

"Ready biodegradability and "simulation testing on ultimate degradation in water" are standard information requirements as laid down respectively in Annex VII, Section 9.2.1.1. and in Annex IX, Section 9.2.1.2. of the REACH Regulation.

Adequate information on these endpoints needs to be present in the technical dossier for the registered substance to meet these information requirements.

Information on biodegradation is necessary for the PBT/vPvB assessment and for the risk assessment and shall be considered for the classification and labelling of the substance.

ECHA notes that no experimental data with the registered substance is available for biodegradation.

In Section 5.2.1 of IUCLID (Biodegradation, screening tests) you have provided an old non-guideline, non-GLP study ([redacted] on the read-across substance vinyl toluene. This study has shown that 13% of vinyl toluene was removed in the first 15 days of the sampling period and 32% in the period of 15 to 20 days.

In section 5.2.2 of IUCLID (Biodegradation, simulation tests), you have provided another old non-guideline, non-GLP study ([redacted])) for the same source substance, i.e. vinyl toluene. This 33 day study was conducted using a simulated sewage treatment plant environment. This study has shown that the primary loss route from sewage treatment plants for vinyl toluene is by aeration/volatilisation rather than by biodegradation.

In addition, also in section 5.2.2 of IUCLID (simulation tests), you submitted a QSAR (Quantitative Structure Activity Relationship) result from model BIOWIN (v 4.1). This model predicts no biodegradability of the registered substance.

Based on these 3 results, you have concluded that the registered substance is not readily biodegradable and that it is very persistent (vP).

ECHA considers that you have not demonstrated that the registered substance is not bioaccumulative (B) or not very bioaccumulative (vB) (see section 9 below) and that it is not toxic (see sections 10-14 below). Therefore a definitive conclusion on persistence is needed for the PBT/vPvB assessment.

As explained above in Appendix 1, section 0(a) of this decision, your adaptation of the information requirement is rejected due to missing documentation and justification of your read-across approach with vinyl toluene.

Besides, the QSAR result you have submitted should be regarded as a screening information only but does not constitute a definitive conclusion that the substance meets the very persistent (vP) criterion or the persistent (P) criterion for the PBT/vPvB assessment. According to Annex XIII 2.1 of the REACH Regulation, if a result from a screening test or from other screening information indicates that "*the substance may have PBT or vPvB properties, the registrant shall generate relevant additional information as set out in Section 3.2 of this Annex*".

Therefore, the information you have provided in the technical dossier is insufficient to conclude on the persistence of the registered substance and therefore on its PBT/vPvB status. Consequently, there is an information gap and it is necessary to provide information on the biodegradability or persistence of the substance.

ECHA notes that the registered substance is volatile (Henry's Law Constant is 723 $Pa.m^3.mol^{-1}$). Therefore you shall use test guidelines appropriate for volatile substances. For ready biodegradability, test guidelines OECD 310 or OECD 301D are considered suitable for volatile substances. However, simulation tests may not be technically feasible with very volatile substances. Still, in order to carry out the PBT/vPvB assessment, it is necessary to gain further insight on the potential for inherent biodegradability or persistence of the substance. ECHA notes that an enhanced biodegradation screening test could provide such insight. Therefore you should consider adapting the test protocols of the requested ready biodegradability tests OECD 310 or OECD 301D in order to have enhanced tests that could be used to clarify whether the substance is inherently biodegradability or not.

According to ECHA's Guidance Section R.7.9.4.1, enhanced biodegradation screening tests are based on the same test guidelines as for ready biodegradability tests, but could include modifications such as:

- Longer test duration: weekly determinations could be continued up to day 60.
- Larger vessels to increase the total number of microorganisms and the number of different types introduced into the test vessel (without changing the density of microorganisms). This increases the probability of introducing a competent microorganism into the test vessel.
- Increased biomass concentration (also changing the density of microorganisms). This will also increase the probability of introducing a competent microorganism into the test vessel.
- Low-level pre-adaptation test systems: e.g. by conducting a second ready biodegradability test using the inoculum derived from the initial study. This should reduce the lag period preceding the onset of biodegradation.

- Semi-continuous assessments, i.e. by conducting a ready biodegradability study using an inoculum derived from test systems fed with the test substance at environmentally realistic concentrations on a semi-continuous basis. This helps to maintain the diversity, viability and nutrient status of the biodegradability tests whilst allowing the potential for adaptation to be determined over time.

Furthermore, you can implement the analytical determination of the parent substance and of its degradation products in order to identify those degradation products and to follow the kinetics of the degradation.

In your comments to the draft decision, you indicated your agreement to perform the requested study on the registered substance.

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: Ready Biodegradability with one of the following test methods: Ready biodegradability – CO2 in sealed vessels (headspace test), OECD 310 or Closed bottle test EU C.4-E/OECD 301D. Furthermore, you should consider adapting the chosen test protocol following Guidance Section R.7.9.4.1 on "Enhanced Biodegradation Screening Tests" in order to investigate the potential inherent biodegradability of your substance.

Note for your consideration

Annex I, Section 4. of the REACH Regulation requires you to perform the PBT and vPvB assessment of your substance. The requested information shall be taken into account for revising the PBT/vPvB assessment in your dossier.

Pursuant to Annex I, Section 0.6.2 and Annex I, Sections 5 and 6. of the REACH Regulation, the requested information shall also be taken into account for revising the exposure assessment and risk characterisation in your dossier.

8. Identification of degradation products (Annex IX, Section 9.2.3.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, your 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 degradation products do not need to be identified if the substance is readily biodegradable.

The identification of degradation products is necessary for the PBT/vPvB assessment (Annex XIII of the REACH Regulation) and for the compilation of safety data sheets (Annex II of the REACH Regulation).
You have concluded that your substance is not readily biodegradable. Nevertheless, your dossier does not contain information on the identity of the degradation products.

You further argue that "*as the molecule consists entirely of carbon and hydrogen it is considered unlikely that degradates following photodecomposition will be of toxicological or ecotoxicological concern*". However, this statement is not supported by any valid and reliable scientific evidence.

As explained also in Section (7) above, ECHA considers that with the current information the CSA cannot be used to justify that there is no need to investigate further the degradation of the substance and its degradation products. ECHA notes further that the information requested here is needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment.

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.

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. As advised in Section (7) above, you have the possibility to obtain this information from a modified enhanced biodegradation test given as option in section (7). You may also obtain this information by some other measure. In any case, you will need to provide a scientifically valid justification for the chosen method.

In your comments to the draft decision, you indicated that you would intend to use a read-across approach but that you considered the timeframe set out in the draft decision too short for that purpose. Furthermore, you stated that ECHA had no right to request studies listed in Annex IX or X of the REACH Regulation in a compliance check and that those studies could only be requested after a registrant had submitted testing proposals.

ECHA acknowledges that the requested information might be adapted as long as the proposed adaptations meet the requirements of Annex XI of the REACH Regulation or of column 2 of Annex IX of the REACH Regulation. However, ECHA notes that you have not provided further details on the read-across approach you intend to apply, and so ECHA cannot assess the validity of this approach.

ECHA further notes that you did not provide a reasoned justification (with documentation of the timeline required) for why you considered the timeframe set out in the decision to be too short, and so ECHA cannot accept your proposal for an extension of the deadline for testing.

Finally, ECHA disagrees with your interpretation that studies listed in Annex IX of the REACH Regulation cannot be requested during a compliance check. There is no provision in the REACH Regulation that states that compliance check cannot address information requirements of Annexes IX and X of the REACH Regulation. On the contrary, Article 41(1)(a) and (1)(b) of the REACH Regulation indicates that ECHA may check the compliance, respectively, of the information provided in the registration dossier with the requirements of Articles 10, 12 and 13 of the REACH Regulation and with Annexes III and VI to X of the REACH Regulation, and of the adaptations provided in the registration dossier with the requirements of Annexes VII to X of the REACH Regulation and with the general rules set out in Annex XI of the REACH Regulation. As explained above, ECHA considers that the adaptations you proposed are not valid and ECHA notes that you did not make testing proposals when you submitted your dossier. There is therefore a data gap for the endpoint, and pursuant to Article 41 of the REACH Regulation, ECHA is entitled to request the missing information in a compliance check.

Therefore, pursuant to Article 41(1)(a) 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.

Notes for your consideration

Annex I, Section 4. of the REACH Regulation requires you to perform the PBT and vPvB assessment of your substance. The requested information shall be taken into account for revising the PBT/vPvB assessment in your dossier.

Pursuant to Column 2 of Section 9.2.3. of Annex IX of the REACH Regulation, the requested information need not be provided if the substance is shown to be readily biodegradable after the ready biodegradability test requested in Section 7 of that decision has been completed.

9. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, your 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 to meet this information requirement.

Information on bioaccumulation is necessary for the PBT/vPvB assessment and for the risk assessment and shall be considered for the classification and labelling of the substance. ECHA notes that you have not provided any experimental data on the registered substance for endpoint bioaccumulation. You have sought to adapt this information requirement instead by applying a read-across adaptation (Annex XI, Section 1.5. of the REACH Regulation) and by using predictions from three different (Q)SAR models (Annex XI, Section 1.3. of the REACH Regulation).

a) Read-across hypothesis (Annex XI, Section 1.5.)

You have provided two results, respectively on *Ictalurus punctatus* and *Lepomis macrochirus*, from an old non-guideline study ([redacted] for the read-across substance p-methyl styrene (synonym: vinyl toluene).

According to Annex XI, Section 1.5. of the REACH Regulation and as further explained in Appendix 1, section 0(a) of this decision, adequate and reliable documentation of the applied method for the read-across approach shall be provided. You have provided no information that would support that similarities relevant for the assessment of the endpoint exist between the target substance and the source substance. In particular, ECHA notes that log Kow for vinyl toluene is 3.44 whereas log Kow for the registered substance is 4.44. Water solubility for vinyl toluene is 117 mg/L whereas it is 5 mg/L for the registered substance. The lower log Kow value and higher water solubility limit of the read-across substance compared to the registered substance suggest that the bioaccumulation potential of the read-across substance is less than for the registered substance, i.e. that the read-across approach you have used could have underestimated the bioaccumulation potential of the registered substance.

Furthermore, ECHA notes that different QSAR models, some of which you have used for your assessment (see section 9(b) below), do not support this read-across approach either: they systematically predict lower bioconcentration factor (BCF) values for the source substance than for the target substance.

Therefore ECHA considers that the read-across approach you have used cannot be accepted.

b) (Q)SAR hypothesis (Annex XI, Section 1.3.)

You have provided (Q)SAR predictions from three different models embedded in the so-called VEGA tool (http://www.vega-qsar.eu/):

- CAESAR model (version 2.1.13)
- EPISUITE BCF model (Meylan) (version 1.0.2)
- "BCF Read-Across" model (version 1.0.2)

The BCF value predicted from the CAESAR model is 939 (log BCF: 2.97). ECHA notes that for this model, multiple descriptors are used but that the choice of these descriptors is not deterministic (use of heuristic and genetic algorithms), therefore a mechanistic interpretation is not possible.

Furthermore, in the report attached to the study summary, the predicted value is provided with its confidence interval. The upper limit of the confidence interval is 4677 (log BCF: 3.67) which is above the B criterion defined in Annex XIII of the REACH Regulation for the identification of PBT/vPvB substances. On this basis, and for the reasons explained under section 0(b) of that decision, the information based on this (Q)SAR model does not meet the list of criteria listed under Annex XI, Section 1.3 of the REACH Regulation and the registered substance cannot be adequately classified as not B and is potentially bioaccumulative.

As for the EPISUITE BCF model (Meylan), although you have used another interface (VEGA tool), this model is based on a regression-based approach as implemented in the US-EPA piece of software, EPI Suite. ECHA notes that the result reported for this model differs between different parts of the dossier or even between different sections of the study summary. The value of 687 (log BCF: 2.84) is given in the report attached to the robust study summary and in the executive summary field of the study summary of IUCLID, whereas the value of 331 (log BCF: 2.52) is reported in the CSR and in the result section of the study summary in IUCLID. No prediction interval is available for this model. Furthermore, ECHA notes that EPI Suite also proposes results for an alternative model, the Arnot-Gobas method, which predicts a higher BCF of 1322. However you have not provided a justification why you had not discussed in your assessment this result which is substantially higher than the one predicted from the regression-based approach (i.e. Meylan method). Therefore, you did not establish the scientific validity of this model nor provide adequate and reliable documentation, as required by Annex XI, Section 1.3, and this result cannot be taken into account

The last (Q)SAR result you have provided is from a model identified as "BCF Read-Across". A log BCF value of 2.49 (BCF: 309) is reported. However, ECHA notes that no information is provided on this model (e.g.: algorithm, domain of applicability, statistical characteristics). Therefore, you did not establish the scientific validity of this model nor provide adequate and reliable documentation, as required by Annex XI, Section 1.3, and this result cannot be taken into account.

c) Other concerns

ECHA notes that in the CSR and in the endpoint summary in IUCLID, the BCF value of 2.49 has been chosen. This value is not correct. It is actually a log value (the corresponding value in the linear scale is a BCF of 309) and must not be used directly as input value for the risk assessment, the PBT/vPvB assessment or for classification and labelling. Furthermore, as explained above (see section 9(b)), the log BCF value of 2.49 (i.e. BCF value of 309) comes from a model whose validity cannot be assessed and which therefore cannot be considered.

ECHA further notes that you have come to conclusions that are not consistent between the different parts of your dossier. In the endpoint summary for bioaccumulation in IUCLID, you have concluded that the substance has a low potential for bioaccumulation. However, for the PBT assessment you have classified the substance as B. Considering that the substance has a log Kow of 4.44, ECHA disagrees with the conclusion that the substance has a low potential for bioaccumulation. ECHA considers that the information you have provided for bioaccumulation per se is either invalid or should be regarded as screening information only. No definitive conclusion is therefore possible on whether the registered substance meets the very bioaccumulative (B) criterion for the PBT/vPvB assessment. According to Annex XIII 2.1 of the REACH Regulation, if a result from a screening test or from other screening information indicates that "*the substance may have PBT or vPvB properties, the registrant shall generate relevant additional information as set out in Section 3.2 of this Annex*".

d) Outcome

From the information provided in the dossier, no definitive conclusion can be drawn with regard to the B status of the substance.

ECHA considers that you have not demonstrated that the registered substance is not persistent (P) or not very persistent (vP) (see section 7 above) or that it is not toxic (see sections 10-14 below). Therefore a definitive conclusion on bioaccumulation is needed for the PBT/vPvB assessment.

As explained above, the information provided on this endpoint in the technical dossier does not meet the information requirement of Annex IX, Section 9.3.2.of the REACH Regulation. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA considers the OECD 305 test guideline (Bioaccumulation in Fish Aqueous and Dietary Exposure), and more particularly part I of that test (OECD 305-I: Aqueous Exposure Bioconcentration Fish Test) to be appropriate to meet that information requirement.

In your comments to the draft decision, you indicated that you would still intend to use a read-across approach but that you considered the timeframe set out in the draft decision too short for that purpose. Furthermore, you stated that ECHA had no right to request studies listed in Annex IX or X of the REACH Regulation in a compliance check and that those studies could only be requested after a registrant had submitted testing proposals.

ECHA acknowledges that the requested information might be adapted as long as the proposed adaptations meet the requirements of Annex XI of the REACH Regulation or of column 2 of Annex IX of the REACH Regulation. However, ECHA notes that you have not provided further details on the read-across approach you intend to apply, and so ECHA cannot assess the validity of this approach.

ECHA further notes that you did not provide a reasoned justification (with documentation of the timeline required) for why you considered the timeframe set out in the decision to be too short, and so ECHA cannot accept your proposal for an extension of the deadline for testing.

Finally, ECHA disagrees with your interpretation that studies listed in Annex IX of the REACH Regulation cannot be requested during a compliance check. There is no provision in the REACH Regulation that states that compliance check cannot address information requirements of Annexes IX and X of the REACH Regulation. On the contrary, Article 41(1)(a) and (1)(b) of the REACH Regulation indicates that ECHA may check the compliance, respectively, of the information provided in the registration dossier with the requirements of Articles 10, 12 and 13 of the REACH Regulation and with Annexes III and VI to X of the REACH Regulation, and of the adaptations provided in the registration dossier with the requirements of Annexes VII to X of the REACH Regulation and with the general rules set out in Annex XI of the REACH Regulation. As explained above, ECHA considers that the adaptations you proposed are not valid and ECHA notes that you did not make testing proposals when you submitted your dossier. There is therefore a data gap for the endpoint, and pursuant to Article 41 of the REACH Regulation, ECHA is entitled to request the missing information in a compliance check.

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: Bioaccumulation in Fish: Aqueous and Dietary Exposure (test method: OECD 305, part I: Aqueous Exposure Bioconcentration Fish Test).

Note for your consideration

Before conducting the above test 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 assessment for further information on the integrated testing strategy for the bioaccumulation assessment of the registered substance. You should revise the PBT assessment when information on bioaccumulation is available.

In addition, you are advised to consult the ECHA Guidance on the standard information requirements and chemical safety assessment (version 2.0, November 2014), Chapters R.4, 5, 6, R.7b and R.7c. Where you decide to adapt the testing requested 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, ECHA refers you to the advice provided in Practical Guides 4, 5 and 6.

Annex I, Section 4. of the REACH Regulation requires you to perform the PBT and vPvB assessment of your substance. The requested information shall be taken into account for revising the PBT/vPvB assessment in your dossier. Pursuant to the CLP Regulation (Regulation (EC) No 1272/2008), you shall also consider revising the classification and labelling of your substance.
Pursuant to Annex I, Section 0.6.2 and Annex I, Sections 5 and 6. of the REACH Regulation, the requested information shall be taken into account for revising the exposure assessment and risk characterisation in your dossier.

10. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, your 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.

"Short-term toxicity testing on fish" is a standard information requirement as laid down in Annex VIII, Section 9.1.3. 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.

Information on short-term toxicity testing on fish is necessary for the risk assessment and shall be considered for the classification and labelling of the substance.
ECHA notes that you have not provided any experimental data on the registered substance for this endpoint. You have sought to adapt this information requirement instead by applying a read-across adaptation (Annex XI, Section 1.5. of the REACH Regulation) and by using predictions from two different (Q)SAR models (Annex XI, Section 1.3. of the REACH Regulation).

a) Read-across hypothesis (Annex XI, Section 1.5.)

You have provided results from three different studies with the read-across substance vinyl toluene:

- The first study ([redacted] was performed on *Pimephales promelas* according to OECD guideline 203 and gives a 96h-LC50 of 5.2 mg/L.

- The second study ([redacted]) was performed on *Lepomis macrochirus* according to an old US-EPA guideline and gives a 96h-LC50 of 2.8 mg/L.

- The third study ([redacted]) was performed on *Oncorhynchus mykiss* according to an old US-EPA guideline and gives a 96h-LC50 of 7.6 mg/L. However, you have discarded that study because it was conducted in a non-sealed static system.

According to Annex XI, Section 1.5. of the REACH Regulation and as further explained in Appendix 1, section 0(a) of this decision, adequate and reliable documentation of the applied method for the read-across approach shall be provided. However, you have provided no information that would support that similarities relevant for the assessment of the endpoint exist between the registered substance and the read-across substance. In particular, ECHA notes that log Kow for vinyl toluene is 3.44 whereas log Kow for the registered substance is 4.44. Water solubility for vinyl toluene is 117 mg/L whereas it is 5 mg/L for the registered substance.

The lower log Kow value and higher water solubility limit of the read-across substance compared to the registered substance suggest that the baseline toxicity of the read-across substance is less than for the registered substance, i.e. that the read-across approach you have used could have underestimated the toxicity of the registered substance. Furthermore, ECHA notes that different QSAR models, some of which you have used for your assessment (see section 10(b) below), do not support this read-across approach either: for each and every model, the predicted EC50 or LC50 are systematically lower for the registered substance than for the read-across substance. This further suggests that the read-across you have applied underestimates the toxicity of the registered substance.

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

b) (Q)SAR hypothesis (Annex XI, Section 1.3.)

You have provided (Q)SAR predictions from two different models embedded in the so-called VEGA tool (http://www.vega-qsar.eu/).

The first QSAR result you have provided predicts a 96h-LC50 of 3.32 mg/L. It is based on a model implemented in the so-called T.E.S.T (Toxicity Estimation Software Tool) software developed by US-EPA (http://www2.epa.gov/chemical-research/toxicity-estimation-software-tool-test). In the report attached to the study summary, it is indicated that the model is based on multiple linear regression, but no further detail on the actual algorithm is provided. According to the US-EPA website, 6 distinct models have been developed in T.E.S.T. for aquatic toxicity:

- *"Hierarchical method – The toxicity for a given query compound is estimated using the weighted average of the predictions from several different models. The different models are obtained by using Ward's method to divide the training set into a series of structurally similar clusters. A genetic algorithm-based technique is used to generate models for each cluster. The models are generated prior to runtime.*
- *FDA method – The prediction for each test chemical is made using a new model that is fit to the chemicals that are most similar to the test compound. Each model is generated at runtime.*
- *Single-model method – Predictions are made using a multilinear regression model that is fit to the training set (using molecular descriptors as independent variables) using a genetic algorithm-based approach. The regression model is generated prior to runtime.*
- *Group contribution method – Predictions are made using a multilinear regression model that is fit to the training set (using molecular fragment counts as independent variables). The regression model is generated prior to runtime.*
- *Nearest neighbor method – The predicted toxicity is estimated by taking an average of the three chemicals in the training set that are most similar to the test chemical.*
- *Consensus method – The predicted toxicity is estimated by taking an average of the predicted toxicities from each of the above QSAR methodologies".*

It is not clear what method has been used for the prediction provided in your dossier. Only the so-called "*single-model method*" and the "*group contribution method*" are said to be based on multiple linear regression, but when running these two models, ECHA could not reproduce the 96h-LC50 of 3.32 mg/L reported in your dossier. ECHA notes that for several of these models, multiple descriptors are used. The choice of these descriptors is not deterministic (use of heuristic and genetic algorithms), therefore a mechanistic interpretation is not possible. Furthermore, ECHA notes that (Q)SAR models (e.g. from T.E.S.T. or from ECOSAR) generally predict higher toxicity (i.e. lower LC50 or EC50 values) than the 96h-LC50 of 3.32 mg/L provided in your dossier. Finally, ECHA notes that prediction intervals calculated in T.E.S.T. are very large. This suggests that those predictions are very uncertain. You have not provided any prediction interval for the 96h-LC50 of 3.32 mg/L, but since this prediction is said to be based on T.E.S.T., ECHA believes it has to be regarded as very uncertain as well.

The second QSAR result that you have provided predicts a classification as "Toxic 2", corresponding to a 96h-LC50 between 1 and 10 mg/L. There is no information on the algorithm used except that it is based on "*fragments built by SarPy software developed by Politecnico di Milano, Italy and Istituto di Ricerche Farmacologiche Mario Negri, Italy*". On the Mario Negri Institute website, the SarPy software is described as a tool to identify fragments of a desired size and related to a target property. This information is insufficient to establish the scientific validity of the model and of the prediction.

Therefore, you did not establish the scientific validity of this model nor provide adequate and reliable documentation, as required by Annex XI, Section 1.3, and these results cannot be taken into account.

c) Other concerns

ECHA notes that the read-across studies and the (Q)SAR predictions result in LC50-values in the range 1-10 mg/L. These results together with the facts that the substance has a log Kow >4 and that the information provided in the dossier is insufficient to conclude that the substance is readily biodegradable warrant a classification as hazardous to the aquatic environment, Category Chronic 2 (H411: Toxic to aquatic life with long lasting effects). However, you have not classified the substance for environmental hazards. You should address this inconsistency.

d) Outcome

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement of Annex VIII, Section 9.1.3. of the REACH Regulation. 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) fish acute toxicity test (test method OECD 203) is the preferred test to cover that information requirement.

In your comments to the draft decision, you indicated your agreement to perform the requested study on the registered substance.

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: Fish, acute toxicity test (test method: OECD 203).

Notes for your consideration

Pursuant to column 2 of Annex VIII, Section 9.1.3., the short-term toxicity testing on fish need not be conducted if a long-term study on fish is available. Thus you may choose to perform the long-term toxicity on fish (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210) requested in section 11 below of this decision and submit the adaptation for the information requirement of short-term toxicity on fish.

Furthermore, due to the volatility of the substance in water, you should consult the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA Guidance, Chapter R7b, table R. 7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested test and for calculation and expression of the results of this test.

Annex I, Section 3.3. of the REACH Regulation requires you to identify Predicted No-Effect Concentrations (PNEC). The requested information shall be taken into account for revising the PNECs in your dossier. Pursuant to the CLP Regulation (Regulation (EC) No 1272/2008), you shall also consider revising the classification and labelling of your substance.

Pursuant to Annex I, Section 0.6.2 and Annex I, Section 6. of the REACH Regulation, the requested information shall be taken into account for revising the risk characterisation in your dossier.

11. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, your 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.

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. 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.
Information on long-term toxicity testing on fish is necessary for the risk assessment and the PBT/vPvB assessment and shall be considered for the classification and labelling of the substance.

ECHA notes that you have not provided any experimental data on the registered substance for this endpoint but that you have presented two (Q)SAR predictions from the ECOSAR model (ECOSAR Class: Neutral Organics), respectively for freshwater and saltwater fish as a weight of evidence approach:

- predicted chronic value for freshwater fish: 0.108 mg/L
- predicted chronic value for saltwater fish: 0.521 mg/L

According to Annex XI 1.2., a weight of evidence shall rely on several independent sources of information. However you have only provided predictions from the same (Q)SAR model. Furthemrore, you have not provided any information on the applicability domain of the model nor any adequate and reliable documentation of the applied method, as required by Annex XI, Section 1.3.

ECHA further notes that you have not used these results for the derivation of the PNEC based on the following justification:

"*The EPIWIN QSAR values for chronic toxicity were several orders of magnitude less than the acute VEGA QSAR value and for the read-across VT* [i.e. vinyl toluene]. *Therefore the long term PNEC values are based on the acute toxicity data, with high assessment factors to account for the uncertainty of chronic toxicity in the aquatic environment. It should be noted that TBS volatises from the surface of water and the conduct of long term aquatic studies in sealed vessels is not feasible. In addition, TBS is of low acute toxicity and shows a low tendency to bioaccumulate (BCF<3), this together with its short half-life in water (1.4 hours) suggest that the presence of concentrations in the aquatic environment are not likely to be of concern*".

You claim that (1) long-term studies are not technically feasible because of the high volatility of the substance. The substance is indeed volatile (Henry's law constant: 723 $Pa.m^3.mole^{-1}$), but ECHA believes it is still possible to perform a long-term test on fish using adequate test procedures as described in OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures (ENV/JM/MONO(2000)6 Monograph Number 23): e.g. by conducting analytical monitoring of the test concentrations, using a flow-through system, no headspace, large test volumes, aeration with pure oxygen. Therefore, your justification does not meet the requirements of Annex XI, Section 2 of the REACH Regulation.

You also state that the substance has a low acute toxicity, a low tendency to bioaccumulate, a short half-life in water and therefore that long-term studies are not relevant. ECHA considers that your claim that the substance has a low tendency to bioaccumulate is not substantiated. The substance is actually quite hydrophobic since log Kow is 4.44 and has quite low water solubility (water solubility of 5 mg/L). BCF predicted from (Q)SAR models are inconclusive with regard to whether the substance is bioaccumulative (B) or not (see section 9(b) above). Hydrophobic substances require longer time to be significantly taken up by the test organisms and so steady state conditions are likely not to be reached within the duration of a short-term toxicity test. For this reason, short-term tests may not give a true measure of toxicity for hydrophobic substances if the test duration is too short.

Long-term toxicity thus cannot be excluded and should be investigated. Annex VIII 9.1.3. and Annex VII 9.1.1. of the REACH Regulation explicitly recommend that long-term aquatic toxicity tests be considered if the substance is poorly water soluble. With regard to your claim that the substance has a short half-life in water and "*that long term aquatic toxicity will not occur as sufficient concentrations will not be reached*", ECHA notes that the substance is not deemed to be readily biodegradable based on the currently available information in your dossier and that actual exposure depends on the mode of releases (continuous or intermittent). This should be addressed in the exposure assessment but it is not related to the hazard assessment. Long-term toxicity information is precisely needed to assess whether toxicity can occur at the predicted environmental concentration. Finally, ECHA notes that chronic effects might be induced by short-term exposure so even if the substance has short half-life in water, potential chronic effects cannot be ruled out. Therefore, the information available does not support the conclusion that there is no need to investigate the long-term toxicity on fish and this test cannot be waived pursuant to column 2 of Annex IX, Section 9.1.

As explained in sections 10-14 of this decision, there are data gaps for the aquatic toxicity endpoints, therefore ECHA considers that the hazard and risk assessments provided in your dossier are not conclusive. Furthermore, there are also data gaps for endpoints biodegradation and bioaccumulation as explained in sections 7-8 and section 9 of this decision, therefore ECHA considers that your PBT/vPvB assessment is not conclusive either.

Therefore, 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 requirement of Annex IX, section 9.1.6. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Regarding the long-term toxicity testing on fish pursuant to Annex IX, section 9.1.6.1, ECHA considers that the fish early-life stage (FELS) toxicity test according to OECD 210 is the most sensitive of the standard fish tests available as it covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth and should therefore be used (see ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R7b, Figure R.7.8-4). Test method OECD 210 is also the only suitable test currently available for examining the potential toxic effects of bioaccumulation (ECHA Guidance Chapter R7b, version 2.0, November 2014). For these reasons, ECHA considers the FELS toxicity test using test method OECD 210 to be appropriate and suitable.

In your comments to the draft decision, you indicated that you would intend to use a read-across approach but that you considered the timeframe set out in the draft decision too short for that purpose. Furthermore, you stated that ECHA had no right to request studies listed in Annex IX or X of the REACH Regulation in a compliance check and that those studies could only be requested after a registrant had submitted testing proposals.

ECHA acknowledges that the requested information might be adapted as long as the proposed adaptations meet the requirements of Annex XI of the REACH Regulation or of column 2 of Annex IX of the REACH Regulation. However, ECHA notes that you have not provided further details on the read-across approach you intend to apply, and so ECHA cannot assess the validity of this approach. ECHA further notes that you did not provide a reasoned justification (with documentation of the timeline required) for why you considered the timeframe set out in the decision to be too short, and so ECHA cannot accept your proposal for an extension of the deadline for testing. Finally, ECHA disagrees with your interpretation that studies listed in Annex IX of the REACH Regulation cannot be requested during a compliance check. There is no provision in the REACH Regulation that states that compliance check cannot address information requirements of Annexes IX and X of the REACH Regulation. On the contrary, Article 41(1)(a) and (1)(b) of the REACH Regulation indicates that ECHA may check the compliance, respectively, of the information provided in the registration dossier with the requirements of Articles 10, 12 and 13 of the REACH Regulation and with Annexes III and VI to X of the REACH Regulation, and of the adaptations provided in the registration dossier with the requirements of Annexes VII to X of the REACH Regulation and with the general rules set out in Annex XI of the REACH Regulation. As explained above, ECHA considers that the adaptations you proposed are not valid and ECHA notes that you did not make testing proposals when you submitted your dossier. There is therefore a data gap for the endpoint, and pursuant to Article 41 of the REACH Regulation, ECHA is entitled to request the missing information in a compliance check.

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: Fish, early-life stage (FELS) toxicity test (test method: OECD 210).

Notes for your consideration

Before conducting any of the tests mentioned in sections 11 and 13 of that decision you shall consult the ECHA *Guidance on information requirements and chemical safety assessment (version 2.0, November 2014)*, Chapter R7b, Section R.7.8.5 to determine the sequence in which the aquatic long-term toxicity tests are to be conducted and the necessity to conduct long-term toxicity testing on fish.

According to above mentioned guidance including Figure R.7.8-4, if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. In such case, according to the integrated testing strategy, the *Daphnia* study is to be conducted first. If based on the results of the long-term *Daphnia* study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, the long-term fish study needs to be conducted.

Furthermore, due to the volatility of the substance, you should consult the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA Guidance, Chapter R7b, table R. 7.8-3 for choosing the design of the requested test and for calculation and expression of the results of this test.

Annex I, Section 3.3. of the REACH Regulation requires you to identify Predicted No-Effect Concentrations (PNEC) and Annex I, Section 4. of the REACH Regulation requires you to perform the PBT and vPvB assessment of your substance. The requested information shall be taken into account for revising the PNECs and the PBT/vPvB assessment in your dossier. Pursuant to the CLP Regulation (Regulation (EC) No 1272/2008), you shall also consider revising the classification and labelling of your substance.

Pursuant to Annex I, Section 0.6.2 and Annex I, Section 6. of the REACH Regulation, the requested information shall be taken into account for revising the risk characterisation in your dossier.

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, your 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.

"Short-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex VII, Section 9.1.1. 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.

Information on short-term toxicity testing on aquatic invertebrate is necessary for the risk assessment and shall be considered for the classification and labelling of the substance.

ECHA notes that you have not provided any experimental data on the registered substance for this endpoint. You have sought to adapt this information requirement instead by applying a read-across adaptation (Annex XI, Section 1.5. of the REACH Regulation) and by using a prediction from a (Q)SAR model (Annex XI, Section 1.3. of the REACH Regulation).

a) Read-across hypothesis (Annex XI, Section 1.5.)

You have provided a study ([redacted]) performed with the read-across substance vinyl toluene according to OECD guideline 202. It gives a 48h-EC50 of 1.3 mg/L.

As explained in details in sections 0(a) and 10 above, ECHA notes that you have provided no information that would support this read-across approach. Therefore ECHA considers that this adaptation cannot be accepted.

b) (Q)SAR hypothesis (Annex XI, Section 1.3.)

The (Q)SAR result was calculated from the VEGA tool (http://www.vega-qsar.eu/). It predicts a 48h-EC50 of 2.13 mg/L. It is based on a model implemented in the so-called T.E.S.T (Toxicity Estimation Software Tool) software developed by US-EPA (http://www2.epa.gov/chemical-research/toxicity-estimation-software-tool-test). In the report attached to the study summary, it is indicated that the model is based on multiple linear regression, but no further detail on the actual algorithm is provided. It is not clear what method has been used for the prediction provided in your dossier. While running the T.E.S.T. software, ECHA could not reproduce the 48h-EC50 of 2.13 mg/L reported in your dossier.
ECHA notes that for several of the models implemented in T.E.S.T., multiple descriptors are used. The choice of these descriptors is not deterministic (use of heuristic and genetic algorithms), therefore a mechanistic interpretation is not possible. Furthermore, ECHA notes that QSAR models (e.g. from T.E.S.T. or from ECOSAR) generally predict higher toxicity than the 48h-EC50 of 2.13 mg/L provided in the dossier. Finally, ECHA notes that prediction intervals calculated in T.E.S.T. are very large. This suggests that those predictions are very uncertain. You have not provided any prediction interval for the 48h-EC50 of 2.13 mg/L, but since this prediction is said to be based on T.E.S.T., it has to be regarded as very uncertain as well.

Therefore, you did not establish the scientific validity of this model nor provide adequate and reliable documentation, as required by Annex XI, Section 1.3, and these results cannot be taken into account.

c) Other concerns

ECHA notes that the provided read-across study and the (Q)SAR prediction result in EC50-values in the range 1-10 mg/L. These results together with the facts that the substance has a log Kow >4 and that the information provided in the dossier is insufficient to conclude that the substance is readily biodegradable warrant a classification as hazardous to the aquatic environment, Category Chronic 2 (H411: Toxic to aquatic life with long lasting effects). However, you have not classified the substance for environmental hazards. You should address this inconsistency.

d) Outcome

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement of Annex VII, Section 9.1.1. of the REACH Regulation. 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) *Daphnia sp.* Acute immobilisation test (test method: OECD 202) is the preferred test to cover that information requirement.

In your comments to the draft decision, you indicated your agreement to perform the requested study on the registered substance.

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: Daphnia sp. Acute immobilisation test (test method: OECD 202).

Notes for your consideration

Pursuant to column 2 of Annex VII, Section 9.1.1., the short-term toxicity testing on Daphnia need not be conducted if a long-term study on Daphnia is available. Thus you may choose to perform the long-term toxicity on Daphnia (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, OECD 211) requested in section 13 below of this decision and submit the adaptation for the information requirement of short-term toxicity on Daphnia.

Furthermore, due to the volatility of the substance, you should consult the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA Guidance, Chapter R7b, table R. 7.8-3 for choosing the design of the requested test and for calculation and expression of the results of this test.

Annex I, Section 3.3. of the REACH Regulation requires you to identify Predicted No-Effect Concentrations (PNEC). The requested information shall be taken into account for revising the PNECs in your dossier. Pursuant to the CLP Regulation (Regulation (EC) No 1272/2008), you shall also consider revising the classification and labelling of your substance.

Pursuant to Annex I, Section 0.6.2 and Annex I, Section 6. of the REACH Regulation, the requested information shall be taken into account for revising the risk characterisation in your dossier.

13. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, your 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.

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. 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.

Information on long-term toxicity testing on aquatic invertebrates is necessary for the risk assessment and the PBT/vPvB assessment and shall be considered for the classification and labelling of the substance.

ECHA notes that you have not provided any experimental data on the registered substance for this endpoint but that you have presented two (Q)SAR predictions from the ECOSAR model (ECOSAR Class: Neutral Organics), respectively for freshwater and saltwater invertebrates as a weight of evidence approach:

- predicted chronic value for Daphnia: 0.11 mg/L
- predicted chronic value for mysid shrimp (saltwater invertebrate): 0.006 mg/L

According to Annex XI 1.2., a weight of evidence shall rely on several independent sources of information. However you have only provided predictions from the same (Q)SAR model. Furthermore, you have not provided any information on the applicability domain of the model nor any adequate and reliable documentation of the applied method, as required by Annex XI, Section 1.3.

ECHA further notes that you have not used these results for the derivation of the PNEC based on the following justification:

"*The EPIWIN QSAR values for chronic toxicity were several orders of magnitude less than the acute VEGA QSAR value and for the read-across VT* [i.e. vinyl toluene]. *Therefore the long term PNEC values are based on the acute toxicity data, with high assessment factors to account for the uncertainty of chronic toxicity in the aquatic environment.*

It should be noted that TBS volatises from the surface of water and the conduct of long term aquatic studies in sealed vessels is not feasible. In addition, TBS is of low acute toxicity and shows a low tendency to bioaccumulate (BCF<3), this together with its short half-life in water (1.4 hours) suggest that the presence of concentrations in the aquatic environment are not likely to be of concern".

You claim that long-term studies are not technically feasible because of the high volatility of the substance. You also state that the substance has a low acute toxicity, a low tendency to bioaccumulate, a short half-life in water and therefore that long-term studies are not relevant. ECHA disagrees with your conclusions. The substance is indeed volatile (Henry's law constant: 723 $Pa.m^3.mole^{-1}$), but ECHA believes it is still possible to perform a long-term test on Daphnia using adequate test procedures as described in OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures (ENV/JM/MONO(2000)6 Monograph Number 23): e.g. by conducting analytical monitoring of the test concentrations, using a flow-through system, no headspace, large test volumes, aeration with pure oxygen. Therefore, your justification does not meet the requirements of Annex XI, Section 2 of the REACH Regulation.

You also state that the substance has a low acute toxicity, a low tendency to bioaccumulate, a short half-life in water and therefore that long-term studies are not relevant. ECHA considers that your claim that the substance has a low tendency to bioaccumulate is not substantiated. The substance is actually quite hydrophobic since log Kow is 4.44 and has a quite low water solubility (water solubility of 5 mg/L). BCF predicted from (Q)SAR models are inconclusive with regard to whether the substance is bioaccumulative (B) or not (see section 9(b) above).

Hydrophobic substances require longer time to be significantly taken up by the test organisms and so steady state conditions are likely not to be reached within the duration of a short-term toxicity test. For this reason, short-term tests may not give a true measure of toxicity for hydrophobic substances if the test duration is too short. Long-term toxicity thus cannot be excluded and should be investigated. Annex VIII 9.1.3. and Annex VII 9.1.1. of the REACH Regulation explicitly recommend that long-term aquatic toxicity tests be considered if the substance is poorly water soluble.

With regard to your claim that the substance has a short half-life in water and "*that long term aquatic toxicity will not occur as sufficient concentrations will not be reached*", ECHA notes that the substance is not deemed to be readily biodegradable based on the currently available information in your dossier and that actual exposure depends on the mode of releases (continuous or intermittent). This should be addressed in the exposure assessment but it is not related to the hazard assessment. Long-term toxicity information is precisely needed to assess whether toxicity can occur at the predicted environmental concentration. Finally, ECHA notes that chronic effects might be induced by short-term exposure so even if the substance has short half-life in water, potential chronic effects cannot be ruled out.

Therefore, the information available does not support the conclusion that there is no need to investigate the long-term toxicity on invertebrates and this test cannot be waived pursuant to column 2 of Annex IX, Section 9.1.

As explained in sections 10-14 of this decision, there are data gaps for the aquatic toxicity endpoints, therefore ECHA considers that the hazard and risk assessments provided in your dossier are not conclusive. Furthermore, there are also data gaps for endpoints biodegradation and bioaccumulation as explained in sections 7-8 and section 9 of this decision, therefore ECHA considers that your PBT/vPvB assessment is not conclusive either.

Therefore, adaptation of the information requirement cannot be accepted.

As explained above, the adaptation provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement of Annex IX, section 9.1.5. 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) *Daphnia magna* reproduction test (test method OECD 211) is the preferred test to cover the standard information requirement of Annex IX, Section 9.1.5.

In your comments to the draft decision, you indicated that you would still intend to use a read-across approach but that you considered the timeframe set out in the draft decision too short for that purpose. Furthermore, you stated that ECHA had no right to request studies listed in Annex IX or X of the REACH Regulation in a compliance check and that those studies could only be requested after a registrant had submitted testing proposals.

ECHA acknowledges that the requested information might be adapted as long as the proposed adaptations meet the requirements of Annex XI of the REACH Regulation or of column 2 of Annex IX of the REACH Regulation. However, ECHA notes that you have not provided further details on the read-across approach you intend to apply, and so ECHA cannot assess the validity of this approach. ECHA further notes that you did not provide a reasoned justification (with documentation of the timeline required) for why you considered the timeframe set out in the decision to be too short, and so ECHA cannot accept your proposal for an extension of the deadline for testing.

Finally, ECHA disagrees with your interpretation that studies listed in Annex IX of the REACH Regulation cannot be requested during a compliance check.

There is no provision in the REACH Regulation that states that compliance check cannot address information requirements of Annexes IX and X of the REACH Regulation. On the contrary, Article 41(1)(a) and (1)(b) of the REACH Regulation indicates that ECHA may check the compliance, respectively, of the information provided in the registration dossier with the requirements of Articles 10, 12 and 13 of the REACH Regulation and with Annexes III and VI to X of the REACH Regulation, and of the adaptations provided in the registration dossier with the requirements of Annexes VII to X of the REACH Regulation and with the general rules set out in Annex XI of the REACH Regulation. As explained above, ECHA considers that the adaptations you proposed are not valid and ECHA notes that you did not make testing proposals when you submitted your dossier. There is therefore a data gap for the endpoint, and pursuant to Article 41 of the REACH Regulation, ECHA is entitled to request the missing information in a compliance check.

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: *Daphnia magna* reproduction test (test method: OECD 211).

Notes for your consideration

Due to the volatility of the substance, you should consult the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA Guidance, Chapter R7b, table R. 7.8-3 for choosing the design of the requested test and for calculation and expression of the results of this test.

Annex I, Section 3.3. of the REACH Regulation requires you to identify Predicted No-Effect Concentrations (PNEC) and Annex I, Section 3.4. of the REACH Regulation requires you to perform the PBT and vPvB assessment of your substance. The requested information shall be taken into account for revising the PNECs and the PBT/vPvB assessment in your dossier. Pursuant to the CLP Regulation (Regulation (EC) No 1272/2008), you shall also consider revising the classification and labelling of your substance.

Pursuant to Annex I, Section 0.6.2 and Annex I, Section 6. of the REACH Regulation, the requested information shall be taken into account for revising the risk characterisation in your dossier.

14. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, your 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.

"Growth inhibition study aquatic plants (algae preferred)" is a standard information requirement as laid down in Annex VII, Section 9.1.2. 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.

Information on growth inhibition study on aquatic plants is necessary for the risk assessment and the PBT/vPvB assessment and shall be considered for the classification and labelling of the substance.

ECHA notes that you have not provided any experimental data on the registered substance for this endpoint. You have sought to adapt this information requirement instead by applying a read-across adaptation (Annex XI, Section 1.5. of the REACH Regulation).

You have provided a study ([redacted]) performed with the read-across substance vinyl toluene according to OECD guideline 201. It gives a 72h-EC50 of 2.6 mg/L and a 72h-NOEC of 1.6 mg/L.

As explained in details in sections 0(a) and 10 above, ECHA considers that this adaptation cannot be accepted. ECHA further notes that the provided read-across study results in a EC50-value in the range 1-10 mg/L. This result together with the facts that the substance is not readily biodegradable and has a log Kow >4 warrant a classification as hazardous to the aquatic environment, Category Chronic 2 (H411: Toxic to aquatic life with long lasting effects). However, you have not classified the substance for environmental hazards. ECHA concludes that you considered this result not adequate for classification and labelling. Therefore the provision of Annex XI, Section 1.5. requiring that read-across results to be "*adequate for the purpose of classification and labelling and/or risk assessment*" is not met. Therefore ECHA considers that this adaptation cannot be accepted.

As explained in sections 10-14 of this decision, there are data gaps for the aquatic toxicity endpoints, therefore ECHA considers that the hazard and risk assessments provided in your dossier is not conclusive. Furthermore, there are also data gaps for endpoints biodegradation and bioaccumulation as explained in sections 7-8 and section 9 of this decision. Therefore, ECHA considers that your PBT/vPvB assessment is not conclusive either.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement of Annex VII, Section 9.1.2. of the REACH Regulation. 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) Algae growth inhibition test (test method OECD 201) is the preferred test to cover that information requirement.

In your comments to the draft decision, you indicated your agreement to perform the requested study on the registered substance.

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: Algae, growth inhibition test (test method: OECD 201).

Notes for your consideration

Due to the volatility of the substance, you should consult the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA Guidance, Chapter R7b, table R. 7.8-3 for choosing the design of the requested test and for calculation and expression of the results of this test.

Annex I, Section 3.3. of the REACH Regulation requires you to identify Predicted No-Effect Concentrations (PNEC) and Annex I, Section 3.4. of the REACH Regulation requires you to perform the PBT and vPvB assessment of your substance. The requested information shall be taken into account for revising the PNECs and the PBT/vPvB assessment in your dossier. Pursuant to the CLP Regulation (Regulation (EC) No 1272/2008), you shall also consider revising the classification and labelling of your substance.

Pursuant to Annex I, Section 0.6.2 and Annex I, Section 6. of the REACH Regulation, the requested information shall be taken into account for revising the risk characterisation in your dossier.

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15. Activated sludge respiration inhibition test (Annex VIII, Section 9.1.4)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, your 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.

"Activated sludge respiration inhibition testing" is a standard information requirement as laid down in Annex VIII, Section 9.1.4. 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.

Information on activated sludge respiration inhibition test is necessary for the risk assessment.

You have not provided any study record of an activated sludge respiration inhibition in the dossier that would meet the information requirement of Annex VIII, Section 9.1.4.. You have sought to adapt this information requirement instead by providing the following justification:

"*Information from the biodegradation studies indicates that the read across material PMS/VT has no adverse effect on the sewage treatment microorganisms. In addition it was shown that microorganisms once adapted to the PMS/VT* [i.e. vinyl toluene] *substrate are quite capable of utilising it as a food source. In view of the low anticipated exposure of microorganisms to the test material in the uses supported in this dossier no additional testing has been conducted*".

You make reference to two old biodegradation studies performed with the read-across substance vinyl toluene to conclude that the registered substance is not toxic to aquatic micro-organisms. As explained in details in sections 0(a) and 10 above, ECHA notes that you have provided no information that would support a read-across approach from vinyl toluene to the registered substance. Therefore your adaptation does not meet the adaptation rules of Annex XI of the REACH Regulation.

ECHA further notes that your adaptation does not meet either the adaptation rules of column 2 of Annex VIII of the REACH Regulation:

- you have not demonstrated the absence of emission of your substance to sewage treatment plant,
- there are no appropriate mitigating factors indicating that microbial toxicity is unlikely to occur (e.g. according to the reported water solubility of 5 mg/L, the substance cannot be considered highly insoluble in water),
- you have not provided any valid evidence that the substance could be readily biodegradable.

Therefore, your adaptation complies neither with the general rule for adaptation of Annex XI of the REACH Regulation nor with the specific rules of column 2 of Annex VIII, Section 9.1.4. of the REACH Regulation. Therefore ECHA considers that your adaptation 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 requirement of Annex VIII, Section 9.1.4. of the REACH Regulation. 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) Activated Sludge, Respiration Inhibition Test (Carbon and Ammonium Oxidation) (test method OECD 209) is the preferred test to cover that information requirement.

In your comments to the draft decision, you indicated your agreement to perform the requested study on the registered substance.

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: Activated Sludge, Respiration Inhibition Test (Carbon and Ammonium Oxidation), test method: OECD 209.

Note for your consideration

Annex I, Section 3.3. of the REACH Regulation requires you to identify Predicted No-Effect Concentrations (PNEC). The requested information shall be taken into account for revising in your dossier the PNEC for sewage treatment plants.

Pursuant to Annex I, Section 0.6.2 and Annex I, Section 6. of the REACH Regulation, the requested information shall also be taken into account for revising the risk characterisation in your dossier.

16. Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for environment: revise the environmental exposure estimation

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.

According to Article 14(4) of the REACH Regulation, if the substance fulfils the criteria for any of the hazard classes of Annex I to Regulation (EC) No 1272/2008 listed in Article 14(4) of the REACH Regulation or is assessed to be a PBT or vPvB, the chemical safety assessment shall include an exposure assessment and risk characterisation. ECHA notes that the registered substance is classified. Therefore an exposure assessment and risk characterisation shall be included in the chemical safety assessment.

The exposure assessment shall be carried out according to Section 5 of Annex I and shall include exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards.

Annex I, Section 6 of the REACH Regulation requires you to characterise the risk for each exposure scenario.
The five following exposure scenarios (ES) are presented in the dossier:
ES1: Production of copolymers of TBS/Butadiene rubbers

ES2: Manufacture of poly TBS
ES3: Manufacture of unsaturated polyester resin
ES4: Production of FRP products in an industrial setting
ES5: Production of cured UP resin mastic

The environmental exposure assessment and risk characterisation you have provided contain several deficiencies as indicated below.

a) Absence of adequate justification for the release factors to air for every exposure scenario

Pursuant to Annex I, Section 5.1.1 of the REACH Regulation, exposure scenarios (ES) shall include, where relevant, a description of operational conditions (OCs) and of risk management measures (RMMs). As indicated in Annex I, Section 5.2.2. of the REACH Regulation, emission estimation shall be performed under the assumption that the risk management measures and operational conditions described in the exposure scenario have been implemented. These RMMs and OCs should be included in the exposure scenarios provided in a CSR.
According to the Guidance on information requirements and chemical safety assessment Chapter R.16: Environmental Exposure Estimation (ECHA, version: 2.1, October 2012), operational conditions "*consist of a set of actions, tools, parameters such as amount of substance, process temperature and pH, duration and frequency of release, type of use (e.g. indoor or outdoor), containment of process (open or closed), continuous or batch process (leading to an intermittent release), capacity of surroundings, etc. having, as a side effect, an impact on the release and the exposure*". Risk management measures "*consist of technologies and procedures aimed at either reducing the releases and/or preventing a release pathway. Examples of risk management measures intended to reduce release are filters, scrubbers, biological or physico-chemical wastewater treatment plants etc.*" Both OCs and RMMs have an impact on the type and amount of release and the resulting exposure. ECHA guidance R.16 specifically provides default release factors associated with different Environmental Release Categories (ERCs). These default release factors can be used for a first tier assessment of the emissions. However, better information may be available that could then be used instead. In particular, release factors can be refined by taking into account RMMs and OCs. In this case, it is important to explicitly link such RMMs and OCs to the release factors and communicate them properly to the downstream users in the exposure scenarios. For example, sector specific environmental release categories (spERCs) developed by industrial sector organisations can be used in place of the conservative default ERCs of ECHA guidance R.16. However, spERCs have to be linked to the applied RMMs and OCs driving the release estimation and that shall be described in the exposure scenarios.

For all exposure scenarios, you have used release factors that deviate from those recommended in guidance R.16. For every scenario, you have used the same release factors:

- Air: 0.2%
- Wastewater: 0.03%
- Soil: 0.01%

For exposure scenarios ES1 and ES2, you have made reference to SpERC ESVOC 42 ("Rubber production and processing"). The corresponding ERC for these 2 scenarios is ERC 6d ("Industrial use of auxiliaries for polymerisation"). For air, the default release factor recommended in ECHA guidance for ERC6d is 35%. SpERC ESVOC 42 recommends 1%. You have actually applied a release factor of 0.2% without any justification. Even though you claim in the CSR that you have applied SpERC ESVOC 42, the value of 0.2% does not correspond to the release factor recommended for that SpERC. Furthermore, you explicitly indicate in the CSR that no RMM has been assumed for releases to air. Therefore there is no justification to support the applied release factor of 0.2% for air.

For exposure scenarios ES3 and ES4, you have made reference to SpERC ESVOC 4 ("Formulation & (re)packing of substances and mixtures"). The corresponding ERC for these 2 scenarios is ERC 6d ("Industrial use of auxiliaries for polymerisation"). According to the SpERC specification, SpERC ESVOC 4 could replace ERC2 but there is no mention that it could replace ERC 6d. SpERC ESVOC 4 ("Formulation & (re)packing of substances and mixtures") does not seem to be relevant for these 2 exposure scenarios which are respectively about "*manufacture of unsaturated polyester resin*" (ES3) or "*production of FRP products in an industrial setting*" (ES4). You have not provided any explanation why this SpERC would be applicable for those 2 exposure scenarios. Furthermore there is no justification for the release factors you have applied. For air, the default release factor for ERC 6d recommended in ECHA guidance is 35%. SpERC ESVOC 4 recommends a release factor of 0.5% for air for substances with vapour pressure of 10-100 Pa. You have actually applied a release factor of 0.2% without any justification. Furthermore, no RMM is specified for releases to air. Therefore there is no justification to support the applied release factor of 0.2% for air.

For exposure scenario ES5, you have made reference to SpERC ESVOC 44 ("Polymer processing"). The corresponding ERC for this scenario is ERC 8f ("Wide dispersive outdoor use, inclusion in matrix"). According to the SpERC specification, this SpERC could replace ERC4 but there is no mention of ERC 8f. SpERC ESVOC 44 is not applicable to professional uses. Furthermore there is no justification for the release factors you have applied. For air, the default release factor recommended in ECHA guidance for ERC 8f is 15%. SpERC ESVOC 44 recommends a release factor of 10% (before RMM) or 2% (after RMM) for air for substances with a vapour pressure <100 Pa. You have actually applied a release factor of 0.2% without any justification. In particular, no RMM is specified for releases to air. Therefore there is no justification to support the applied release factor of 0.2%. This value seems unrealistically low especially for professional uses when possibilities for very efficient RMMs are rather limited. Adequate and realistic RMM need to be specified to justify release factors that deviate from default values recommended in ECHA guidance.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation you are requested to use default release factors to air and other recommendations of ECHA Guidance R.16 for every exposure scenario and revise the risk characterisation accordingly *or* to provide a detailed justification (e.g. based on RMMs and/or OCs and/or substance properties) for not using the default values as recommended in ECHA Guidance R.16 for estimation of environmental exposure.

b) Lack of justification for the assumed number of release days per year

Pursuant to Annex I, Section 5.2.1 of the REACH Regulation the exposure estimation as part of the exposure assessment entails three elements: emission estimation, assessment of chemical fate and pathways and estimation of exposure levels. Pursuant to Annex I, Section 5.1.1 and 5.2.4. of the REACH Regulation, exposure estimation shall take account of the duration and frequency of emissions of the substance to the different environmental compartments and sewage treatment systems.

You have assumed a number of release days of 300 days/year for exposure scenarios ES1, ES2, ES3 and ES4. These four exposure scenarios are all about industrial uses and for tonnages below 100 tonnes/year. The default number of release days recommended in the Guidance on information requirements and chemical safety assessment Chapter R.16: Environmental Exposure Estimation (ECHA, version: 2.1, October 2012) is 20 days/year for industrial uses and for tonnages below 100 tonnes/year (see page 14 of guidance R.16.). The underlying assumption behind those default values is that, for uses in industrial sites, large tonnages are more likely to be used continuously whereas low tonnages are more likely to be used for shorter periods of time.

The value of 300 days/year is given in SpERC ESVOC 42, which you have used for ES1 and ES2, and in SpERC ESVOC 4, which you have used for ES3 and ES4. However these deviations from ECHA guidance are not substantiated by any justification, positive evidence or actual data in the documentation available for those SpERCs.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation you are requested to use the default number of release days in accordance with the recommendations of ECHA Guidance R.16 or to provide adequate justification for any deviation from these recommendations.

c) For ES1, ES2, ES3 and ES4 the assumed "fraction of the main source" (i.e. annual use at a site) is lower than 100%

Pursuant to Annex I, Section 5.2.1 of the REACH Regulation the exposure estimation as part of the exposure assessment entails three elements: emission estimation, assessment of chemical fate and pathways and estimation of exposure levels. Pursuant to Annex I, Section 5.2.2. of the REACH Regulation, emission estimation shall consider the emissions during all relevant parts of the life-cycle of the substance resulting from the manufacture and each of the identified uses.

For point sources, a protective estimation of the emissions requires that the capacity of the largest point source for the particular stage of the life cycle be estimated. The main source thus represents the emission source where the largest fraction of the production volume or market volume of the substance is handled. If this information is not known, it has to be estimated from the registered total annual tonnage.

For exposure scenarios ES1, ES2, ES3 and ES4, you have assumed that the fraction of the main local source is 33% of the registered total annual tonnage.

The Guidance on information requirements and chemical safety assessment Chapter R.16: Environmental Exposure Estimation (ECHA, version: 2.1, October 2012, page 15) recommends that, for an industrial site, the annual use at the site be set, by default, to 100% of the total annual tonnage for the use, i.e. that the fraction of the main source be set to 100%. Exposure scenarios ES1, ES2, ES3 and ES4 all apply to industrial sites, and therefore by default the annual use at a site should have been assumed to be 100% for these four exposure scenarios. This default value of 100% is a worst case to cover situations where the total registered tonnage is processed by at a single site. By assuming lower values, you may have underestimated the local exposure.

The ECHA guidance specifies that the default value of 100% can be overwritten, on the basis of site specific information or of information on the actual amount used by the largest downstream user (ECHA guidance R.16, pages 18-19). However no such information is provided in the dossier, and you have not provided any justification for deviating from the default recommendation of the guidance.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, you are requested to apply a "fraction of the main source" for exposure scenarios ES1, ES2, ES3 and ES4 in accordance with the recommendations of ECHA Guidance R.16 or to provide adequate justification for any deviation from these recommendations.

17. Exposure assessment and risk characterisation (Annex I, Section 5.1.1) for human health

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.

Article 14(6) as well as Annex I, 0.1., 5.1.1., 5.2.4. and 6.2. of the REACH Regulation require you to identify and apply appropriate measures to adequately control the risks identified in a CSR. The exposure shall be estimated and risks shall be characterised in the CSR under the assumption that relevant risk management measures have been implemented.

According to Annex I, 0.3., 0.5. and 5.1.1. the applied Risk Management Measures (RMM) have to be described in the CSR. The CSR needs to contain sufficient information to allow ECHA to gain assurance that the risks are adequately controlled and that appropriate risk management measures can be prescribed by actors in the supply chain. Accordingly, the supplier is required to describe the relevant RMM in detail in the Safety Data Sheet in order to minimise the exposure for workers handling the registered substance (e.g. the type of gloves to be worn, protection equipment for parts of the body other than the hand or respiratory protection shall be clearly specified based on the hazard of the substance or mixture and potential for contact and with regard to the amount and duration of exposure in accordance with Annex II, section 8.2.2.2.(b)(i), (ii) and 8.2.2.2.(c) respectively).

The information provided in the Safety Data Sheet (SDS) shall be consistent with information in the Chemical Safety Report (Annex II, section 0.1.2. of the REACH Regulation).

ECHA notes that specific detailed information on the recommended personal protective equipment is missing both from the CSR and from the information on safe use within the IUCLID dossier. In the dossier, you have indicated the following for hand protection: Gloves according to EN 374 required to protect against skin irritancy. However, neither in the CSR nor in section 11 of IUCLID you have specified the glove material, breakthrough time or thickness of the glove.

To ensure the safe use of a substance, Annex I, Section 5.1.1. requires a description of the risk management measures to reduce or avoid direct and indirect exposure of humans. Gloves are reported in the CSR and IUCLID section 11 as required personal protective equipment to prevent dermal exposure to the substance. Generally, gloves that are capable of preventing exposure to the skin for a pre-determined duration shall be specified. Typically, this information, as a minimum, has to specify the glove material and, depending on the exposure scenarios, may also need to include the breakthrough time and thickness of the glove material.

Therefore, pursuant to Article 41(1) you are requested to provide documentation for the recommended personal protective equipment, i.e. skin protection (i.e. Hand protection): specify the type of glove material, thickness and breakthrough times.

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 20 November 2015.

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 took into account your comments, which were sent within the commenting period, and they are reflected in the Reasons (Appendix 1).

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) for amendment(s).

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

In addition, you provided comments on the draft decision. These comments were not taken into account by the Member State Committee as they were considered to be outside of the scope of Article 51(5).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-50 written procedure and ECHA took the decision according to Article 51(6) 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 carrying out the test(s) required by the present decision it is important to ensure that the particular sample of substance tested 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. If the registration of the substance covers different grades, the sample used for the new test(s) must be suitable to assess these. Furthermore, 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.