Helsinki, 20 August 2019

Addressee: [redacted]

Decision number: CCH-D-2114479060-54-01/F
Substance name: reaction products of c3 alcohols and c3 alkenes obtained as by-products from the manufacture of propan-2-ol by hydration of propylene
EC number: 701-241-0
CAS number: NS
Registration number: [redacted]
Submission number: [redacted]
Submission date: 10/07/2018
Registered tonnage band: Over 1000

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. **Revision of the robust study summary for short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1., in conjunction with Annex I, Section 3.1.5. of the REACH Regulation) as specified in Appendix 1, section 1 below;**

2. **Revision of the robust study summary for growth inhibition study on aquatic plants (Annex VII, Section 9.1.2., in conjunction with Annex I, Section 3.1.5. of the REACH Regulation) as specified in Appendix 1, section 2 below;**

3. **Revision of the robust study summary for short-term toxicity testing on fish (Annex VIII Section 9.1.3., in conjunction with Annex I, Section 3.1.5. of the REACH Regulation) as specified in Appendix 1, section 3 below.**

You are required to submit the requested information in an updated registration dossier by ***27 February 2020***. You shall also update the chemical safety report (CSR), where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and 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, has to 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 Wim De Coen, Head of Unit, Hazard Assessment.

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

Pursuant to Article 10(a)(vii) and Annex I, Section 3.1.5. of the REACH Regulation, the information set out in Annex VII to X must be provided in the form of robust study summaries for all key data used in the hazard assessment. Article 3(28) defines a robust study summary as a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report. Guidance on the preparation of the robust study summaries is provided in ECHA Practical Guide 3: 'How to report robust study summaries'[2].

1. **Revision of robust study summaries for short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1., in conjunction with Annex I, Section 3.1.5.)**

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.

In your technical dossier you have provided a study record for a short-term toxicity study on *Daphnia magna* performed according to OECD Guideline 202 (*Daphnia sp.* Acute Immobilisation Test) ([redacted] 2010a)[3].

ECHA has analysed this study record and considers that the result reported is not adequate to meet the information requirement of this endpoint, as explained below.

The registered substance is very volatile. A vapour pressure of 23 kPa at 25°C is reported in your technical dossier. Furthermore, the registered substance is a UVCB with most of its identified constituents expected to be very volatile as well. Thus, losses of the test substance due to its volatilisation from the test vessels may have occurred.

In your technical dossier, you mention that prior stability tests have been conducted and have shown that only 2% of the test substance was recovered after 48 hours in open vessels. On the contrary, no significant losses, e.g. from photodegradation or adsorption, have been observed in sealed vessels. This confirms that losses due to volatilisation could be very important if no or insufficient precautions are taken and should be addressed in the hazard assessment of the substance.

In the short-term toxicity study on *Daphnia magna* ([redacted] 2010a), daphnids were exposed to water accommodated fractions (WAF) of the test substance over a range of nominal loading rates of 10, 18, 32, 56 and 100 mg/L for a period of 48 hours under static test conditions. Testing was conducted in completely filled, stoppered test vessels in order to

[2] https://echa.europa.eu/practical-guides
[3] [redacted] (2010a). [redacted]

minimise losses due to volatilisation. Chemical analyses were performed which however show that significant losses still occurred:

- analysis of the freshly prepared test media at 0 hour showed recovery rates to range from 37.6% to 47.1%;
- analysis of the old media at 48 hours showed recovery rates to range from 30.5% to 36.8%.

Yet the 48 hour EL50 of 35 mg/L reported in your dossier was based on nominal loading rates. ECHA considers that this EL50 value underestimates the toxicity of the registered substance.

The effects observed during a test relate to the actual concentrations to which the test organisms were exposed. Hence, nominal concentrations should only be used if it can be demonstrated that the test concentrations measured analytically remain close to the nominal concentrations. In particular, the OECD guidance document on aqueous-phase aquatic toxicity testing of difficult test chemicals[4] explicitly indicates that "*if measured concentrations in samples do not remain within 80-120% of nominal, the effect concentration should be expressed relative to the measured concentrations*". Chemical analyses have confirmed that the recovery rates for the short-term toxicity study on *Daphnia magna* ([redacted] 2010a) were significantly below 80%. This indicates that the concentrations to which the test organisms were actually exposed were much lower than the nominal concentrations and hence that the 48 hour EL50 of 35 mg/L based on nominal loading rates is inadequate to assess the hazard of the registered substance. The effect concentration should have been calculated based on measured concentrations instead of nominal loading rates.

In your comments following the procedure set out in Article 50(1) of the REACH Regulation you made reference to the substance properties to justify the use of WAF for preparing the aqueous test media. You acknowledged that measured concentrations of the test material in the WAF were lower than the loading rates, and you proposed some possible explanations. However, you reiterated that results should in your opinion be calculated from nominal loading rates rather than from measured concentrations.

You referred to the OECD guidance document on aqueous-phase aquatic toxicity testing of difficult test chemicals and to Chapter R.7b of the ECHA guidance on Information Requirements and Chemical Safety Assessment to claim that whenever WAF were used for performing a test, the results should be calculated from the loading rates. However, ECHA disagrees with your interpretation of these two pieces of guidance. OECD and ECHA documents acknowledge that measuring test concentrations may be difficult for UVCB substances, and in such a situation results based on loading rates may then indeed be the only available option. However, both documents also indicate that results can be calculated from measured concentrations if available. For example Section 7.9.2.5 of the OECD document mentions that "*the measured concentrations of dissolved and/or emulsified key or major components would greatly improve interpretation and also assist in evaluating acceptable loading values for a UVCB, thus, underscoring the importance of chemical-specific analytical determinations*". Similarly, Table R.7.8—3 in chapter R7b of ECHA guidance indicates that "*the measured mass of test substance in the WAF can also be used (as a concentration)*".

Results based on measured concentrations are obviously much more relevant than those based on nominal loading rates. Indeed, the latter do not take into account potential losses

[4] Guidance document on aqueous-phase aquatic toxicity testing of difficult test chemicals. Series on testing and assessment. No. 23 (Second Edition), 6 July 2018, ENV/JM/MONO(2000)6/REV1

of the substance occurring during the preparation of the test media and during the course of the tests. As such, results based on loading rates highly depend on whether and to which extend measures were taken to limit the losses of the test substance. Consequently, the toxicity of the substance may be critically underestimated. On the contrary, results based on measured concentrations are much more satisfactory for assessing the intrinsic toxicity of the substance as they establish a direct link between the effects observed and the actual substance concentrations measured in the test media.

For the three aquatic toxicity tests you have provided, for fish, *Daphnia* and algae, it was possible to measure concentrations of the test substance in the test media at the beginning and at different times during the tests. They were measured as the total peak area associated with the test item in a headspace GC analysis. These measured values show sometimes very large differences between the nominal loading rates and the actual test concentrations to which the test organisms were exposed during the tests.

Therefore, ECHA considers that it is not only possible but also highly relevant to calculate the results based on the measured concentrations.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to revise in your registration dossier the robust study summary for the short-term toxicity study on *Daphnia magna* ([redacted] 2010a) with an effect concentration recalculated from measured test concentrations.

You shall update your chemical safety report accordingly. In particular, predicted no effect concentrations (PNEC) may need to be revised. In addition, a more severe classification and labelling of the substance may be warranted.

2. Revision of robust study summaries for growth inhibition study on aquatic plants (Annex VII, Section 9.1.2., in conjunction with Annex I, Section 3.1.5.)

Growth inhibition study on aquatic plants 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.

In your technical dossier you have provided a study record for a toxicity study on algae performed with test species *Desmodesmus subspicatus* and according to OECD Guideline 201 (Alga, Growth Inhibition Test) ([redacted] 2010)[5].

ECHA has analysed this study record and considers that the results reported are not adequate to meet the information requirement of this endpoint, as explained below.

The registered substance is very volatile. A vapour pressure of 23 kPa at 25°C is reported in your technical dossier. Furthermore, the registered substance is a UVCB with most of its identified constituents expected to be very volatile as well. Thus, losses of the test substance due to its volatilisation from the test vessels may have occurred.

In your technical dossier, you mention that prior stability tests have been conducted and have shown that the substance could not be measured after 72 h in open vessels. On the contrary,

[5] [redacted] (2010). [redacted]

no significant losses, e.g. from photodegradation or adsorption, have been observed in sealed vessels. This confirms that losses due to volatilisation could be very important if no or insufficient precautions are taken and should be addressed in the hazard assessment of the substance.

In the toxicity study ([redacted] 2010), algae were exposed to water accommodated fractions (WAF) of the test substance over a range of nominal loading rates of 10, 20, 40, 80 and 160 mg/L for 72 hours under static test conditions. Testing was conducted in completely filled, stoppered test vessels in order to minimise losses due to volatilisation. Chemical analyses were performed which however show that significant losses still occurred:

- analysis of the freshly prepared test media at 0 hour showed recovery rates to range from 20.6% to 53%;
- analysis of the old media at 72 hours showed recovery rates to range from 12.9% to 17.9%.

Yet the 72 hour EL50 of > 160 mg/L and NOEL of 800 mg/L reported in your dossier were based on nominal loading rates. ECHA considers that these values underestimate the toxicity of the registered substance.

The effects observed during a test relate to the actual concentrations to which the test organisms were exposed. Hence, nominal concentrations should only be used if it can be demonstrated that the test concentrations measured analytically remain close to the nominal concentrations. In particular, the OECD guidance document on aqueous-phase aquatic toxicity testing of difficult test chemicals[6] explicitly indicates that "*if measured concentrations in samples do not remain within 80-120% of nominal, the effect concentration should be expressed relative to the measured concentrations*". Chemical analyses have confirmed that the recovery rates for the toxicity study on algae ([redacted] 2010) were significantly below 80%. This indicates that the concentrations to which the test organisms were actually exposed were much lower than the nominal concentrations and hence that the 72 hour EL50 of > 160 mg/L and NOEL of 800 mg/L based on nominal loading rates are inadequate to assess the hazard of the registered substance. The effect concentrations should have been calculated based on measured concentrations instead of nominal loading rates.

In your comments following the procedure set out in Article 50(1) of the REACH Regulation you made reference to the substance properties to justify the use of WAF for preparing the aqueous test media. You acknowledged that measured concentrations of the test material in the WAF were lower than the loading rates, and you proposed some possible explanations. However, you reiterated that results should in your opinion be calculated from nominal loading rates rather than from measured concentrations.

You referred to the OECD guidance document on aqueous-phase aquatic toxicity testing of difficult test chemicals and to Chapter R.7b of the ECHA guidance on Information Requirements and Chemical Safety Assessment to claim that whenever WAF were used for performing a test, the results should be calculated from the loading rates. However, ECHA disagrees with your interpretation of these two pieces of guidance. OECD and ECHA documents acknowledge that measuring test concentrations may be difficult for UVCB substances, and in such a situation results based on loading rates may then indeed be the only available option. However, both documents also indicate that results can be calculated

[6] Guidance document on aqueous-phase aquatic toxicity testing of difficult test chemicals. Series on testing and assessment. No. 23 (Second Edition), 6 July 2018, ENV/JM/MONO(2000)6/REV1

from measured concentrations if available. For example Section 7.9.2.5 of the OECD document mentions that "*the measured concentrations of dissolved and/or emulsified key or major components would greatly improve interpretation and also assist in evaluating acceptable loading values for a UVCB, thus, underscoring the importance of chemical-specific analytical determinations*". Similarly, Table R.7.8—3 in chapter R7b of ECHA guidance indicates that "*the measured mass of test substance in the WAF can also be used (as a concentration)*".

Results based on measured concentrations are obviously much more relevant than those based on nominal loading rates. Indeed, the latter do not take into account potential losses of the substance occurring during the preparation of the test media and during the course of the tests. As such, results based on loading rates highly depend on whether and to which extend measures were taken to limit the losses of the test substance. Consequently, the toxicity of the substance may be critically underestimated. On the contrary, results based on measured concentrations are much more satisfactory for assessing the intrinsic toxicity of the substance as they establish a direct link between the effects observed and the actual substance concentrations measured in the test media.

For the three aquatic toxicity tests you have provided, for fish, *Daphnia* and algae, it was possible to measure concentrations of the test substance in the test media at the beginning and at different times during the tests. They were measured as the total peak area associated with the test item in a headspace GC analysis. These measured values show sometimes very large differences between the nominal loading rates and the actual test concentrations to which the test organisms were exposed during the tests.

Therefore, ECHA considers that it is not only possible but also highly relevant to calculate the results based on the measured concentrations.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to revise in your registration dossier the robust study summary for the toxicity study on algae ([redacted] 2010) with effect concentrations recalculated from measured test concentrations.

You shall update your chemical safety report accordingly. In particular, predicted no effect concentrations (PNEC) may need to be revised. In addition, a more severe classification and labelling of the substance may be warranted.

3. Revision of robust study summaries for short-term toxicity testing in fish (Annex VIII Section 9.1.3., in conjunction with Annex I, Section 3.1.5.)

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.

In your technical dossier you have provided a study record for a short-term toxicity study on fish performed with test species *Oncorhynchus mykiss* and according to OECD Guideline 203 (Fish, Acute Toxicity Test) ([redacted] 2010b)[7].

[7] [redacted] (2010b). [redacted]

ECHA has analysed this study record and considers that the result reported is not adequate to meet the information requirement of this endpoint, as explained below.

The registered substance is very volatile. A vapour pressure of 23 kPa at 25°C is reported in your technical dossier. Furthermore, the registered substance is a UVCB with most of its identified constituents expected to be very volatile as well. Thus, losses of the test substance due to its volatilisation from the test vessels may have occurred.

In your technical dossier, you mention that prior stability tests have been conducted and have shown that only 23% of the test substance was recovered after 24 hours in open vessels. On the contrary, no significant losses, e.g. from photodegradation or adsorption, have been observed in sealed vessels. This confirms that losses due to volatilisation could be very important if no or insufficient precautions are taken and should be addressed in the hazard assessment of the substance.

In the short-term toxicity study (Priestly and Mullee, 2010b), fish were exposed to water accommodated fractions (WAF) of the test substance over a range of nominal loading rates of 1.0, 3.2, 10, 32 and 100 mg/L for a period of 96 hours in sealed vessels and under semi-static test conditions (renewal every 24 hours). Chemical analyses were performed which show that significant losses still occurred:

- analysis of the freshly prepared test media at 0 and 72 hours showed recovery rates to range from 21.8% to 117%;
- analysis of the old media at 24 and 96 hours showed recovery rates to range from 19% to 98.9%.

Yet the 96 hour LL50 of 18 mg/L reported in your dossier was based on nominal loading rates. ECHA considers that this LL50 value underestimates the toxicity of the registered substance.

The effects observed during a test relate to the actual concentrations to which the test organisms were exposed. Hence, nominal concentrations should only be used if it can be demonstrated that the test concentrations measured analytically remain close to the nominal concentrations. In particular, OECD test guideline 203 (Fish, Acute Toxicity Test) explicitly indicates that in order the test to be regarded as valid, "*there must be evidence that the concentration of the substance being tested has been satisfactorily maintained, and preferably it should be at least 80 per cent of the nominal concentration throughout the test. If the deviation from the nominal concentration is greater than 20 per cent, results should be based on the measured concentration*". Similarly, the OECD guidance document on aqueous-phase aquatic toxicity testing of difficult test chemicals[8] recommends that "*if measured concentrations in samples do not remain within 80-120% of nominal, the effect concentration should be expressed relative to the measured concentrations*". Chemical analyses have confirmed that the recovery rates for the short-term toxicity study on fish ([redacted] 2010b) were significantly below 80% for some test concentrations. This indicates that the concentrations to which the test organisms were actually exposed were for some of them much lower than the nominal concentrations and hence that the 96 hour LL50 of 18 mg/L based on nominal loading rates is inadequate to assess the hazard of the registered substance. The effect concentration should have been calculated based on measured concentrations instead of nominal loading rates.

[8] Guidance document on aqueous-phase aquatic toxicity testing of difficult test chemicals. Series on testing and assessment. No. 23 (Second Edition), 6 July 2018, ENV/JM/MONO(2000)6/REV1

In your comments following the procedure set out in Article 50(1) of the REACH Regulation you made reference to the substance properties to justify the use of WAF for preparing the aqueous test media. You acknowledged that measured concentrations of the test material in the WAF were lower than the loading rates, and you proposed some possible explanations. However, you reiterated that results should in your opinion be calculated from nominal loading rates rather than from measured concentrations.

You referred to the OECD guidance document on aqueous-phase aquatic toxicity testing of difficult test chemicals and to Chapter R.7b of the ECHA guidance on Information Requirements and Chemical Safety Assessment to claim that whenever WAF were used for performing a test, the results should be calculated from the loading rates. However, ECHA disagrees with your interpretation of these two pieces of guidance. OECD and ECHA documents acknowledge that measuring test concentrations may be difficult for UVCB substances, and in such a situation results based on loading rates may then indeed be the only available option. However, both documents also indicate that results can be calculated from measured concentrations if available. For example Section 7.9.2.5 of the OECD document mentions that "*the measured concentrations of dissolved and/or emulsified key or major components would greatly improve interpretation and also assist in evaluating acceptable loading values for a UVCB, thus, underscoring the importance of chemical-specific analytical determinations*". Similarly, Table R.7.8—3 in chapter R7b of ECHA guidance indicates that "*the measured mass of test substance in the WAF can also be used (as a concentration)*".

Results based on measured concentrations are obviously much more relevant than those based on nominal loading rates. Indeed, the latter do not take into account potential losses of the substance occurring during the preparation of the test media and during the course of the tests. As such, results based on loading rates highly depend on whether and to which extend measures were taken to limit the losses of the test substance. Consequently, the toxicity of the substance may be critically underestimated. On the contrary, results based on measured concentrations are much more satisfactory for assessing the intrinsic toxicity of the substance as they establish a direct link between the effects observed and the actual substance concentrations measured in the test media.

For the three aquatic toxicity tests you have provided, for fish, *Daphnia* and algae, it was possible to measure concentrations of the test substance in the test media at the beginning and at different times during the tests. They were measured as the total peak area associated with the test item in a headspace GC analysis. These measured values show sometimes very large differences between the nominal loading rates and the actual test concentrations to which the test organisms were exposed during the tests.

Therefore, ECHA considers that it is not only possible but also highly relevant to calculate the results based on the measured concentrations.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to revise in your registration dossier the robust study summary for the short-term toxicity study on fish ([redacted] 2010b) with an effect concentration recalculated from measured test concentrations.

You shall update your chemical safety report accordingly. In particular, predicted no effect concentrations (PNEC) may need to be revised. In addition, a more severe classification and labelling of the substance may be warranted.

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 24 July 2018.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and did not amend the requests.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

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

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

3. In carrying out the tests 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 tests must be suitable to assess these.

   Furthermore, there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.