Helsinki, 15 October 2020

Addressees
Registrants of EC_273-601-0 CAS_68990-47-6 JS listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
12/11/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Fatty acids, tall-oil, reaction products with diethylenetriamine, maleic anhydride, tetraethylenepentamine and triethylenetetramine
EC number: 273-601-0
CAS number: 68990-47-6

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

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadlines provided.

A. Requirements applicable to all the Registrants subject to Annex VII of REACH

1. Water solubility (Annex VII, Section 7.7.; test method: OECD TG 105) with the Substance;

B. Requirements applicable to all the Registrants subject to Annex IX of REACH

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method OECD TG 408) in rats, with the Substance;

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method OECD TG 414) in a first species (rat or rabbit), oral route with the Substance;

3. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method EU C.20./OECD TG 211) with the Substance;

4. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method OECD TG 210) with the Substance;

5. Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method with the Substance, as described under Appendix B, Section 5;

C. Requirements applicable to all the Registrants subject to Annex X of REACH

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method OECD TG 414) in a second species (rat or rabbit), oral route with the Substance.

Conditions to comply with the requested information

Each addressee of this decision is bound by the requests for information corresponding to the REACH Annexes applicable to their own registered tonnage of the Substance at the time of evaluation of the jointly submitted dossier.

To identify your legal obligations, please refer to the following:

- you have to comply with the requirements of Annexes VII, VIII and IX of REACH, if you have registered a substance at 100-1000 tpa;
- you have to comply with the requirements of Annexes VII to X of REACH, if you have registered a substance at above 1000 tpa.

Registrants are only required to share the costs of information that they must submit to fulfil the information requirements for their registration.

The Appendices state the reasons for the requests for information to fulfil the requirements set out in the respective Annexes of REACH.

The Appendix entitled Observations and technical guidance addresses the generic approach for the selection and reporting of the test material used to perform the required studies and provides generic recommendations and references to ECHA guidance and other reference documents.

You must submit the information requested in points A.1., B.2. – B.5., C.1. above in an updated registration dossier by ***22 January 2024***, and the information requested in point B.1. above by ***21 July 2022***.

You must also update the chemical safety report, where relevant, including any changes to classification and labelling based on the newly generated information. The timeline has been set to allow for sequential testing where relevant.

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] under the authority of Christel Schilliger-Musset, Director of 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 A: Reasons for the requests to comply with Annex VII of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 1 to 10 tonnes or more per year must contain, as a minimum, the information specified in Annex VII to REACH.

1. Water solubility (Annex VII, Section 7.7.)

Water solubility is a standard information requirement in Annex VII to REACH.

You have provided the following information for this endpoint:
- An experimental study (2010) (Key study)

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

Tests on substances must be conducted in accordance with the OECD test guidelines or other internationally recognised test method (Article 13(3) of REACH).

OECD TG 105 is the standard test guideline which establishes the requirements for the data to be reported for a water solubility study. It requires that the following conditions are met:
1. Three measurements are required with equilibration at the test temperature for 24 hours, 2 days and 3 days, and the concentration in at least the last two flasks should not differ by more than 15%
2. All information relevant for the interpretation of the results is required. For example, pH of the saturated solution and the temperature of the water solubility measurement.

You have provided this information requirement by using:
- An experimental study (2010) according to a non-standard method (Key study). A single experiment was conducted by ultrasonication and occasional vortex mixing of a mixture of the substance and water at 60°C for an unspecified duration, then cooling the mixture to room temperature for an unspecified time, removing undissolved solid by centrifugation and filtration and determination of the concentration of the substance in the filtrate by HPLC-MS analysis, providing a water solubility value of 2.17 mg/L without reporting the temperature or solution pH.

Your non-guideline method does not follow the OECD TG 105. In particular:
- It is not possible to determine if equilibrium was established between undissolved solid and solution because there was only one measurement indicated. Therefore, ECHA cannot ascertain if the measured concentrations in the last two flasks differ by more than 15%. Consequently, the aforementioned condition (1.) of the standard OECD test guideline is not met.
- Concerning all information relevant for the interpretation of the results, you did not report the pH of the saturated solution and the temperature of the water solubility measurement but it was only described qualitatively as room temperature. Consequently, the aforementioned condition (2.) of the standard OECD test guideline is not met.
  Providing a water solubility value of 2.17 mg/L and not providing the temperature at which the measurement has been done, it cannot be assured that the value of water solubility is not much lower at the 20°C outlined by OECD TG 105.

In your comments to the draft decision, you indicated your agreement to perform a new study according to OECD TG 105.

Therefore, the provided information is rejected and the information requirement is not fulfilled.

Appendix B: Reasons for the requests to comply with Annex IX of REACH

In accordance with Articles 10(a) and 12(1) of the REACH, a technical dossier registered at 100 to 1000 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII-IX to the REACH.

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

A Sub-chronic toxicity study (90 day) is a standard information requirement in Annex IX to REACH.

You have provided a key study for this endpoint in your dossier:

i. A Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) with the Substance, 2010.

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

The Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) you have submitted does not have the required exposure duration of 90 days as required in OECD TG 408, because the exposure duration of this screening test was 54 days. Furthermore, the organ weight and histopathological investigations in OECD TG 422 are only conducted using 5 animals per sex per group and not 10 per sex per group as in OECD TG 408.

In your comment to the draft decision, you propose a waiver accordance with the provisions in the column two of Annex IX, point 8.6.2. ECHA finds that in the 28-day study, effects in respiratory tract were observed, e.g. multifocal bronchopneumonia, infiltration with mononuclear cells, histiocytes and occasional multinucleated cells. In addition, intrahistiocytic black material was seen in the lung of each one male treated at 300 or 1000 mg/kg/day. With these findings, the specific criteria of the adaptation, i.e. "no evidence of toxicity in a 28-day" cannot be met.

Moreover, the information in the dossier does not meet the criteria that concerns exposure, because in the Exposure scenario 3: [redacted], and therefore the human exposure cannot be considered "limited".

Based on the above, the information you provided do not fulfil the information requirement.

Following the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity. As the substance is a solid, the sub-chronic toxicity study must be performed according to the OECD TG 408, in rats and with oral administration of the Substance.

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

A Pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is a standard information requirement under Annex IX to REACH.

You have provided

A. A Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) with the Substance, according to GLP, [redacted] 2010;
B. Data adaptation that refers to low toxicity and no significant human exposure.

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

A. OECD TG 422 study

In order to be considered compliant and enable assessing if the Substance is a developmental toxicant, information provided has to meet the requirements of OECD TG 414 in one species.

You have not provided information following OECD TG 414. Instead, you have provided a "reproduction/ developmental toxicity screening test" (OECD TG 421)/ "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (OECD TG 422). In this study, structural malformations and variations are not investigated as required in the PNDT study (OECD TG 414).

Based on the above, the information you provided do not fulfil the information requirement.

B. Data adaptation

According to Annex IX, Section 8.7., Column 2, third indent, the study does not need to be conducted if the substance is of low toxicological activity. This needs to be demonstrated with three concomitant criteria:

- that there is no evidence of toxicity seen in any of the tests available;
- that it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure; and
- that there is no or no significant human exposure.

In your adaptation, you have claimed that "*Acute oral and dermal toxicity studies in rats: in the limit test at a fixed dose of 2000 mg/kg no significant treatment related effects were seen. In such studies LD50 was higher than 2000 mg/kg. The repeated administration in the 13-week toxicity combined with reproductive endpoint study in rodents by oral did not showed any adverse systemic effects. The lack of general effects and of the target organ toxicity does not lead to conclude that the test item is adsorbed and distributed systemically. Skin and eye irritation studies did not show any local or systemic toxicity. Furthermore not significant exposure to the substance is foreseen for humans and environment during all steps of life cycle under the operational conditions and the risk management measures implemented and recommended (see Chemical Safety Report).*"

ECHA interprets this as an attempt to apply the adaptation specified in Annex IX, Section 8.7., Column 2, third indent. However, you have not provided any toxicokinetic data to show that there is no systemic absorption. Furthermore, the uses of the Substance indicate that there is significant human exposure (RCR [redacted] from combined routes).

In your comment to the draft decision, you again propose waiver accordance with the provisions in the column two of Annex IX, point 8.7., and refer to the OECD TG 422 test, which did not provide evidence of reproductive/ developmental toxicity. As specified above, all the cumulative criteria of this adaptation have to be met in order waive the test. Because the criteria that concerns toxicokinetics and exposure are not met, the information requirement cannot be met with the results of the OECD TG 422 study, and other information currently provided.

Based on the above, your adaptation is rejected.

A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral[2] administration of the Substance.

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

Long-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex IX to the REACH Regulation.

You have provided an adaptation arguing that (1) no toxic effects were observed in short-term aquatic toxicity tests up to the water solubility limit of the Substance and (2) that environmental exposure is negligible.

To adapt the information requirement for long-term toxicity to aquatic invertebrates based on Annex IX, Section 9.1., Column 2, the Chemical Safety Assessment (CSA) needs to demonstrate that risks towards the aquatic compartment arising from the use of the Substance are controlled and that there is no need to conduct further testing (as per Annex I, section 0.1).

In particular, you need to take into account the following elements in your justification:
- all relevant hazard information from your registration dossier,
- the outcome of the exposure assessment in relation to the uses of the Substance,
- the outcome of the PBT/vPvB assessment including information on relevant degradation products and constituents present in concentration at or above 0.1% (w/w).

In addition, for poorly water soluble substances long-term toxicity study (on aquatic invertebrates) must be considered instead of an acute test (REACH Annex VII, Section 9.1.1, Column 2).

We have assessed your CSA and your adaptation and identified the following issues:

A. Absence of observed short-term effects does not rule out potential long-term effects

In your dossier, you have provided a study for short-term toxicity on *Daphnia*. In this study, no effects were observed up to the solubility limit of the Substance.

However, the Substance is regarded as poorly water soluble. You have reported a water solubility of 2.17 mg/L for the Substance, but the actual water solubility is expected to be much lower. In the current dossier, under the water solubility section 4.8. under the Applicant's summary and conclusions, you state the following "*Interpretation of results (migrated information): slightly soluble (0.1-100 mg/L)*". In addition, in the current dossier, under the Adsorption/ desorption section 5.4.1. under the Applicant's summary and conclusions, you state the following "*On the basis of the very low water solubility and its chemical nature, the substance is expected to have a high ability to absorb to soil*". The above quotes from the current dossier suggests that the lower water solubility value range is below 1 mg/L and that the Substance has a very low water solubility. This is also supported by the chemical structure due to the long carbon chains of the Substance.

[2] ECHA Guidance R.7a, Section R.7.6.2.3.2.

The Substance is made of very large constituents. When assessing its bioaccumulation potential, you calculated the following descriptors based on the structure for the "worst-case" constituent: molecular weights [redacted], maximum molecular lengths [redacted] and average maximum diameters (Dmax average) [redacted]. You explained that the Substance was unlikely to cross biological membranes.

Passive diffusion across cell membranes is one mechanism of absorption. However, other uptake mechanisms may also play a role.

Steric hindrance and low water solubility of the Substance can result in decreased uptake rates. It implies that longer time will be necessary for the Substance to be significantly absorbed by the test organisms and to reach steady state conditions. For this reason, the short-term aquatic toxicity tests provided in your dossier may not give a true measure of the aquatic toxicity of the Substance.

The Substance contains several structural alerts, in particular for Michael-type additions [redacted] which as such cause concerns for potential high toxicity as the Substance may react with proteins and DNA once it is absorbed.

Therefore, you have not demonstrated that there is no need to conduct further long-term testing.

B. Environmental exposure cannot be ruled out and may not be negligible

The substance is mainly used in drilling fluids for both on-shore and off-shore operations.

You have claimed that EUSES, which is the model recommended for assessing exposure and risks under REACH, is not appropriate for assessing this use. You have provided only a qualitative environmental exposure assessment from which you have considered that exposure is negligible:

[redacted]

However, the Substance is not handled under strictly controlled conditions throughout its life cycle. The identified risk management measures do not imply the absence of any release into the environment even during normal operating conditions. Therefore, environmental exposure cannot be ruled out.

Since you have not provided a quantitative environmental exposure assessment, it is not possible to assess whether environmental exposure is negligible. Contrary to your claim, the EUSES model can be used to perform a quantitative environmental exposure assessment. Manufacture and formulation are covered by standard REACH exposure scenarios in EUSES. As for [redacted], they could be assessed using EUSES exposure scenarios for [redacted].

C. Conclusion

Based on the above, neither long-term aquatic toxicity nor environmental exposure can be ruled out for the Substance.

Since your CSA contains neither a quantitative environmental exposure assessment nor a true measure of the aquatic toxicity of the Substance, it does not demonstrate that risks toward the aquatic compartment arising from the use of the Substance are controlled.

In your comments to the draft decision, you indicated that you would attempt to provide the requested information taking into account the outcome of the water solubility study requested under Section A.1 of the present Decision, as well as possible other information. It is in your discretion to generate and provide the necessary information in order to justify any adaptation. If you do so, you are responsible for demonstrating the fulfilment of the requirements of the relevant section to REACH. If it fails and the resulting data does not support, or even contradict, your hypothesis, you remain responsible for complying with this decision by the set deadline.

Therefore, your adaptation does not fulfil the information requirement. You must perform long-term toxicity testing on aquatic invertebrates.

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

Long-term toxicity testing on fish is a standard information requirement in Annex IX to the REACH Regulation.

You have provided an adaptation based on the same considerations as those you have used for long-term toxicity on aquatic invertebrates.

We have assessed your adaptation and identified the same deficiencies as for long-term toxicity on aquatic invertebrates (see Section B.3 of the present Decision).

In your comments to the draft decision, you indicated that you would attempt to provide the requested information taking into account the outcome of the water solubility study requested under Section A.1 of the present Decision, the outcome of the long-term toxicity testing on aquatic invertebrates requested under Section B.3 of the present Decision, as well as possible other information. It is in your discretion to generate and provide the necessary information in order to justify any adaptation. If you do so, you are responsible for demonstrating the fulfilment of the requirements of the relevant section to REACH. If it fails and the resulting data does not support, or even contradict, your hypothesis, you remain responsible for complying with this decision by the set deadline.

Therefore, your adaptation does not fulfil the information requirement. You must perform long-term toxicity testing on fish.

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

Identification of the degradation products is a standard information requirement at Annex IX of REACH.

You have not provided information for this standard information requirement.

The CSA needs to assess and document that risks arising from the Substance and its degradation products are controlled to demonstrate that there is no need to conduct further testing (Annex IX, Section 9.2, Column 2).

In particular the following element(s) need to be included:
- a justification for why there is no need to provide any further information for the degradation products to be considered in hazard assessment and exposure assessment,
- a PBT/vPvB assessment including information on relevant degradation products.

Identification of degradation products does not need to be conducted if the substance is readily biodegradable (Annex IX, Section 9.2.3, column 2).

In your CSA, and in particular in a document attached to your technical dossier[3], you have explained that:
- You do not expect the Substance to be biodegradable. For the PBT/vPvB assessment, you have assumed that the Substance is persistent (P) or very persistent (vP).
- You do not expect the substance to be bioaccumulative because of the large molecular sizes and weights of its constituents. Consequently, you have claimed that the Substance does not pose PBT/vPvB concerns.
- You consider that environmental exposure is negligible because risk management measures are implemented to limit environmental releases.

We have assessed your CSA and your adaptation and identified the following issues:

A. Non ready biodegradability does not necessarily implies that degradation products are not formed

Only 2.7 % mineralisation was observed after 28 days in a test performed according to OECD Guideline 301 D (Ready Biodegradability: Closed Bottle Test). You have indicated that the inoculum used for this study was derived from the secondary effluent of the manufacturer's treatment plant. This implies that the inoculum may have been adapted to the Substance. Consequently, you have considered that this test should not be regarded as a ready biodegradability test and you have concluded that the Substance is not inherently biodegradable and should be regarded as P/vP.

However, any mineralisation measured in screening biodegradability tests (ready biodegradability tests or inherent biodegradability tests) would denote only ultimate biodegradation. The lack of observed mineralisation in a ready or in an inherent biodegradability test does not necessarily imply that the Substance is intrinsically persistent because partial degradation could take place. Any partial degradation would imply the formation of degradation products, for which a PBT/vPvB assessment must be performed.

B. Potential degradation products may pose PBT/vPvB concerns

In a document attached to your technical dossier[4], you have explained that the Substance is made of very large constituents. You calculated the following descriptors based on the structure for the "worst-case" constituent: molecular weights [redacted] maximum molecular lengths [redacted], and average maximum diameters (Dmax average) [redacted] On this basis, you have considered that the Substance is unlikely to cross biological membranes and as such has a limited bioaccumulation potential. You concluded that it did not pose PBT/vPvB concerns.

However, you have not performed a PBT/vPvB assessment for the potential degradation

[redacted]

products of the Substance as required under Annex XIII to REACH. Degradation products would be smaller molecules and more bioavailable than the parent Substance, and may therefore be more likely to pose PBT/vPvB concerns. Different QSAR models can be used to predict and get indicative information on potential degradation products of the Substance. For example, many of the degradation products predicted by program CATALOGIC were identified as probably not readily biodegradable. Therefore, they may be recalcitrant, i.e. they may meet the P or vP criteria. In addition, most of them have predicted log Kow values that are in the range indicative of potential high bioaccumulation. Therefore, they may meet the B or vB criteria too. They may also be toxic since most contains structural alerts for high toxicity/CMR properties ([redacted] Therefore, they may meet the T criteria as well.

C. Environmental exposure cannot be ruled out and may not be negligible

The substance is mainly used in [redacted]. You have explained that those activities are regulated by *ad hoc* legislation and guidelines aimed at minimising the impact to the environmental compartments and therefore the exposure to the environment can be regarded as negligible.

As explained in Section B.3.B of the present Decision, you have not demonstrated that risk management measures prevent any release into the environment. Therefore, environmental exposure cannot be ruled out.

For substances (or degradation products) satisfying the PBT and vPvB criteria, it is difficult to estimate with sufficient reliability risks toward the environment. Even small amounts of PBT/vPvB substances (or degradation products) released into the environment could induce risks. Therefore, the available data does not allow to conclude that environmental exposure is negligible.

D. Conclusion

Based on the above, we conclude that:
- the Substance is not readily biodegradable,
- your CSA does not demonstrate that risks and potential PBT/vPvB concerns arising from the Substance and its degradation products are controlled.

In your comments to the draft decision, you highlighted the technical and analytical difficulties of identifying the potential degradation products for the Substance. You indicated that you would rather attempt to provide the requested information by investigating possible alternative approaches. It is in your discretion to generate and provide the necessary information in order to justify any adaptation. If you do so, you are responsible for demonstrating the fulfilment of the requirements of the relevant section to REACH. If it fails and the resulting data does not support, or even contradict, your hypothesis, you remain responsible for complying with this decision by the set deadline.

Therefore, your adaptation does not fulfil the information requirement. You must provide information on the potential degradation products of the Substance and assess whether they have PBT/vPvB properties.

Regarding the appropriate and suitable test method, you are recommended to perform a simulation test (OECD Test Guideline 307, 308 or 309). If technically feasible, OECD test guideline 309 is to be preferred. If you choose to use OECD test guideline 309, you must apply the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (ECHA Guidance

R.11). To overcome the potential analytical limitations in the identification and quantification of the degradation products you may use higher concentrations of the test substance (e.g. >100 µg/L) and perform the test at the temperature of 20 °C, as specified in OECD test guideline 309.

You may also use other appropriate and suitable approaches to provide information on the identity of the degradation products, for example by using enhanced screening level degradation test(s) or modelling tools. You will need to provide a scientifically valid justification for that approach.

Appendix C: Reasons for the requests to comply with Annex X of REACH

In accordance with Articles 10(a) and 12(1) of the REACH, a technical dossier at tonnage above 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII-X to the REACH.

1. **Pre-natal developmental toxicity study (Annex X, Section 8.7.2.) in a second species**

Pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is a standard information requirement under Annex X to REACH.

You have provided
A. A Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) with the Substance, according to GLP, [redacted] 2010;
B. Data adaptation that refers to low toxicity and no significant human exposure.

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

A. OECD TG 422 study

In order to be considered compliant and enable assessing if the Substance is a developmental toxicant, information provided has to meet the requirements of OECD TG 414 in two species.

You have not provided information following OECD TG 414. Instead, you have provided a "reproduction/ developmental toxicity screening test" (OECD TG 421)/ "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (OECD TG 422). In this study, structural malformations and variations are not investigated as required in the PNDT study (OECD TG 414).

Based on the above, the information you provided do not fulfil the information requirement.

B. Data adaptation

According to Annex X, Section 8.7., Column 2, third indent, the study does not need to be conducted if the substance is of low toxicological activity. This needs to be demonstrated with three concomitant criteria:

- that there is no evidence of toxicity seen in any of the tests available;
- that it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure; and
- that there is no or no significant human exposure.

As explained under point B.2 above, ECHA interprets that you attempt to apply the adaptation specified in Annex X, Section 8.7., Column 2, third indent. However, you have not provided any toxicokinetic data to show that there is no systemic absorption. Furthermore, the uses of the Substance indicate that there is significant human exposure (for example, the RCR [redacted]).

In your comments to the draft decision, you have indicated your agreement to perform the requested test.

Based on the above, the information you provided do not fulfil the information requirement.

A PNDT study according to the OECD TG 414 study must be performed in rabbit or rat as the preferred second species, depending on the choice of species in the PNDT study in the first species (request B.2. in this decision).

ECHA
EUROPEAN CHEMICALS AGENCY

Appendix D: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of the REACH Regulation.

The compliance check was initiated on 11 March 2019.

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

ECHA took into account your comments and amended the deadline.

Registrant requested prolongation of timeline

The timeline indicated in the draft decision to provide the information requested is 24 months from the date of adoption of the decision for the information requested in points A.1., B.2. – B.5., C.1. above. For the information requested in point B.1. above, the timeline is 12 months.

In your comments on the draft decision, you requested an extension of the timeline to 36 months. You justified your request stating that:

- additional time was needed for the coordination of the activities among the co-registrants and some end-users,
- the availability of the test laboratories was limited,
- the Substance being UVCB, specific analytical method would need to be developed and validated.

Therefore, ECHA has modified the deadline of the decision and granted the request based on the foreseen required Substance specific analytical method development and set the deadline(s) from 12 to 18 months for B1, only and from 24 to 36 months months for all the remaining requests, from the date of adoption of the decision.

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

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix E: Observations and technical guidance

1. The information requirement under Section 8.7.3. of Annex IX/X to REACH (Extended one-generation reproductive toxicity study, EOGRTS) is not addressed in this decision, because the information from the Sub-chronic toxicity study (90-day), requested in the present this decision, is relevant for the design of the EOGRTS.

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

3. 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 the Member States.

4. Test guidelines, GLP requirements and reporting

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

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

   Under Article 10 (a) (vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide: 'How to report robust study summaries[5]'.

5. Test material

   The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

   While selecting the test material you must take into account the impact of each constituent/impurity on the test results for the endpoint to be assessed. For example, if a constituent/impurity of the Substance is known to have an impact on (eco)toxicity, the selected test material must contain that constituent/impurity. Any constituents that have harmonised classification and labelling according to the CLP Regulation (Regulation (EC) No 1272/2008) must be identified and quantified using the appropriate analytical methods.

   The OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 11 [ENV/MC/CHEM(98)16] requires a careful identification of the test material and description of its characteristics. In addition, the Test Methods Regulation (EU) 440/2008, as amended by Regulation (EU) 2016/266, requires that "*if the test method is used for the testing of a* [...] *UVCB* [...] *sufficient information on its composition should be made available, as far as possible, e.g. by the chemical identity of its constituents,*

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

their quantitative occurrence, and relevant properties of the constituents".

In order to meet this requirement, all the constituents of the test material used for each test shall be identified as far as possible. For each constituent the concentration value in the test material shall be reported in the Test material section of the endpoint study record.

Technical Reporting of the test material for UVCB substances

The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers" on the ECHA website[6].

6. List of references of the ECHA Guidance and other guidance/ reference documents[7]

<u>Evaluation of available information</u>
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 in this decision.

<u>QSARs, read-across and grouping</u>
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 in this decision.

ECHA Read-across assessment framework (RAAF, March 2017)[8]

<u>Physical-chemical properties</u>
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

<u>Toxicology</u>
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

<u>Environmental toxicology and fate</u>
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

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[6] https://echa.europa.eu/manuals
[7] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[8] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

OECD Guidance documents[9]
Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD23.
Guidance Document supporting the OECD TG 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD151.

[9] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix F: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fulfilled
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.