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Helsinki, 08 July 2019

Substance name: Bis(isopropyl)naphthalene
EC number: 254-052-6
CAS number: 38640-62-9
Date of submission(s) subject to follow-up evaluation[1]: 26 October 2017
Decision/annotation number: Please refer to the REACH-IT message which delivered this communication (in format SEV-D-XXXXXXXXXX-XX-XX/F)
Addressee(s): Registrant(s)[2] of Bis(isopropyl)naphthalene

DECISION ON SUBSTANCE EVALUATION

This decision consists of two parts, Part I concerning an existing information request that has not been fulfilled and Part II concerning a new information request to clarify the PBT concern.

Part I

Based on Article 46(3) of the REACH Regulation (Regulation (EC) No 1907/2006), the evaluating Member State competent authority (evaluating MSCA) has examined the information you submitted as a response to decision SEV-D-2114308353-59-01/F[3] dated 31 August 2015 ("the original decision"). ECHA concludes that after the expiry of the deadline set in the original decision, your registration does not comply with the following information request:

1. Aerobic mineralisation in surface water according to test guideline EU C.25 /OECD 309 "Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test" at a temperature of 12°C, preferably using carbon 14 ring-labelled test substance. The degradation half-life should primarily be determined for the isomers 1,3- and 1,4-DIPN.

The original decision set a deadline to provide the requested information. You did not provide the requested information by that deadline, and therefore this decision (Part I) is sent to the respective Member State competent authority (MSCA) and national enforcement authority (NEA)[4]. They may consider enforcement actions to secure the implementation of the original decision.

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[1] This decision is based on the registration dossier(s) considered during the follow-up evaluation period.

[2] The terms registrant(s), dossier(s) or registration(s) are used throughout the decision, irrespective of the number of registrants addressed by the decision.

[3] This decision number refers to the notification sent to the lead registrant. All member registrants have an individual number of the substance evaluation decision notifications. Those are listed in the Annex where also the relevant registration numbers are provided.

[4] The decision will be sent to the Member State competent authority and to the focal points of the national enforcement authorities relevant for the recipients of the decision. On that basis the national enforcement authorities can consider enforcement actions.

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Part II
Based on Article 46(3) of the REACH Regulation (Regulation (EC) No 1907/2006), ECHA requests you to submit the following information:

2. *Daphnia magna* reproduction test according to test guideline EU C.20/OECD 211 with the isomers 1,3- and 1,4-DIPN of the registered substance tested separately and in parallel. In order to maintain stable test concentrations the tests shall be performed in flow-through test systems.

3. Fish early life stage tests according to test guideline OECD 210 under flow through conditions, with the isomers 1,3- and 1,4-DIPN of the registered substance tested sequentially (as further specified in Appendix 1: Reasons).
   You can decide which isomer to test first. If testing the first isomer demonstrates that it fulfils the REACH Annex XIII criteria for T (NOEC < 10µg/l), testing of the second isomer is not required. Also, in case one of the isomers, based on the results of request 1, does not fulfil the REACH Annex XIII criteria for P (DT50 > 40 d) you do not have to test it.

If one of the following conditions are met there is no need to perform the tests in request 3:
- Based on the result of request 1, either isomer fulfils the REACH Annex XIII criteria for vP (DT50 > 60 d).
- Based on the result of request 1, both isomers do not fulfil the REACH Annex XIII criteria for P (DT50 > 40 d).
- Based on the results of request 1 and 2, either isomer fulfils the REACH Annex XIII criteria for both P (DT50 > 40 d) and T (NOEC < 10µg/l).

You have to provide an update of the registration dossier(s) containing the requested information, including robust study summaries and, where relevant, an update of the chemical safety report. The information required according to request 2 shall be generated and provided by **08 July 2020**. When applicable, the information required according to request 3 above on the first isomer tested shall be generated and provided by **08 July 2021**. When applicable, the information required according to request 3 above on the second isomer shall be generated and provided by **08 July 2022**.

In addition to the robust study summaries, you shall submit full study reports for the requested studies by the same deadlines.

The deadline takes into account the time that you may need to agree on which of the registrant(s) will perform the required tests (3 months is allocated for this). These deadlines are relevant for Part II only.

Common to Part I and II requests

The reasons of this decision and any further test specifications of the requirements are set out in Appendix 1. The procedural history is described in Appendix 2. Further information, observations and technical guidance as appropriate are provided in Appendix 3. Appendix 4 contains a list of registration numbers for the addressees of this decision. This appendix is confidential and not included in the public version of this decision.

Based on Article 53 of the REACH Regulation, you are requested to inform ECHA who will carry out the study/ies on behalf of all registrant(s) within 90 days. Instructions on how to do this are provided in Appendix 3.

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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 a suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals

Authorised[5] by Christel Schilliger-Musset, Director of Hazard Assessment

[5] 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

General considerations

Bis(isopropyl)naphthalene (DIPN) is an isomeric mixture. The marketed mixture consists of 7 isomers each making up from [redacted] to [redacted] % of the mixture. Studies on the mixture have revealed that the different isomers differ in persistency and bioaccumulation. Screening tests have shown that the isomers 1,5-, 1,6-, 2,6- and 2,7-DIPN degrade to the extent that they are unlikely to fulfil the P-criterion and thus, the PBT/vPvB criteria of REACH Annex XIII. The other three isomers, 1,3-, 1,4 and 1,7-DIPN are less degradable and may fulfil the P/vP criteria. However, in the absence of a simulation study no definitive conclusion on their persistence can be drawn.

Two of these three isomers, 1,3- and 1,4-DIPN have lipid normalised, but not growth corrected, BCF-values >5000 in a BCF study performed at an exposure concentration of 5 µg/l and >2000 at an exposure concentration of 0.5 µg/l. In the absence of a plausible explanation for this difference ECHA considers that the BCFs obtained at the higher exposure concentration should be used for assessing against the B and vB criterion of REACH Annex XIII. The isomer 1,7-DIPN is less bioaccumulative with a BCF< 5000 at 5 µg/l and <2000 at 0.5 µg/l. Therefore, 1,3- and 1,4-DIPN are considered to represent the worst case of the P- and B-properties of all DIPN-isomers. ECHA considers that the available information is sufficient to assess the bioaccumulation for this substance at this step of the evaluation.

No information on the toxicity of the individual isomers is available. However, the *Daphnia magna* reproduction test requested in the original decision gave a NOEC of 12 µg/l for the isomeric mixture. This is very close to the REACH Annex XIII T-criterion of 10 µg/l and it cannot be excluded that individual isomers fulfil the T-criterion.

Therefore, ECHA considers that a simulation test as already requested in the original decision and further information on the toxicity of individual isomers (i.e. 1,3- and 1,4-DIPN) as requested in Part II of this decision are necessary to enable the evaluating MSCA to conclude on the PBT assessment.

For the reasons explained below, two isomers (1,3- and 1,4-DIPN) have to be tested in parallel and not sequentially in both simulation study and long term Daphnia study, to assess the P and T properties of the substance.

The P-properties of these isomers could have been already clarified if the simulation test requested in the original decision had been performed. In order not to further delay the clarification of the identified concern, ECHA also considers it necessary to request toxicity testing in Daphnia in parallel with clarifying the P-properties for the two isomers. Testing on Fish, in order to minimise unnecessary vertebrate animal testing, is requested conditionally - based on the results from the simulation and Daphnia testing, and sequentially - on the two isomers 1,3- and 1,4-DIPN. This is because if the PBT concern can be substantiated already with the first isomer tested, there is no need to test the second isomer.

The tiered strategy proposed by you in the comments to the draft decision would mean a possible delay of several months, in clarifying the identified concern. However, the time is of critical value because the Substance is not readily biodegradable and, according to information in the chemical safety report, is used in e.g. coatings, adhesives and sealants,

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carbonless copy paper and heat transfer fluids, with a wide dispersive use. Given this wide dispersive use pattern and available information on degradation, exposure to the environment is likely.

Since the Substance would remain on the market for a significant period of time while the concern is being clarified, any further delays in obtaining the necessary information will increase the time of exposure to the environment. Due to its intrinsic properties, such prolonged exposure may result in the Substance irreversibly remaining and accumulating in the environment leading to widespread distribution and with potential to cause effects that are unpredictable in the long-term and are difficult to reverse (even when emissions cease).

In addition, ECHA considers that the concerns are clearly identified and each information request is necessary, appropriate, and the least onerous measure to clarify the concern.

Part I

Based on the evaluation of all relevant information submitted on Bis(isopropyl)naphthalene, ECHA concludes that you have not provided all the information requested in the original decision dated 31 August 2015. For that reason the evaluating Member State competent authority (evaluating MSCA) is not able to complete the evaluation of whether the substance constitutes a risk to the environment.

1. **Aerobic mineralisation in surface water according to test guideline EU C.25 /OECD 309 "Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test" at a temperature of 12°C, preferably using carbon 14 ring-labelled test substance. The degradation half-life should primarily be determined for the isomers 1,3- and 1,4-DIPN.**

Bis(isopropyl)naphthalene was assessed under the substance evaluation procedure by Sweden in 2013. In the original decision, ECHA required you to submit a simulation biodegradation test in surface water according to test guideline EU C.25 /OECD 309 "Aerobic Mineralisation in Surface Water. This request was based on the concern that some of the isomers of DIPN and specifically the isomers 1,3- and 1,4-DIPN may fulfil the vP-criterion and thus potentially would fulfil the vPvB/PBT-criteria of REACH Annex XIII.

In June 2017, you updated the registration dossier but did not provide the requested simulation study. According to the updated dossier, you consider that Bis(isopropyl)naphthalene fulfils the vP-criterion and that a simulation study would be unlikely to come to another result.

You refer to the fact that the available studies used for the evaluation of the substance did not demonstrate ready or inherent biodegradability. You assessed the substance as vP based on a primary degradation study following OECD guideline 310. The study reported a primary biodegradation rate of 21-30% for the whole substance (sum of isomers). A study on the ultimate degradation determined a biodegradation rate of < 0.05%. Furthermore, you refer to studies performed in 2005, but previously not included in your registration dossier. These studies according to OECD 301D (closed-bottle test) (Fresenius 2005a) and a follow-up test according to OECD 302 D (Fresenius 2005b) failed to show ultimate biodegradation after extension of the incubation period to 56 days. While the ready-test did not exceed 18% O_2 -consumption, the inherent test after adaptation of the inoculum attained O_2 consumption of 37%, apparently levelling off after 56 days.

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From these results, you concluded that DIPN fulfils at least the criteria of persistence P and that for several DIPN-isomers, subsequent simulation testing may result in vP, in particular under the stringent conditions of 12 °C imposed by ECHA´s decision.

ECHA assessment

ECHA notes that in the updated dossier you consider the substance to meet the criteria for vP on the basis of existing data. In the registration dossier you claim that a simulation study is not expected to lead to other results and, therefore, omitted further testing.

ECHA disagrees with your conclusion and considers the information currently available insufficient for concluding that the vP-criterion is fulfilled.

In two reliable studies using the OECD 310 method DIPN was not ready biodegradable. No carbon dioxide was formed during 56 days of incubation at room temperature (22±2°C) without direct lighting. However, these studies show that DIPN undergoes primary degradation and that the different isomers have largely differing degradation rates. One isomer, 2,6-DIPN disappeared completely within 28 days of incubation. For three of the isomers 1,5-, 1,6-, and 2,7-DIPN the decrease was 52, 92 and 78 %, respectively after 56 days of incubation. Subtracting the decrease observed in abiotic flasks gives an estimated primary biodegradation of 15, 36 and 56 % for the three isomers, respectively. The three remaining isomers were less degraded. For the isomers 1,3- 1,4 and 1,7 DIPN the decrease was 17, 21 and 28 %, respectively after 56 days of incubation. Subtracting the decrease observed in abiotic flasks gives an estimated primary biodegradation of 0 % for each of these isomers.

However, ECHA does not consider it possible from these results to conclude on whether or not these isomers fulfil the P/vP criteria of Annex XIII of the REACH Regulation and the concern remains.

Furthermore, the two existing studies referred by you as Fresenius 2005a, a ready test performed according to OECD guideline 301D and Fresenius 2005b, an inherent test performed according to OECD guideline 302D, were not previously included in the registration dossier.

The OECD 301D study gave 3% degradation during 28 days of incubation based on O_2-consumption. With adapted inoculum the degradation was 17 %. This study indicates that DIPN can be degraded but confirms that it is not ready biodegradable. The OECD 302D study used adapted inoculum and was prolonged to 56 days. The degradation based on O_2 -consumption was 26 % after 7 days, but did only increase to 37 % after 56 days. None of these two studies gives information on the degradability of the individual isomers.

According to the ECHA Guidance on information requirements and chemical safety assessment Chapter R.11: PBT/vPvB assessment (version 3.0, June 2017) lack of degradation (<20% degradation) in an inherent biodegradability test equivalent to the OECD TG 302 series may provide sufficient information to confirm that the P-criteria are fulfilled without the need for further simulation testing for the purpose of PBT/vPvB assessment. This was not the case with the present inherent study. Overall ECHA does not consider it possible from these results to conclude on whether or not DIPN and specifically the 1,3- and 1,4 isomers fulfil the P/vP criteria of Annex XIII of REACH.

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Consideration of your comments

In your comment to the draft decision you agree to ECHA's request for simulation testing of the two isomers 1,3- and 1,4-DIPN according to test guideline EU C.25/OECD 309. However, you suggest a stepwise procedure, first testing the 1,3-isomer for which available data indicate that it is slightly more recalcitrant than the 1,4-isomer. If the 1,3 isomer turns out to fulfil the vP-criterion you are going to critically reassess the available experimental bioaccumulation data. In case that the fulfilment of the vB-criterion cannot be rejected, the 1,3-isomer can be concluded as vPvB and no further data needs to be generated. You consider testing of the 1,4-isomer to be justified only if the 1,3-isomer does not fulfil the vP-criterion.

ECHA considers the tiered approach you suggest not acceptable for the reasons explained above in Appendix 1: Reasons under 'General considerations'.

Conclusion

As detailed above, the information request outlined in the decision of 31 August 2015 has not been met, and the vP concern still remains to be clarified. Accordingly, you are required to provide an aerobic mineralisation test in surface water according to test guideline EU C.25 /OECD 309 "Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test at a temperature of 12°C, preferably using carbon 14 ring-labelled test substance. The degradation half-life should primarily be determined for the isomers 1,3- and 1,4-DIPN. The test should be carried out according to the specifications given in the decision of 31 August 2015.

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Part II
Based on the evaluation of all relevant information submitted on Bis(isopropyl)naphthalene (DIPN) and other relevant and available information ECHA concludes that further information is required in order to clarify whether or not DIPN meets the T-criterion of Annex XIII of REACH and enable the evaluating MSCA to conclude on the PBT-assessment.

The evaluating MSCA will subsequently review the information submitted by you and evaluate if further information should be requested to clarify the PBT/vPvB concern in the follow up process.

Explanation of the testing strategy

The original draft decision contained, to clarify the T criterion, only a request for long term toxicity to fish on the two isomers 1,3- and 1,4-DIPN. Following the consultation with the MSCAs, proposals for amendment (PfA) were submitted. One PfA suggested to first request long term toxicity to Daphnia on the two isomers and to make the request for fish testing conditional to the results of the Daphnia test (and the results of the simulation test requested in part I of the decision) to avoid unnecessary vertebrate animal testing. Another PfA suggested to test long term toxicity to fish sequentially on the two isomers 1,3- and 1,4-DIPN, again with the reason to avoid unnecessary vertebrate animal testing.

ECHA accepted the PfAs and modified the testing strategy in the decision accordingly. The testing strategy laid out in this decision considers that, to clarify the T criterion in the most proportionate way, taking into account also animal welfare considerations, it is appropriate to perform long term toxicity testing on Daphnia first (on the two isomers 1,3- and 1,4-DIPN in parallel), and then testing on fish only conditionally and also in a sequential manner on the two isomers.

2. *Daphnia magna* reproduction test according to test guideline EU C.20/OECD 211 with the isomers 1,3- and 1,4-DIPN of the registered substance tested separately and in parallel.

The concern(s) identified

With a NOEC of 13 µg/l, an earlier less reliable chronic toxicity study on *Daphnia magna* indicates that DIPN has high aquatic toxicity. This is confirmed by the result from the new Daphnia study. This study gave a NOEC of 12 µg/l which is very close to the T-criterion of 10 µg/l of Annex XIII, section 1.1.3. of the REACH Regulation.

The high chronic toxicity to Daphnia of the isomeric mixture indicates that one or more of the DIPN isomers may have NOEC-values below 10 µg/l, thus fulfilling the T criterion for Daphnia. The different isomers have different persistency and bioaccumulation potential. However, currently there is no information available on the toxicity of the individual isomers. Showing a relatively high primary degradation in a ready biodegradability test and having BCF-values below 5000, the isomers 1,5-, 1,6-, 2,6- and 2,7- DIPN are considered less likely to fulfil the PBT/vPvB criteria of REACH Annex XIII. For the isomers 1,3-, 1,4- and 1,7-DIPN on the other hand, the estimated primary biodegradation was 0 %. In addition the isomers 1,3- and 1,4-DIPN have BCF-values above 5000. Therefore, 1,3- and 1,4-DIPN are the most persistent and bioaccumulating isomers of the DIPN

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isomeric mixture, but there are no reliable aquatic chronic studies on those isomers to allow ECHA to conclude on the T-properties of DIPN.

Why new information is needed

Chronic toxicity studies on Daphnia are considered necessary in order to conclude on the T-properties of the most persistent and bioaccumulating isomers 1,3- and 1,4-DIPN and to conclude the PBT assessment of DIPN.

The Daphnia study delivered by you was not performed under flow conditions as requested in the decision. Instead a semistatic test regime was used with three renewals/week (in total 8 renewals) during the 21 days of the test. The test solution was prepared as a Water Accommodated Fraction (WAF)-solution by dissolving the test substance in M4 medium which rendered a stock solution of 140 µg DIPN/l (the isomeric composition of the stock solution is not known). The Daphnia were exposed to 5 different nominal concentrations of DIPN, 60, 39, 25, 16, and 10 µg/l. Analytical confirmation of the test solutions was made by analysing new test solutions 4 times and old test solutions 4 times. The test concentrations were not stable and decreased between 30 and 60 % between renewals. The results were therefore based on time weighted average concentrations (TWA).

At the two highest test concentrations 42 and 29 µg/ (TWA) the mortality was 100 %. The LOEC was 17 µg/l and the NOEC 12 µg/l. All validity criteria were fulfilled and despite the uncertainty caused by the decreasing test concentrations between renewals the evaluating MSCA considers the study reliable.

The NOEC (12 µg/l) of this study is very close to the T-criterion of Annex XIII, section 1.1.3.(a) of REACH (10 µg/l) indicating that one or several of the DIPN isomers may have a higher toxicity (i.e. NOEC < 10µg/l). Therefore, without having experimental data on the chronic toxicity of the two most persistent and bioaccumulating isomers (1,3- and 1,4 – DIPN) in Daphnia, it is not considered possible to conclude whether or not these two isomers fulfil the T-criterion of Annex XIII.

What is the possible regulatory outcome

If DIPN (i.e. 1,3- and/or 1,4 DIPN) is identified as fulfilling the PBT/vPvB criteria in Annex XIII of REACH, the substance may become a candidate for identification as substance of very high concern or other regulatory activities that will be determined afterwards.

Considerations on the test method and testing strategy

The test shall be performed according to OECD test guideline 211 under flow through conditions to keep the test concentrations stable. The test shall be performed with 1,3- and 1,4- DIPN. The 1,3- and 1,4-DIPN isomers have been identified as the worst case isomers of the DIPN mixture regarding P- and B-properties with similar results in an enhanced ready biodegradation test (decrease of around 20 %) and lipid normalised BCF-values of ca. 7000 for both isomers. There is however, no information available on the toxicity of individual isomers of the DIPN mixture. Consequently, there is little information available to judge if the toxicity of these two isomers is similar and thus, it is not possible to beforehand identify a worst case isomer for toxicity testing. Therefore, to avoid unnecessary delays, both isomers shall be tested separately and in parallel.

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In order to maintain stable test concentrations, the tests shall be performed in flow-through test systems. This is because, for a substance like DIPN, due to its moderate volatility, adsorption potential and due to the possibility of photolysis in test conditions, maintaining stable test concentratios in static test systems may be difficult. Earlier studies have given proof of this. E.g. in a limit test with fish, it was noted that the measured test concentration after 24 hours was approx. 27 % and after 96 hours approx. 20 % of the initial concentration. Also in the most recent Daphnia reprotox study which was performed under static conditions test concentrations decreased between 30 and 60 % between renewals.

You shall submit full study reports for the required studies.

Considering the complexity of the case as described above a complete rationale and access to all information available in the full study report (implemented method, raw data collected, interpretations and calculations, consideration of uncertainties, argumentation, etc.) are needed. This will allow the evaluating MSCA to fully assess the provided information, including the statistical analysis, and to efficiently clarify the concern for PBT properties.

Consideration of alternative approaches

There is no experimental study available at this stage that will generate the necessary information on the chronic toxicity of 1,3- and 1,4-DIPN to *Daphnia*.

Conclusion

Therefore, based on the substance evaluation and in accordance with Article 46(3) of the REACH Regulation, ECHA concludes that you are required to carry out the following studies:

A *Daphnia magna* reproduction test according to test guideline EU C.20/OECD 211 with the isomers 1,3- and 1,4-DIPN of the registered substance tested separately and in parallel. In order to maintain stable test concentrations the tests shall be performed in flow-through test systems.

3 Fish early life stage test according to tests guideline OECD 210 under flow through conditions, with the isomers 1,3- and 1,4-DIPN of the registered substance tested sequentially.

The concern(s) identified

As explained in Section 2 above, there is a concern that the substance fulfils the T criterion.

There is no evidence showing that fish is less sensitive than Daphnia, as explained below:

None of the acute aquatic toxicity studies performed with DIPN are considered reliable because of the lack of analytical monitoring of test concentrations. For fish LC_{50}-values of 2.44 and 4.5 mg/l based on nominal concentrations are reported in two acute toxicity studies, respectively. This is at least one order of magnitude higher than the water

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solubility of DIPN. For *Daphnia magna* 48 hour EC_{50}- values of >0.16 mg/l, 1.7 mg/l and 2.3 mg/l from three different studies are available, none of them considered fully reliable due to the lack of analytical monitoring. In addition to this, the Ministry of Environment, Japan (2005) reports a 48 hour EC_{50} for *Daphnia magna* of 0.035 mg/l from a semi static study performed at 20 ± 1°C, using nominal test concentrations of 0.013, 0.023, 0.041, 0.073 and 0.130 mg DIPN/L. No further details on the test are available in English. Thus, with the exception of one study, the available data do not indicate a difference in toxicity of DIPN between fish and Daphnia.

In addition, ECOSAR v2.0 indicates that fish and Daphnia have similar acute toxicity with a predicted 96 hour LC_{50} for fish of 42 µg/l and a predicted 48 hour LC_{50} for Daphnia of 43 µg/l, which is in good agreement with the results of the only acute Daphnia study reporting effects below the water solubility of DIPN. For chronic toxicity ECOSAR predicts fish to be slightly more sensitive than daphnids. The chronic value predicted for fish (geometric mean between LOEC and NOEC) is 6 µg DIPN/l and for daphnids 10 µg DIPN/l.

Why new information is needed

As explained in Section 2 above, the available information on aquatic toxicity do not allow a conclusion on whether the T criterion is met for the two isomers 1,3- and 1,4-DIPN that are considered to be the most persistent and bioaccumulative. If also the long term toxicity to Daphnia studies requested in this decision (request 2) are not conclusive, there is the need to generate new data on fish to clarify the T concern.

What is the possible regulatory outcome

If DIPN (i.e. 1,3- and/or 1,4 DIPN) is identified as fulfilling the PBT/vPvB criteria in Annex XIII of REACH, the substance may become a candidate for identification as substance of very high concern or other regulatory activities that will be determined afterwards.

Considerations on the test method and testing strategy

The test shall be performed according to OECD test guideline 210 under flow through conditions to keep the test concentrations stable.

You shall submit full study reports for the required studies.

Considering the complexity of the case as described above a complete rationale and access to all information available in the full study report (implemented method, raw data collected, interpretations and calculations, consideration of uncertainties, argumentation, etc.) are needed. This will allow the evaluating MSCA to fully assess the provided information, including the statistical analysis, and to efficiently clarify the concern for PBT properties.

Consideration of alternative approaches

Other options for experimental testing, i.e. a fish, juvenile growth test according to OECD guideline 215 or a fish sexual development test according to OECD guideline 234, have been considered. However, there are no indications that growth is the most sensitive

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endpoint or that DIPN has endocrine disrupting properties. A Fish Early Life Stage test according to OECD test guideline 210 is therefore considered to be the most suitable test for addressing the concern for chronic effects on fish in this case.

Consideration of your comments on the original Decision request and the Proposals for Amendment

In your comments to the draft decision which originally requested only a long term toxicity to fish for the assessment of the T criterion, you agreed with the reasoning of ECHA as to why testing according to OECD test guideline 210 is needed to conclude on the T-criterion for 1,3- and 1,4.DIPN. However, you argued that the fish testing may not be necessary if either of the two isomers 1,3- or 1,4-DIPN fulfils the vPvB-criterion. You suggested that first the 1,3-isomer should be tested in a simulation test. If it fulfils the vP-criterion and, after critical reassessment of the available bioaccumulation data vB cannot be rejected, vPvB can be concluded and no further testing would be necessary. In that case testing on vertebrates would be avoided. If the 1,3-isomer fulfils the P-criterion but not the vP-criterion, T-testing with the 1,3-isomer should be performed. If however the 1,3 isomer does not fulfil the T-criterion the 1,4 isomer should be tested following the same tiered approach as suggested for the 1,3-isomer.

For the reasons explained in Appendix 1: Reasons under 'General considerations', approval of sequential testing of isomers for simulation testing is not possible, while ECHA took your reasons for sequential testing of isomers for fish study into account for the testing strategy as currently requested.

As a part of the tiered approach you suggested to critically reassess the available bioaccumulation data to make sure that the fulfilment of the vB-criterion is scientifically justified if 1,3-DIPN turns out to fulfil the vP-criterion. ECHA notes that you already in the dossier update of June 2017 provided an assessment of the bioaccumulation potential of DIPN. In this assessment your conclusion was that 1,3- and 1,4-DIPN, in a worst case, fulfil the B criterion but not the vB-criterion. In the absence of newly generated data, it is not clear on what basis the reassessment should be done. In any case, the reassessment based on the existing data would not remove the current information request.

As explained in part II, 'Explanation of the testing strategy', in consequence of the submitted PfAs the request for testing long term toxicity on fish was made conditional and testing of isomers sequential.

In your comments to the PfAs you agreed to test long term toxicity to fish sequentially.

Conclusion

Therefore, based on the substance evaluation and in accordance with Article 46(3) of the REACH Regulation, ECHA concludes that you are required to carry out the following studies:

Fish early life stage tests according to OECD test guideline 210 under flow through conditions, with the isomers 1,3- and 1,4-DIPN of the registered substance tested sequentially (as further specified in Appendix 1: Reasons).

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You can decide which isomer to test first. If testing the first isomer demonstrates that it fulfils the REACH Annex XIII criteria for T (NOEC < 10µg/l), testing of the second isomer is not required. Also, in case one of the isomers, based on the results of request 1, does not fulfil the REACH Annex XIII criteria for P (DT50 > 40 d) you do not have to test it.

If one of the following conditions are met there is no need to perform the tests in request 3:

- Based on the result of request 1, either isomer fulfils the REACH Annex XIII criteria for vP (DT50 > 60 d).
- Based on the result of request 1, both isomers do not fulfil the REACH Annex XIII criteria for P (DT50 > 40 d).
- Based on the results of request 1 and 2, either isomer fulfils the REACH Annex XIII criteria for both P (DT50 > 40 d) and T (NOEC < 10µg/l).

Consideration of the time needed to perform the requested studies

In the draft decision communicated to you, the time indicated to provide the requested information was 15 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision only requested a long term toxicity to fish. As a long term toxicity to Daphnia has been added to the decision and the long term fish toxicity test is conditional to the results of the Daphnia test, ECHA has modified the deadline for provision of the required information.

References

Ministry of Environment, Japan (2005)
https://www.env.go.jp/chemi/sesaku/mat02e.pdf

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Appendix 2: Procedural history

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to suspected PBT/vPvB properties, Bis(isopropyl)naphthalene CAS No 38640-62-9 (EC No 254-052-6) was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2013. The updated CoRAP was published on the ECHA website on 20 March 2013. The competent authority of Sweden (hereafter called the evaluating MSCA) was appointed to carry out the evaluation.

In accordance with Article 46(1) of the REACH Regulation, a substance evaluation decision was issued on 31 August 2015 requesting further information. You submitted a part of the requested information on 7 June 2017. The evaluating MSCA carried out the evaluation of the information in your updated registration(s) and other relevant and available information.

The evaluating MSCA considered that the submitted information did not fully comply with the decision of 31 August 2015. It also considered that further information was required to clarify the above concerns. Therefore, it prepared a draft decision under Article 46(3) of the REACH Regulation to request further information. It subsequently submitted the draft decision to ECHA on 7 June 2018.

The decision making followed the procedure of Articles 50 and 52 of the REACH Regulation as described below.

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

Registrant(s)' commenting phase

ECHA received comments from you and forwarded them to the evaluating MSCA without delay.

The evaluating MSCA took the comments from you, which were sent within the commenting period, into account and they are reflected in the reasons (Appendix 1). The request(s) and the deadline were not amended.

Proposals for amendment by other MSCAs and ECHA and referral to the Member State Committee

The evaluating MSCA notified the draft decision to the competent authorities of the other Member States and ECHA for proposal(s) for amendment.

Subsequently, the evaluating MSCA received proposal(s) for amendment to the draft decision and modified the draft decision.

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

ECHA referred the draft decision, together with your comments, to the Member State Committee.

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

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You also provided comments on the draft decision. Your comments were not taken into account by the Member State Committee as they were considered to be outside of the scope of Article 52(2) and Article 51(5)

MSC agreement seeking stage

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-65 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

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Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided by you in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on your dossier(s) at a later stage, nor does it prevent a subsequent decision under the current substance evaluation or a new substance evaluation process once the present substance evaluation has been completed.

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