EUROPEAN CHEMICALS AGENCY

Helsinki, 31 August 2015

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

DECISION ON SUBSTANCE EVALUATION PURSUANT TO ARTICLE 46(1) OF REGULATION (EC) NO 1907/2006

For Bis(isopropyl)naphthalene, CAS No 38640-62-9 (EC No 254-052-6)

Addressees: Registrant(s) [1] of Bis(isopropyl)naphthalene

This decision is addressed to all Registrants of the above substance with active registrations on the date on which the draft for the decision was first sent, with the exception of the cases listed in the following paragraph. A list of all the relevant registration numbers subject to this decision is provided as an annex to this decision.

Registrants meeting the following criteria are *not* addressees of this decision: i) Registrants who exclusively use the above substance as an on-site isolated intermediate and under strictly controlled conditions and ii) Registrants who have ceased manufacture/import of the above substance in accordance with Article 50(3)of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation) before the decision is adopted by ECHA.

Based on an evaluation by Swedish Chemicals Agency as the Competent Authority of Sweden (evaluating MSCA), the European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 52 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

This decision is based on the registration dossier(s) on 29 April 2014, i.e. the day on which the draft decision was notified to the Registrant(s) pursuant to Article 50(1) of the REACH Regulation.

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

I. Procedure

Pursuant to Article 45(4) of the REACH Regulation the Competent Authority of Sweden has initiated substance evaluation for Bis(isopropyl)naphthalene CAS No 38640-62-9 (EC No 254-052-6) based on registration(s) submitted by the Registrant(s) and other relevant and available information and prepared the present decision in accordance with Article 46(1) of the REACH Regulation.

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 was

[1] The term Registrant(s) is used throughout the decision, irrespective of the number of Registrants addressed by the decision.

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 was appointed to carry out the evaluation.

The evaluating MSCA considered that further information was required to clarify the above mentioned concerns. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 20 March 2014.

On 29 April 2014 ECHA sent the draft decision to the Registrant(s) and invited them pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

Registrant commenting phase

By 5 June 2014 ECHA received comments from the Registrant(s) of which it informed the evaluating MSCA without delay.

The evaluating MSCA considered the comments received from the Registrant(s). The information contained therein is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

Commenting by other MSCAs and ECHA

In accordance with Article 52(1) of the REACH Regulation, on March 5 2015 the evaluating MSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days.

Subsequently, two Competent Authorities of the Member States and ECHA submitted proposals for amendment (PfAs) to the draft decision.

On the 10 April 2015 ECHA notified the Registrant(s) of the proposals for amendment to the draft decision and invited them pursuant to Articles 52(2) and 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

Referral to Member State Committee

On 20 April 2015 ECHA referred the draft decision to the Member State Committee.

By 11 May 2015, in accordance to Article 51(5), the Registrant(s) provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant(s) on the proposals for amendment into account and, where considered appropriate, amended the draft decision accordingly.

After discussion in the Member State Committee meeting on 8-11 June 2015, a unanimous agreement of the Member State Committee on the draft decision, as modified at the meeting, was reached on 10 June 2015.

ECHA took the decision pursuant to Article 52(2) and Article 51(6) of the REACH Regulation.

II. Information required

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information using the indicated test methods/instructions (in accordance with Article 13 (3) and (4) of the REACH Regulation) and the registered substance subject to the present decision:

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.

2. *Daphnia magna* reproduction test according to test guideline EU C.20/OECD 211. In order to maintain stable test concentrations the test shall be performed in a flow-through test system.

Depending on the outcome of the requested tests and the revised PBT-assessment the evaluating Member State may in the follow-up evaluation consider requesting a sediment simulation degradation test and/or a long-term toxicity test on fish.

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by **07 June 2017** an update of the registration(s) containing the information required by this decision including robust study summaries and, where relevant, an update of the Chemical Safety Report.

III. Statement of reasons

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 PBT/vPvB criteria of REACH Annex XIII and enable the evaluating MSCA to conclude on the PBT-assessment.

The scope of the evaluation by the evaluating MSCA was limited to the environmental aspects of the PBT concern only and the human health part was not evaluated. During MSCA/ECHA consultation, one MSCA made a PfA to include the requirement for extended one-generation reproductive toxicity study in order to clarify the concern for reproductive toxicity, also in light of evaluating the PBT properties of the substance.

In their comments to the PfAs the Registrant(s) did not agree with the request to conduct the extended one-generation reproductive toxicity study.

The evaluating MSCA may assess possible concerns for human health including the already identified concern for the reproductive toxicity of the substance, also in light of the T-criterion of the PBT assessment, during the follow-up evaluation in accordance with Article 46(3) of the REACH Regulation.

1. Persistence

The available data did not enable the evaluating MSCA to conclude on the persistency of the registered substance and more specifically if it fulfils the P/vP criteria of REACH Annex XIII. In order to clarify this concern further biodegradation testing is required. In the original draft decision a sediment simulation test according to test guideline EU C.24 /OECD 308 "Aerobic and anaerobic transformation in aquatic sediment systems" was chosen by the evaluating MSCA as the most appropriate test.

Two PfAs were received proposing that instead of a sediment simulation test, a test on Aerobic Mineralization in Surface Water (Simulation Biodegradation Test according to test guideline C.25/OECD 309) should be requested. The reason for these proposals was that also water is a relevant compartment according to the fugacity modelling and that simulation testing in surface water is more straightforward than sediment testing where the possible formation of non extractable residues (NER) may give rise to interpretation problems. Both PfAs proposed to focus the testing on the isomers 1,3- & 1,4- DIPN which showed no primary biotic degradation in the most reliable available biodegradation screening test. These isomers are also the most bioaccumulative isomers. The isomer 1,3 DIPN has a lipid normalised BCF-value of 7400 at a test concentration of 5 µg/L. The isomer 1,4 DIPN, which is the penultimate peak in the elution pattern of DIPN in GC chromatograms run using polar column, has a lipid normalized BCF of 7800 at a test concentration of 5 µg/L.

One PfA proposed a testing strategy where the degradation half-life in surface water should primarily be determined for the isomers 1,3- and 1,4-DIPN and when these isomers do not fulfil the degradation half life criterion for freshwater, they should be tested for aerobic transformation in aquatic sediment systems. The other PfA suggested that the need for a simulation degradation test in sediment should be decided in a later follow up decision, depending on the outcome of other tests required by this decision.

ECHA accepted the proposal to require a surface water degradation simulation test instead of a sediment degradation simulation test and that the testing shall be focussed primarily on the 1,3- and 1,4-DIPN isomers. The need for a simulation degradation test in sediment will be decided on in a later follow up evaluation, depending on the outcome of other tests required by this decision.

DIPN is hydrolytically stable as it does not contain any hydrolysable groups. The photolytic half life is rather fast (1.94 hours) according to calculation with AOPWIN™ v.1.92. The measured photolysis in distilled water for 2,6-DIPN and 2,7-DIPN was 16 and 6.4 hours, respectively.

A biodegradation study using a method similar to OECD 301 B (Yoshida and Kojima, 1978) indicate that DIPN may be readily biodegradable. This study is however assessed as unreliable because e.g. the test material was not specified and the test method used is not suitable for volatile substances. In reliable studies using the OECD 310 method (Laus 2011 a and b) 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 also 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. Three of the isomers (i.e. 1,3-, 1,4-, and 1,7-DIPN) did not undergo any biotic primary degradation during 56 days of incubation, although some abiotic degradation (17-28 %) was observed. It can therefore be concluded that at least these isomers may fulfil the P/vP-criterion of REACH Annex XIII. However, as no simulation degradation test in a relevant environmental compartment is available no conclusion on the P/vP criteria can be drawn.

The Registrant(s) in their comments argue that DIPN isomers may be persistent (P) but not very persistent (vP). They refer to the degradability of monoisopropylnaphthalene (MIPN), which they claim is easily biodegradable, close to "readily biodegradable". The Registrant(s) argue that a second isopropyl substituent in the ring significantly delays aerobic biodegradation under stringent standard ready conditions, in particular depending on the ring position; however, the molecular structure of DIPN provides no structural alert for a total blockage. Furthermore, the Registrant(s) argue that under standard test conditions

particular DIPN isomers may be bioaccumulating (B), but not very bioaccumulating (vB). Referring to a Japanese monitoring study (Suzuki et al. 2012), the Registrant(s) argue that overall in reality DIPN has no significant bioaccumulation potential in the environment and that there is also for this reason no need for making a distinction between P and vP concluding that there is no need for further complex biodegradation experiments.

The reasoning of the Registrant(s) regarding the degradability of DIPN isomers cannot overrule the results from the two most reliable screening biodegradation studies. From these studies it is evident that at least three of the isomers are recalcitrant to degradation. It is however, not possible from these results to conclude on whether or not these isomers meet the P/vP criteria of REACH Annex XIII. Considering that two DIPN isomers (1,3- and 1,4- DIPN) had lipid normalised BCF-values > 7000 at an exposure concentration of 5 µg/l and close to 3000 at an exposure concentration of 0.5 µg/l, it can not be safely concluded that neither of these two isomers fulfil the vB criterion, on the contrary the data indicate that both isomers meet the vB criterion. Furthermore, in the Japanese monitoring study referred to by the Registrant(s) the DIPN concentration in Japanese perch (*Lateolabrax japonicus*) was more than 1000 times higher than the concentration in sea water sampled at the same site. The concentration of DIPN (sum of isomers) in fillet of Japanese perch ranged from 1.2 – 3.4 µg DIPN/kg wwt whereas the concentration in sea water was below LOD (<1.9 ng/l). In the study it is also mentioned that in female perch mainly 1,3- and 1,4-DIPN was detected. Thus, the monitoring data does not support the Registrant(s) conclusion that DIPN has no significant bioaccumulation potential in the environment. On the contrary, the monitoring data indicate that the bioaccumulation potential of some of the DIPN-isomers is substantial. Therefore, confirmatory P-testing is needed. This testing should primarily focus on the isomers 1,3- and 1,4-DIPN.

For a PBT and vPvB assessment, the identification of the relevant environmental compartment(s) and, hence, the subsequent selection of suitable simulation test(s), should be based on the identified uses and releases patterns as well as the intrinsic properties of the substance (e.g. water solubility, vapour pressure, Log K_{ow}, Kp) significantly influencing the environmental fate of the substance (*ECHA Guidance R11*). According to the fugacity modelling (EPI Suite™) performed by the Registrant(s) using the standard settings of the model with equal emission to air, water and soil the mass distribution of DIPN at steady state will be: air 0.45%, water 7.8%, soil 76.7 and sediment 15%. These values already indicate that surface water is a relevant compartment. In their exposure assessment the Registrant(s) sum up the total releases to the environment from all exposure scenarios. According to this summation the total release to air, water and soil was [redacted], [redacted] and [redacted] kg/year respectively. Fugacity modelling, based on this emission pattern (97% of the DIPN emissions are assumed to be to air) as input in the model, gives the following mass distribution at steady state: Air 0.17 %, Water 34 %, Soil 0.5 % and Sediment 65,4 %, indicating that DIPN is mainly distributed to sediment and surface water. In a recent monitoring study from Japan (Suzuki *et.al*, 2012) DIPN levels in water ranged from <1.9 - 9.8 ng/l and the concentrations in sediment ranged from 1-4,400 µg/kg dw. On this basis it is confirmed that surface water is a relevant compartment and it can be concluded that surface water and sediment are the most relevant compartments for testing of the persistency of DIPN.

Results from surface water tests are generally easier to interprete than results from sediments tests, e.g. due to formation of non extractable residues (NER) in sediment test. REACH guidance Chapter R. 11 states that if a substance is highly insoluble in water it may not be technically possible to conduct a simulation study which provides reliable results, and at very low concentrations technical issues may make it very difficult to establish a reliable degradation curve in the study. For DIPN this should not be a problem as the water solubility is 125 µg/l. Therefore, a surface water simulation test is required to determine if

the 1,3- and 1,4-DIPN isomers fulfil the P/vP criteria of REACH Annex XIII.

Both the kinetic part of the study and the degradation pathway part of the study shall be conducted. The test substance should be preferably ^{14}C-labelled as recommended in OECD guideline 309. ^{14}C-labelling enables ultimate biodegradability to be determined and allows for the phase distribution to be checked. If a sensitive specific analytical method is available, primary biodegradation can be assessed by measuring the total residual concentration of test substance instead of using radiolabelling techniques.

Pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the registered substance subject to this decision: 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. The degradation half-life for the isomers 1,3- and 1,4-DIPN shall be determined. Depending on the outcome of the required tests and the revised PBT-assessment the evaluating Member State may in the follow-up evaluation consider requesting a sediment simulation degradation test.

2. Aquatic Toxicity

None of the acute aquatic toxicity studies performed with DIPN are considered reliable because of the lack of analytical monitoring of test concentrations. The exposure concentration was measured only in one of them. In this study, which was a limit test with fish, it was noted that the measured test concentration after 24h was approx. 27% and after 96 h approx. 20% of the initial concentration. For a substance like DIPN , due to its moderate volatility, adsorption potential and due to the possibility of photolysis in test conditions, analytical monitoring is necessary in order to define whether a toxicity study is reliable. Overall, despite the deficiencies of the individual studies no acute lethal effects on fish were observed within the range of water solubility of diisopropylnaphthalene (0.1 to 0.2 mg/L). For aquatic invertebrates a nominal 48h EC50 for *Daphnia magna* of 0.035 mg/l has been reported indicating that invertebrates may be more sensitive to DIPN than fish.

No long term studies on fish are available. For invertebrates two semistatic 96h reproduction studies with the marine copepod *Acartia tonsa* and one 21 d reproduction study on *Daphnia magna* according to OECD guideline 211 are available. The studies on *Acartia* gave NOEC values of approx. 0.05 mg/l and 0.02 mg/l, respectively. In both studies it was noted that DIPN had decreased considerably from the medium at renewal. The NOEC values relate to the initial measured concentration and are therefore not considered reliable.

The *Daphnia magna* reproduction test gave a nominal NOEC of 0.013 mg/l i.e. on the borderline of meeting the T-criterion of 0.01 mg/l. However, the NOEC is based on nominal concentrations and no analytical monitoring was performed. The fact that there have been problems with maintaining test concentrations in all aquatic toxicity studies where test concentrations have been monitored indicates that this study may underestimate the toxicity of DIPN. On the other hand, the reproduction rate in the controls was lower than the validity criteria of the guideline which may indicate that the test animal health was not optimal. Taken together, this renders also this study unreliable. Therefore, no definitive conclusion can be drawn on whether or not the T-criterion is fulfilled.

The Registrant(s) acknowledge the qualitative limitation of the available daphnia reproduction study and, in principle advocate ECHA´s approach to require a repetition of this study. However, the Registrant(s) argue that sediment rather than the water phase may be considered as main target compartment for DIPN and that furthermore, the technical complexity of the flow through design with a poorly water-soluble substance does

not favour the choice of an aquatic toxicity study. The Registrant(s) therefore, suggest that sediment toxicity testing should performed instead of a *Daphnia magna* reproduction study. The limited monitoring data available indicate that sediment living organisms are exposed to higher DIPN concentrations than aquatic organisms. However, PBT-assessment is not compartment specific and the numerical T-criterion of Annex XIII is based on aquatic toxicity. It could be justified to use sediment toxicity testing if aquatic testing would be very difficult (or impossible) to perform due to the physico-chemical properties of the substance. This is not the case for DIPN. For this reason and to avoid introducing unnecessary interpretation problems and uncertainty due to extrapolation, aquatic toxicity is considered to be the best option for resolving the T-issue.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the registered substance subject to this decision: *Daphnia magna* reproduction test according to EU test guideline C.20/OECD 211"Daphnia magna reproduction test". The test must be performed in a flow through test system in order to maintain stable test concentrations. Depending on the outcome of the requested tests and the revised PBT-assessment the evaluating Member State may in the follow-up evaluation consider requesting a long-term toxicity test on fish.

IV. Adequate identification of the composition of the tested material

In relation to the required experimental studies, the sample of the substance to be used shall have a composition that is within the specifications of the substance composition that are given by all Registrant(s). It is the responsibility of all the Registrant(s) to agree on the tested material to be subjected to the test(s) subject to this decision and to document the necessary information on composition of the test material. The substance identity information of the registered substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation. Finally, the test(s) must be shared by the Registrant(s).

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Articles 52(2) and 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at
http://echa.europa.eu/web/quest/regulations/appleals
The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[2] by Leena Ylä-Mononen, Director of Evaluation

Annex: List of registration numbers for the addressees of this decision. This annex is confidential and not included in the public version of this decision.

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