EUROPEAN CHEMICALS AGENCY

Helsinki, 3 May 2016

Addressee: [redacted]

Decision number: CCH-D-2114328639-39-01/F
Substance name: N-ethyl-N-[2-[1-(2-methylpropoxy)ethoxy]ethyl]-4-(phenylazo)aniline
EC number: 252-021-1
CAS number: 34432-92-3
Registration number: [redacted]
Submission number: [redacted]
Submission date: 29 May 2015
Registered tonnage band: 100-1000T

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on

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

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

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

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

5. **Soil simulation testing (Annex IX, Section 9.2.1.3; test method: Aerobic and anaerobic transformation in soil, EU C.23/OECD TG 307) at a temperature of 12 °C with the registered substance;**

6. **Sediment simulation testing (Annex IX, Section 9.2.1.4; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24 / OECD TG 308) at a temperature of 12 °C with the registered substance;**

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

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

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **10 May 2018**. You shall also update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals.]

Authorised[1] by Ofelia Bercaru, Head of Unit, Evaluation E3

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

Appendix 1: Reasons

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

A "sub-chronic toxicity study (90 day)" is a standard information requirement as laid down in Annex IX, Section 8.6.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

Adaptation based on severe toxicity effects according to the criteria for classifying the substance as R48 (STOT RE 2)

You have sought to adapt this information requirement according to Annex IX, Section 8.6.2., column 2. You provided the following justification for the adaptation: *"In accordance with column 2 of REACH Annex IX, the sub-chronic toxicity study (90 days) does not need to be conducted as the reliable short-term toxicity study (28 days) is available showing severe toxicity effects according to the criteria for classifying the substance as R48 (STOT RE 2)."*

According to the REACH regulation, "*the sub-chronic toxicity study (90 days) does not need to be conducted if a reliable short-term toxicity study (28 days) is available showing severe toxicity effects according to the criteria for classifying the substance as R48, for which the observed NOAEL-28 days, with the application of an appropriate uncertainty factor, allows the extrapolation towards the NOAEL-90 days for the same route of exposure.*"

Severe toxicity effects according to the criteria for classifying the substance as R48 (STOT RE 2)

According to the "Guidance on the Application of the CLP Criteria, Version 4.1 – June 2015", page 451, a value range of $30 < C \leq 300$ mg/kg bw/day applies for category 2 classification for STOT Rep. Exp. when "significant toxic effects" are observed in a 28 day study.

As it is summarised in the dossier study summary of the combined repeated dose toxicity study (OECD 422), the haematological effects were observed at 100 mg/kg bw/day which falls within the value range for STOT Rep. Exp. category 2.According to Annex I, Section 3.9.2.7.3.c), of the CLP Regulation and the CLP guidance, page 467, "*any consistent and significant adverse changes in haematology*" warrant classification according to STOT Rep. Exp. category 2. In this respect it is noted that you reported *"statistically significantly decreased [...] concentration of haemoglobin, haematocrit and significantly increased MCV".* However, Annex I, Section 3.9.2.8.1.a) of the CLP Regulation and the CLP guidance, pages 468 and 469, also state that *"It is recognised that effects may be seen in humans and/or animals that do not justify classification. Such effects include, but are not limited to: [...] small changes in clinical biochemistry, haematology or urinalysis parameters and/or transient effects, when such changes or effects are of doubtful or minimal toxicological importance."* For such effects which do not warrant classification, the CLP guidance gives the following example: *"Significant decrease in Hb without any other significant indicators of haemolytic anaemia."*

You did not demonstrate that the findings in the OECD 422 study met the criteria for classifying the substance as R48.

Derivation of reliable NOAEL 90 days from NOAEL 28 days

It is noted that the registered substance may show accumulation in the organism. In this respect, you stated that the substance exerts a "*possible accumulation potential based on substance Kow*". Furthermore, ECHA notes that the haematotoxic effects observed in the OECD 422 study were not fully reversible or were even irreversible which might stem from accumulation of the registered substance or any of its (bio)transformation products in the organism.

Such accumulation potential complicates the derivation of an appropriate NOAEL-90 days from the NOAEL-28 days because extrapolation without additional data on the extent of accumulation is usually not possible but needs to be addressed. It is also noted that, currently, you have not considered the accumulation potential in your NOAEC/NOAEL derivations for calculating DNELs.

ECHA concludes that the NOAEL from the OECD 422 study does not reliably allow the extrapolation towards the NOAEL-90 days for the same route of exposure.

Consequently, ECHA considers that the adaptation you used cannot be justified because the haematotoxicity observed in the OECD 422 study does not warrant classification as R48/ STOT Rep. Exp. 2. Furthermore, a reliable NOAEL-90 days has not been derived from the identified NOAEL-28 days which takes into account the potential bioaccumulation. Therefore, your adaptation of the information requirement cannot be accepted.

ECHA acknowledges your comments to the draft decision.

With respect to R48 classification, you state in your comments that most haematological changes are in excess of [redacted] % and that these findings together with other study results (e.g. increased MCV, increased spleen weights, hepatic extramedullary haemopoiesis, excretion of urobilinogen and bilirubin in the urine) would warrant STOT classification. With respect to the first requirement of the first indent of column 2 of Section 8.6.2., Annex IX (i.e., showing severe effects according to R48 classification), ECHA refers to the argumentation here above. Further reference is made to the *Guidance on the Application of the CLP Criteria* (Version 4.1 – June 2015, 3.9.2.5.2., pages 467 to 469) where the criteria for classification due to hematotoxicity/ haemolytic anaemia is further explained by examples.

However and irrespective of whether the results the 28-day study would warrant R48 classification or not, ECHA is of the opinion that the second requirement of the first indent of column 2 of Section 8.6.2., Annex IX (i.e., that the observed NOAEL-28 days, with the application of an appropriate uncertainty factor, allows the extrapolation towards the NOAEL-90 days for the same route of exposure) is still not met for the reasons outlined above. In particular, ECHA emphasises again that the accumulation potential of the registered substance complicates the derivation of an appropriate NOAEL-90 days from the NOAEL-28 days because extrapolation without additional data on the extent of accumulation is usually not possible but needs to be addressed.

Furthermore, you state in your comments that you should "*be allowed to revisit the CSR for the substance, and should a suitably low RCR value be demonstrated as a result of the risk assessment, then no further testing for this endpoint should be required and the Registrant would seek ECHA's guidance on the selection of a suitable assessment factor determined from the current understanding of the substance in order to minimise the use of vertebrate animal testing.*"

As indicated in the notification letter to the draft decision, "*ECHA does not take into account any dossier updates after the notification of this draft decision.*" Hence, an updated CSR as part of a dossier update is also not taken into account.

ECHA concludes that the adaptation requirements according to first indent of column 2 of Section 8.6.2., Annex IX are still not met.

Therefore, according to REACH requirement Annex VIII, Section 8.6.2., the endpoint requirement is not fulfilled.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA has evaluated the most appropriate route of administration for the study. The most appropriate route of exposure for sub-chronic toxicity testing is oral because the substance is a liquid with low vapour pressure which is not classified as skin/eye irritation and which is bioavailable after oral exposure resulting in systemic effects (as witnessed in the oral OECD 422 study). Hence, the test shall be performed by the oral route using the test method EU B.26./OECD TG 408.

According to the test method EU B.26./OECD TG 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Repeated dose 90-day oral toxicity study (test method: EU B.26./OECD TG 408) in rats.

Note for your consideration

Assessment factors for DNEL derivation:
You are reminded to use the appropriate assessment factors to derive DNELs according to the ECHA Guidance R.8 and to revise the risk characterisation accordingly, or to provide a detailed justification for not using the recommendations of ECHA Guidance for DNEL derivation.

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

A "pre-natal developmental toxicity study" (test method EU B.31./OECD TG 414) for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement. In the technical dossier you have provided a study record for a "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (test method: OECD TG 422). However, this study does not provide the information required by Annex IX, Section 8.7.2. because it does not cover key parameters of a pre-natal developmental toxicity study like examinations of foetuses for skeletal and visceral alterations. Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to the test method EU B.31/OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default assumption ECHA considers testing should be performed with rats or rabbits as a first species.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, July 2015) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD TG 414) in a first species (rats or rabbits) by the oral route.

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex IX, Section 9.1.5., column 2. You provided the following justification: *"In accordance with column 2 of REACH Annex IX, the study shall be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. Acute toxicity tests on all three trophic levels were performed and the L(E)C50 values (daphnia, fish, algae) exceeded the range of substance water solubility 0.03 mg/L which is interpreted as "no acute toxicity" according to CLP classification. When results from tests are above the limit of solubility, for poorly soluble substance (solubility <1mg/L) a chronic study should be considered to confirm the findings of the acute tests that the substance has no toxic properties up to its water solubility.*

It is taken into account that a generated aqueous effluent is treated on registrant´s site before being discharged to an authority effluent treatment plant. There are specifications that have to be achieved for the effluent to be discharged to the authority facility. That treatment involves neutralisation, settling and solids removal followed by catalytic oxidation and biological treatment. Solid waste goes to a certified land fill site.
End use of the substance is fuel marker with content [redacted] *with possibility of exposure only as an accidental case."*
In your adaptation you also refer to an alleged lack of exposure. ECHA considers this also as an adaptation, according to Annex XI, Section 3.1. and 3.2. of the REACH Regulation, which refers to substance-tailored exposure-driven testing.

ECHA notes the following deficiencies in your argumentations:

- The short-term toxicity tests are based on nominal concentrations, as you claim that there is no suitable analytical method available. Considering the low water solubility of the substance, it is therefore not possible to determine to what concentrations the organisms were really exposed and thus it is not possible to firmly conclude on the lack of toxicity to the aquatic compartment.
- You acknowledge that there is indirect exposure to the environment as a result of the treated effluent. However, as no measured concentrations are provided, it is not possible to conclude that there would be no significant exposure to relevant concentrations.
- The substance has wide dispersive professional and consumer uses; therefore, the application of risk management measures (RMMs) cannot be considered as sufficient to address the safe use of the chemicals and claim no exposure to environmental compartments.
- You have not provided adequate documentation to support your claim, as indicated in Section 3.2(a)(i) of Annex XI.
- As you also indicate in your justification, the substance is poorly water soluble (0.03 mg/l) and this is a trigger for long-term toxicity testing, as indicated in Column 2 of Annex VII, Section 9.1.1.

Therefore, the two adaptations cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 2.0, November 2014) *Daphnia magna* reproduction test (test method EU C.20. / OECD TG 211) is the preferred test to cover the standard information requirement of Annex IX, Section 9.1.5.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Daphnia magna reproduction test (test method: EU C.20./OECD TG 211).

ECHA acknowledges your comments on the draft decision and, specifically, your intention to review the use pattern of the substance and its exposure to the environment. Furthermore, ECHA notes your acceptance to conduct the test in the instance that no adequate alternative methods to testing are identified.

Notes for your consideration

Due to the low solubility of the substance in water you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity tests and for calculation and expression of the result of the tests.

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation. Adequate information on Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.), or Fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2.), or Fish, juvenile growth test (Annex IX, 9.1.6.3.) needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement using the same justification used for the long-term toxicity to aquatic invertebrates. For the same reasons outlined above in section 3, with the only difference that testing for long-term toxicity to fish is triggered by Column 2 of Annex VIII, Section 9.1.3., your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 2.0, November 2014) fish early-life stage toxicity test (test method OECD TG 210), fish short-term toxicity test on embryo and sac-fry stages (test method EU C.15. / OECD TG 212) and fish juvenile growth test (test method EU C.14. / OECD TG 215) are the preferred tests to cover the standard information requirement of Annex IX, Section 9.1.6.

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

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

ECHA acknowledges your comments on the draft decision and, specifically, your intention to review the use pattern of the substance and its exposure to the environment. Furthermore, ECHA notes your acceptance to conduct the test in the instance that no adequate alternative methods to testing are identified.

Notes for your consideration

Before conducting any of the tests mentioned above in points 3 and 4, you shall consult the ECHA *Guidance on information requirements and chemical safety assessment (version 2.0, November 2014)*, Chapter R7b, Section R.7.8.5 to determine the sequence in which the aquatic long-term toxicity tests are to be conducted and the necessity to conduct long-term toxicity testing on fish.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R7b (Section R.7.8.5., including Figure R.7.8-4), if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. In such case, according to the integrated testing strategy, the *Daphnia* study is to be conducted first. If based on the results of the long-term *Daphnia* study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, the long-term fish study needs to be conducted.

Due to the low solubility of the substance in water you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity tests and for calculation and expression of the result of the tests.

5. Soil simulation testing (Annex IX, Section 9.2.1.3.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"Soil simulation testing" is a standard information requirement as laid down in Annex IX, 9.2.1.3 of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have concluded that the substance is not readily biodegradable according to an OECD 301B ready biodegradability test, which showed less than [redacted]% degradation in 28 days (CO_2 evolution). Therefore, the substance is to be considered potentially persistent in the environment. Nevertheless, you sought to adapt this information requirement according to Annex IX, Section 9.2.1.3., column 2. You provided the following justification for the adaptation: "*In accordance with column 2 of REACH Annex IX, the Soil simulation testing (required in section 9.2.1.3) does not need to be conducted as direct and indirect exposure of soil is unlikely.*

The substance is poorly soluble and the generated aqueous effluent is treated on site before being discharged to an authority effluent treatment plant. There are specifications that have to be achieved for the effluent to be discharged to the authority facility. The effluent treatment involves neutralization, settling and solids removal followed by catalytic oxidation and biological treatment. Solid waste goes to a certified land fill site."

Column 2 of Section 9.2.1.3 of Annex IX indicates that the soil simulation study does not need to be conducted if the substance is readily biodegradable or if direct and indirect exposure of soil is unlikely.

ECHA notes that the substance has wide dispersive professional and consumer uses and therefore exposure to all environmental compartments cannot be excluded. In addition, this means that the proposed RMMs of discharge to a landfill, as well as other operations before that, cannot be foreseen as suitable RMMs as this cannot be controlled nor guaranteed by you.

Therefore, your adaptation of the information requirement cannot be accepted and ECHA considers that information in the registration dossier provided on degradation is not sufficient to conclude on the degradation of the registered substance and the relevant transformation and/or degradation products in soil. As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirements of Annex IX, 9.2.1.3. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 2.0, November 2014) Aerobic and anaerobic transformation in soil (test method EU C.23. / OECD TG 307) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.3.

One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of REACH regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions". The Guidance on information requirements and chemical safety assessment R.7b (version 2.0, November 2014) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-9 (version 2.1 October 2012) indicates 12 °C (285 K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12 °C is within the applicable test conditions of the Test Guideline OECD 307, OECD 308 and OECD 309. Therefore, the test should be performed at the temperature of 12 °C.

As the registered substance has low water solubility of 0.03 mg/L, the partition coefficient log K_{ow} is 6.06 and the adsorption coefficient log $K_{oc,soil}$ is 4.6, indicating adsorptive properties, and exposure to soil compartment cannot be excluded, ECHA considers that testing degradation in soil according to OECD 307 is an appropriate test method.

Therefore, pursuant to Article 41(1)(a) and (b) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance: Aerobic and anaerobic transformation in soil simulation biodegradation study (EU C.23./OECD 307) at a temperature of 12 °C.

ECHA acknowledges your comments on the draft decision and, specifically, your intention to review the use pattern of the substance and its exposure to the environment. Furthermore, ECHA notes your acceptance to conduct the test in the instance that no adequate alternative methods to testing are identified.

6. Sediment simulation testing (Annex IX, Section 9.2.1.4.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"Sediment simulation testing" is a standard information requirement as laid down in Annex IX, section 9.2.1.4. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement using the same justification used for the soil simulation testing. For the same reasons outlined above in section 5, your adaptation cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

As the registered substance has low water solubility of 0.03 mg/L, the partition coefficient log K_{ow} is 6.06 and the adsorption coefficient log $K_{oc,soil}$ is 4.6, indicating adsorptive properties, and exposure to sediment compartment cannot be excluded, ECHA considers that testing further degradation in sediments is appropriate.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 2.0, November 2014) Aerobic and anaerobic transformation in aquatic sediment systems (test method EU C.24. / OECD TG 308) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.4.

One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of REACH regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*". The Guidance on information requirements and chemical safety assessment R.7b (version 2.0, November 2014) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-9 (version 2.1 October 2012) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment.

Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD TG 308. Therefore, the test should be performed at the temperature of 12°C.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Aerobic and anaerobic transformation in aquatic sediment systems (test method: EU C.24./OECD TG 308).

ECHA acknowledges your comments on the draft decision and, specifically, your intention to review the use pattern of the substance and its exposure to the environment. Furthermore, ECHA notes your acceptance to conduct the test in the instance that no adequate alternative methods to testing are identified.

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

The identification of the degradation products is a standard information requirement according to column 1, Section 9.2.3. of Annex IX of the REACH Regulation. Column 2 of Section 9.2.3. of Annex IX further states that the study does not need to be conducted if the substance is readily biodegradable.

You have concluded the registered substance to be not readily biodegradable as described above in section 5. No further information on biotic degradation in water, sediment or soil or information on related degradation products has been provided.

Therefore, there is an information gap and it is necessary to provide information for this endpoint.

Regarding appropriate and suitable test method to identify degradation products, the methods will have to be substance specific. When analytically possible, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound should be evaluated. In addition degradation half-life, log Kow and potential toxicity of the metabolite may be investigated.

ECHA acknowledges your comments on the draft decision agreeing to the request. In your comments, you outlined a strategy to cover the information requirement which is based on the use of the EAWAG-BBD Pathway Prediction System and, potentially, of several (Q)SAR models. ECHA reminds you of the acceptability criteria outlined in the general rules for adaption of the standard information requirements of Annex XI to the REACH Regulation.

Therefore, pursuant to Article 41(1)(a) and (b) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision:

> Identification of the degradation products using an appropriate and suitable test method, as explained above in this section.

Note for your consideration

Before conducting the above test you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 1.2, November 2012), Chapter ECHA Guidance on information requirements and chemical safety assessment Sections R.7.9.2.3 and R.7.9.4. These guidance documents explain that the data on degradation products is only required if information on the degradation products following primary degradation is required in order to complete the chemical safety assessment. Section R.7.9.4. further states that when substance is not fully degraded or mineralised, degradation products may be determined by chemical analysis.

Before conducting any of the tests indicated above in sections 5, 6 and 7 you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 1.2,November 2012), Chapter R7b, Sections R.7.9.4 and R.7.9.6 and Chapter R.11.1.3 on PBT assessment to determine the sequence in which the simulation tests are to be conducted and the necessity to conduct all of them. The order in which the simulation biodegradation tests are performed needs to take into account the intrinsic properties of the registered substance and the identified use and release patterns which could significantly influence the environmental fate of the registered substance.

Based on the above, you are advised to consult the REACH guidance on information requirements chemical safety assessment in Chapter R.11.1.3. and Figure R. 11-1 on PBT assessment for the integrated testing strategy for persistency assessment taking into account the potential degradation products of the registered substance, and to update the CSR accordingly when results of the tests detailed above are available.

Moreover, pursuant to Annex I, section 4.1., you shall consider the information relevant for screening for P, B and T properties of the parent substance and the degradation products to decide whether further information needs to be generated for the PBT and vPvB assessment. Where only degradation of the parent substance is monitored, this does not address all concerns and further assessment of the degradation products may be required in order to complete the PBT/vPvB assessment. If testing in accordance with Annex IX or X of the REACH Regulation is deemed necessary, you are required to submit a testing proposal.

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"Bioaccumulation in aquatic species" is a standard information requirement as laid down in Annex IX, Section 9.3.2.of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex IX, Section 9.3.2., column 2. You provided the following justification for the adaptation: "*In accordance with column 2 of REACH Annex IX, the Bioaccumulation in aquatic species (required in section 9.3.2) does not need to be conducted as direct and indirect exposure of the aquatic compartments is unlikely. The substance is poorly soluble and the generated aqueous effluent is treated on site before being discharged to an authority effluent treatment plant. There are specifications that have to be achieved for the effluent to be discharged to the authority facility. The effluent treatment involves neutralization, settling and solids removal followed by catalytic oxidation and biological treatment. Solid waste goes to a certified land fill site.*"

Therefore, you propose to waive this information requirement on the basis of no direct and indirect exposure, poor water solubility and controlled treatment of the effluents and solid waste. However, ECHA notes that your adapation does not meet the specific rules for adapation of Annex IX, Section 9.3.2., column 2 because there are multiple wide dispersive consumer and professional uses where the effluent or solid waste treatment cannot be controlled by means of risk management measures. Therefore, your adaptation cannot be accepted. In addition, the substance has a log Kow >3, which indicates that the substance has potential to bioaccumulate.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7c* (version 2.0, November 2014) bioaccumulation in fish: aqueous and dietary exposure (test method EU C.13. / OECD TG 305) is the preferred test to cover the standard information requirement of Annex IX, Section 9.3.2.

If the substance has low water solubility the technical challenges need to be taken into account before an OECD 305 test is conducted. If it is found that the validity criteria cannot be fulfilled (which may depend on the analytical detection limit as well as physico-chemical properties) it is recommended that, for substances with log Kow>6, a dietary study is used as a replacement to estimate BCF. Generally, due to problems related to the interpretation of the dietary test results, the Guidance on information requirements (Chapter R.11: PBT/vPvB assessment, Version 2.0, November 2014) advises the use of the aqueous exposure route: "*For strongly hydrophobic substances (Log Kow > 5 and a water solubility below ~ 0.01-0.1 mg/L), testing via aqueous exposure may become increasingly difficult.*

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Bioaccumulation in fish: aqueous or dietary exposure (test method: OECD TG 305).

ECHA acknowledges your comments on the draft decision and, specifically, your intention to review the use pattern of the substance and its exposure to the environment. Furthermore, ECHA notes your acceptance to conduct the test in the instance that no adequate alternative methods to testing are identified.

Notes for your consideration

Before conducting the above test you are advised to consult the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R.11.4. and Figure R.11-4 on the PBT assessment for further information on the integrated testing strategy for the bioaccumulation assessment of the registered substance. You should revise the PBT assessment when information on bioaccumulation is available.

General comments

In your comments on the draft decision you indicated your concern about the potentially unnecessary vertebrate animal testing that would have to be carried out for a substance which will be removed from the market by the European Commission. In fact, the registered substance is used to mark low tax and tax rebated fuel across Europe. It is specified in Commission Decision 2011/544/EC and is subject to review by the Commission by the end of December 2016. You state that "*It is entirely likely that this review will recommend that Solvent Yellow 124 is replaced as the marker (Euromarker) and thus remove the market need for it and any REACH registration requirements.*"
However, ECHA notes that even if the Commisison Decision would confirm your statement, the technical dossier identifies other professional and consumer uses in addition to the one as marker. Thus, there is still a need to obtain standard information on the hazard properties of the substance.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 30 October 2015.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation

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

ECHA took into account your comments and did not amend the request(s).

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

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

Appendix 3: Further information, observations and technical guidance

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

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

3. In relation to the information required by the present decision, the sample of substance used for the new test(s) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance composition manufactured or imported by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of substance tested in the new test(s) is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new test(s) must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the test(s) to be assessed.