EUROPEAN CHEMICALS AGENCY

Helsinki, 10 November 2017

Addressee: [redacted]

Decision number: CCH-D-2114376212-55-01/F
Substance name: N-[2-(piperazin-1-yl)ethyl]C18-unsatured-alkylamide
EC number: 629-767-5
CAS number: 1228186-18-2
Registration number: [redacted]
Submission number: [redacted]
Submission date: 25/04/2014
Registered tonnage band: 100-1000

DECISION ON A COMPLIANCE CHECK

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

1. **Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD TG 309) at a temperature of 12 °C with the registered substance (as specified in Appendix 1, section 1). The biodegradation of each constituent and relevant impurity present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed as further specified in Appendix 1, section 1. This can be done simultaneously during the same study.**

2. **Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method with the registered substance;**

3. **Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD TG 305, aqueous exposure or dietary exposure) with the registered substance (as specified in Appendix 1, section 3). The bioaccumulation of each constituent and relevant impurity present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed as further specified in Appendix 1, section 3. This can be done simultaneously during the same study.**

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 to the REACH Regulation. 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 adequate and reliable documentation.

You have to submit the requested information in an updated registration dossier by **17 February 2020**. You also have to 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 and advice and further observations are provided in Appendix 3.

Appeal

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

Authorised[1] by Claudio Carlon, Head of Unit, Evaluation E2

[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.

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Appendix 1: Reasons

1. **Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.)**

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Simulation testing on ultimate degradation in water" is a standard information requirement as laid down in Annex IX, section 9.2.1.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier you have provided a study record for an OECD 303 Simulation Test - Aerobic Sewage Treatment - A: Activated Sludge Units. However, this study does not provide the information required by Annex IX, Section 9.2.1.2., because it does not simulate degradation under environmentally realistic conditions as explained in ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7b. which states that "*Results from tests simulating the conditions in a sewage treatment plant (STP) (e.g. the OECD303) cannot be used for assessing the degradation in the aquatic environment*".

Furthermore, ECHA notes that the degradation curve based on DOC measurements (Figure 3 in the technical dossier) shows high % removal (almost 100%) from the beginning of the test without a lag phase, indicating that adsorption rather than biodegradation may be the significant process responsible for the removal. The test report also explains that direct analysis of a representative component of the substance was used to supplement the DOC measurements.

The report states that "*The mean removal percentage of tall oil, reaction products with N-(2-aminoethyl)piperazine in the test unit was assessed with the specific analysis from day 44 to 48 was >99.999% using octadecenyl amide of N-(2-aminoethyl)piperazine as representative component. These analyses demonstrate that the removal of tall oil, reaction products with N-(2-aminoethyl)piperazine is complete. Tall oil, reaction products with N-(2-aminoethyl)piperazine concentrations in the sludge of the reactor sampled on days 47 and 48 were 0.88 and 0.80 mg/L. The mean removal percentage of tall oil, reaction products with N-(2-aminoethyl)piperazine from the influent through adsorption onto sludge assessed in two samples was therefore 0.04 -0.044%. This percentage demonstrates that tall oil, reaction products with N-(2-aminoethyl)piperazine are almost completely removed by biodegradation*".

While these analyses appear to demonstrate complete removal by biodegradation, there is no information available on the extraction methods employed for analysis of the substance adsorbed to sludge and consequently ECHA considers that complete biodegradation cannot be confirmed in the absence of this information.

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According to Annex IX, Section 9.2.1.2, column 2 of the REACH Regulation, simulation testing on ultimate degradation in surface water does not need to be conducted if the substance is highly insoluble in water or is readily biodegradable.

ECHA notes that based on the information in the technical dossier, the registered substance was not readily biodegradable in an OECD 301D test (36% degradation after 70 days). The registered substance is a surface active UVCB with a critical micelle concentration (CMC) of 32 mg/L at pH 7.0 and 23°C and so cannot be considered highly insoluble. Simulation testing can therefore not be omitted based on Annex IX, Section 9.2.1.2, column 2.

The substance has high log Kow >5 and wide dispersive outdoor use, so direct release to the environment seems likely.

ECHA concludes that based on the information provided in the dossier the substance could potentially be P or vP. There is also no information available on the degradation products and their fate and bioaccumulation information has also been requested in this decision. ECHA hence considers that at this stage the information in the chemical safety assessment (CSA) is not complete due to the information gaps addressed in this decision. On this basis, the CSA cannot be used to justify that there is no need to investigate further the degradation of the substance and its degradation products.

In conclusion, ECHA considers that the information is needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment.

In your comments on the draft decision you have provided further information on the OECD TG 303 study. You have provided a description of the extraction methods used and thus clarified the potential degradation in a sewage water treatment plant (STP). The study results support your conclusion that exposure through the STP is likely to be limited. ECHA notes that while exposure via the STP is likely to be limited there is exposure expected via the reported professional outdoor uses and so the exposure to environment cannot be excluded. You also agree that the OECD TG 303 does not provide key information on degradation under environmentally realistic conditions but consider this information useful in support of the results from a publication by Geerts et al (2014) which also forms parts of your comments.

The publication by Geerts et al describes the potential of the enriched bacterial pure cultures to degrade N-(1-ethyl-piperazine) tall oil amide which is a major constituent of the registered substance. It also provides evidence that a major degradation product is N-(2-aminoethyl)piperazine which is one of the hydrolysis products following initial hydrolysis of the amide bond. You have provided information on the PBT properties of this degradation product, which indicates that bioaccumulation potential is low given the very low log kow.

ECHA considers that you have provided relevant information on the potential degradation products of N-(1-ethyl-piperazine) tall oil amide which is present in a concentration range of [redacted]% in this UVCB substance. However, as the study was conducted with enriched bacterial pure cultures ECHA considers that it does not provide information on the rate of the degradation of the registered substance under environmentally relevant conditions. Annex XIII of REACH requires that the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions.

ECHA further notes that no conclusion on degradation products and persistence can be drawn for the diamine constituents of the registered substance i.e. (9Z)-N-(2-{4-[(9Z)-octadec-9-enoyl]piperazin-1-yl}ethyl)octadec-9-enamide from the study by Geerts et al. This group of constituents contains a tertiary amide group and the publication by Geerts et al. clearly indicates that the biodegradation pathways described therein only apply to primary and secondary fatty acid amides stating that *"The ability of secondary fatty acid amides grown microorganisms to oxidize fatty acid amides is restricted to substances with primary and secondary amide bonds. Tertiary fatty acid amides should therefore not be included in the "family" used to read-across the biodegradability of primary and secondary fatty acid amides."*

The authors also conclude that *"secondary fatty acid amides can only be classified readily biodegradable through read-across if the liberated amine is known to be readily biodegradable".*

ECHA concludes that you have not considered the degradation of all relevant constituents present in concentration of ≥ 0.1% (w/w). As noted above there is no information available on the degradation rate of the main constituent N-(1-ethyl-piperazine) tall oil amide under environmentally relevant conditions without enriched bacterial cultures. Additionally, there is no information available on the ultimate degradation of the other groups of constituents of the registered substance. Therefore ECHA concludes that with the information provided a definitive conclusion on persistence cannot be reached and further information on degradation is still needed.

ECHA notes your clarifications on the use of the substance indicating that exposure to the aquatic compartment is likely to be minimal. However, exposure to the aquatic compartment cannot be excluded and consequently simulation testing is required. ECHA considers that testing in the OECD TG 309 is technically feasible and there is no evidence that the persistence criteria would be more likely to be met in any other compartment, consequently the aquatic compartment is preferred. If the persistence assessment cannot be concluded after the simulation test in water further testing should be considered.

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.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) Aerobic mineralisation in surface water – simulation biodegradation (test method EU C.25. / OECD TG 309) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.2.

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 the 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 4.0, June 2017) 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.16-8 (version 3.0 February 2016) 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 309. Therefore, the test should be performed at the temperature of 12°C.

In the OECD TG 309 Guideline two test options, the "pelagic test" and the "suspended sediment test", are described. ECHA considers that the pelagic test option should be followed as that is the recommended option for P assessment. The amount of suspended solids in the pelagic test should be representative of the level of suspended solids in EU surface water. The concentration of suspended solids in the surface water sample used should therefore be approximately 15 mg dw/L. Testing natural surface water containing between 10 and 20 mg SPM dw/L is considered acceptable. Furthermore, when reporting the non-extractable residues (NER) in your test results you should explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

Section R.11.4.1 of The Guidance on information requirements and chemical safety assessment R.11 on PBT/vPvB assessment (version 2.0, November 2014), indicates that *"constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w)"*. Individual concentrations < 0.1 % (w/w) normally need not be considered. Before conducting bioaccumulation testing it is necessary to conclude on the persistency information for all relevant constituents present in concentrations of ≥ 0.1% (w/w).

The registered UVCB substance consists of several constituents in variable concentrations, which means that it is necessary to assess the persistency of all relevant constituents, as set out above. ECHA notes that some of these constituents could potentially be metabolites of other constituents present in the substance and consequently there may be interference issues when measuring primary degradation and when identifying metabolites in a simulation test. These are both critical parameters for data interpretation, thus, in order to fulfill this information requirement and to reduce the likelihood that additional simulation tests may be required during the forthcoming substance evaluation process, you are therefore required to carefully consider whether one or more constituents/fractions of the substance may be more relevant for testing instead of testing the registered UVCB substance as such. In order to select appropriate constituent(s)/fraction(s) for simulation testing you should consider those constituents/fractions which are most relevant for PBT assessment while avoiding constituents which are likely metabolites of other present constituents. Given the findings reported in the study by Geerts et al. you are invited to consider whether testing should be conducted with the diamine fraction of the UVCB substance due to the presence of tertiary amide moieties in this group of constituents. You shall clearly explain the choice of constituent(s)/fraction(s) and justify it in the study documentation provided. Finally, ECHA notes that for many of the constituents of the registered substance, speciation may have an impact on the results as protonated species will dominate at environmentally relevant pHs. Due consideration shall be given to this when designing the test.

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 mineralisation in surface water – simulation biodegradation test (test method: EU C.25./OECD TG 309) at a temperature of 12 °C. You shall provide information on the degradation of all relevant constituents present in concentration of ≥ 0.1% (w/w). Alternatively, you shall provide a justification for why you consider certain constituents present in concentration of ≥ 0.1% (w/w) or certain constituent fractions/blocks as most relevant or not relevant for the PBT/vPvB assessment.

Notes for your consideration

Before conducting the requested test you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapter R7b, Sections R.7.9.4 and R.7.9.6 (version 4.0, June 2017) and Chapter R.11, Section R.11.4.1.1 (version 3.0, June 2017) on PBT assessment.

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the test detailed above are available. You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017), Chapter R.11, Section R.11.4.1.1. and Figure R. 11-3 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

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

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. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier you have provided the following statements on degradation products *"The results of the readily biodegradability test with N-[2-(piperazin-1-yl)ethyl]C18-insaturated-alkylamide show that after an initial quick increase of the oxygen consumption up to 36% the degradation stops. This is a strong indication that the parent is readily degraded to form most likely 1-Piperazineethanamine. No further biodegradation has been observed for 1-Piperazineethanamine (CAS Num: 140-31-8) under the conditions tested"* and *"Based on the available biodegradation results partial biodegradation of N-[2 -(piperazin-1 -yl) ethyl]C18 -insaturated-alkylamide is anticipated because 1 –Piperazine ethanamine (CAS Num: 140 -31 -8) has been observed as metabolite. This means that N-[2 -(piperazin-1 -yl) ethyl]C18 -insaturated-alkylamide is not persistent because it is completely degraded into an intermediate within 28 days in the ready test."*

However, this information does not provide the information required by Annex IX, Section 9.2.3., because there is no evidence provided of the formation of this and other degradation products.

According to Annex IX, Section 9.2.3., column 2 of the REACH Regulation, identification of degradation products is not needed if the substance is readily biodegradable. ECHA notes that based on the information in the technical dossier, the registered substance is not readily biodegradable in as also discussed in section 1 above. The conditions for this exception are thus not met.

Furthermore, ECHA notes that you have not provided any justification in your chemical safety assessment (CSA) or in the technical dossier for why there is no need to provide information on the degradation products. ECHA considers that this information is needed in relation to the PBT/vPvB assessment and risk assessment.

According to Annex XIII of REACH, the identification of PBT/vPvB substances shall take account of the PBT/vPvB-properties of relevant constituents of the substance. Section R.11.4.1 of REACH Guidance document R.11 on PBT/vPvB assessment (version 2.0, November 2014) indicates that *"constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w)."* Therefore degradation products should be identified for each constituent and relevant impurity present in the registered substance in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable.

In your comments on the draft decision you have referred to a publication by Geerts et al (2014) which describes the potential of the enriched bacterial pure cultures to degrade N-(1-ethyl-piperazine) tall oil amide which is a major constituent of the registered substance. It also provides evidence that a major degradation product is N-(2-aminoethyl)piperazine which is one of the hydrolysis products following initial hydrolysis of the amide bond.

However, ECHA notes that no conclusion on degradation products can be drawn for the diamine constituents of the registered substance from the study by Geerts et al.
This group of constituents contains a tertiary amide group and the publication by Geerts et al. clearly indicates that the biodegradation pathways described therein only apply to primary and secondary fatty acid amides stating that *"The ability of secondary fatty acid amides grown microorganisms to oxidize fatty acid amides is restricted to substances with primary and secondary amide bonds. Tertiary fatty acid amides should therefore not be included in the "family" used to read-across the biodegradability of primary and secondary fatty acid amides."*

The authors also conclude that *"secondary fatty acid amides can only be classified readily biodegradable through read-across if the liberated amine is known to be readily biodegradable".*

ECHA concludes that you have not considered the degradation of all relevant constituents present in concentration of ≥ 0.1% (w/w). While there is information available for the main constituent of this UVCB substance i.e. N-(1-ethyl-piperazine) tall oil amide, there is no information available on the degradation products arising from the degradation of the other groups of constituents of the registered substance.

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.
Regarding appropriate and suitable test method, 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. You may obtain this information from the simulation study also requested in this decision, or by some other measure. You will need to provide a scientifically valid justification for the chosen method.

You should provide information on the degradation products of all relevant constituents, impurities and additives present in concentration of ≥ 0.1% (w/w). Alternatively, you should provide a justification for why you consider certain constituents present in concentration of ≥ 0.1% (w/w) or certain constituent fractions/blocks as not relevant for the PBT/vPvB assessment or risk assessment.

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:

Identification of the degradation products (Annex IX, Section 9.2.3.) by using an appropriate and suitable test method, as explained above in this section.

Notes for your consideration

Before providing the above information you are advised to consult the ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R.7b., 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.

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

"Bioaccumulation in aquatic species, preferably fish" 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. You provided the following justification for the adaptation

"To address the bioaccumulation potential according to REACH requirements, the logKow of N-[2-(piperazin-1-yl) ethyl]C18-insaturated-alkylamide was measured applying slow stirring method according to OECD 123. The observed log Kow value (Log Kow>3) indicates that the substance has a bioaccumulation potential if N-[2-(piperazin-1-yl) ethyl]C18-insaturated-alkylamide would have been a narcotic substance. For polar narcotics like the N-[2-(piperazin-1-yl)ethyl]C18-insaturated-alkylamide however there is only limited information on the relationship between log Kow and BCF. Performance of a standard aquatic exposure based OECD 305 test is however not considered. N-[2-(piperazin-1-yl) ethyl]C18-insaturated-alkylamide sorbs easily to negatively charged surfaces like glassware, clay etc and the parent is biodegraded into N-(2-aminoethyl)piperazine which has a shorter alkyl chain and a very low calculated log Kow. Standard OECD 305 tests are therefore technically not feasible with these strongly sorbing easily degradable substances. In addition is the route of exposure unrealistic for these substances because the substance will either be sorbed or biodegraded. N-[2-(piperazin-1-yl) ethyl]C18-insaturated-alkylamide is thus quickly biodegraded into a product which has a much lower calculated log Kow and it is therefore unlikely that N-[2-(piperazin-1-yl) ethyl]C18-insaturated-alkylamide will accumulate in the food chain.

For this reason and also for ethical reasons it will be evaluated if the parent substance is like in the biodegradation test, metabolized by an hepatic S9 fraction of rainbow trout. At the moment the substance is metabolized, the chance of accumulation of N-[2-(piperazin-1-yl)ethyl]C18-insaturated-alkylamide in fish is small (WOE-approach), Therefore, in case transformation is observed, the substance is considered to have a low bioaccumulation potential."

While you have not explicitly claimed any adaptation rule under the REACH Regulation, you have provided information that could be interpreted as an attempt to adapt the information requirement according to Annex XI, Section 2 "testing is technically not possible".

However, ECHA notes that your adaptation does not meet the general rule for adaptation of Annex XI; Section 2 because the arguments raised with regard to the potential difficulties in testing this surface active substance are not supported by documentary evidence. Furthermore, the statements made with regards to difficulties in testing seem to be contradicted by the information in the technical dossier. ECHA notes that some of the aquatic toxicity tests provided in the dossier included analytical monitoring and that the test substance was measureable in the water at the beginning and end of the test at concentrations close to the nominal ones indicating no such issues with sorption to surfaces at the concentrations used.

Additionally you have argued that the substance *"N-[2-(piperazin-1-yl) ethyl]C18-insaturated-alkylamide is thus quickly biodegraded into a product which has a much lower calculated log Kow and it is therefore unlikely that N-[2-(piperazin-1-yl) ethyl]C18-insaturated-alkylamide will accumulate in the food chain".*

ECHA interprets the above as an attempt to adapt the information requirement by demonstrating that the substance has a low potential for bioaccumulation as a result of degradation to substances with low logKow in accordance with Annex IX; Section 9.3.2, column 2. However, as explained in sections 1 and 2 above, the information provided on biodegradation and identification of degradation products is not sufficient.

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 ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7c* (version 3.0, June 2017) 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. ECHA Guidance defines further that results obtained from a test with aqueous exposure can be used directly for comparison with the B and vB criteria of Annex XIII of REACH Regulation and can be used for hazard classification and risk assessment. Comparing the results of a dietary study with the REACH Annex XIII B and vB criteria is more complex and has higher uncertainty. Therefore, the aqueous route of exposure is the preferred route and shall be used whenever technically feasible. If you decided to conduct the study using the dietary exposure route, you shall provide scientifically valid justification for your decision.

You shall also attempt to estimate the corresponding BCF value from the dietary test data by using the approaches given in Annex 8 of the OECD 305 TG. In any case you shall report all data derived from the dietary test as listed in the OECD 305 TG.

Section R.11.4.1 of The Guidance on information requirements and chemical safety assessment R.11 on PBT/vPvB assessment (version 2.0, November 2014), indicates that *"constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w)"*. Individual concentrations < 0.1 % (w/w) normally need not be considered.

The registered UVCB substance consists of several constituents in variable concentrations which means that it is necessary to assess the bioaccumulation of all relevant constituents, as set out above. In order to fulfill this information requirement and to reduce the likelihood that additional tests may be required during the forthcoming substance evaluation process, you are required to carefully consider whether one or more constituent(s)/fraction(s) of the substance may be more relevant for testing instead of testing the registered UVCB substance as such. In order to select an appropriate constituent or fraction for bioaccumulation testing you should consider those constituents/fractions which are most relevant for PBT assessment. The choice of constituent(s)/fraction(s) shall be clearly explained and justified in the study documentation provided.

In your comments on the draft decision you state that *"the information on the persistency (primary degradation) of AA-AEP and unlikeliness of direct or indirect exposure of the aquatic compartment is considered adequate to conclude that further persistency and bioaccumulation testing according to respectively OECD 309 and 305 is of limited added value and not justified based on the information now available on AA-AEP."* However, as explained above under section 1) ECHA does not consider the available information as adequate to conclude on persistency and bioaccumulation.

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 bioaccumulation fish test (test method: OECD TG 305). You shall provide information on the bioaccumulation of all relevant constituents present in concentration of ≥ 0.1% (w/w). Alternatively, you shall provide a justification for why you consider certain constituents present in concentration of ≥ 0.1% (w/w) or certain constituent fractions/blocks as most relevant or not relevant for the PBT/vPvB assessment.

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 3.0, June 2017), 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.

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 14 March 2017.

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

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

ECHA took into account your comments and did not amend the request(s).
ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

ECHA received proposal(s) for amendment and modified the draft decision.

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

ECHA referred the draft decision to the Member State Committee.

You did not provide any comments on the proposed amendment(s).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-56 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for the start of substance evaluation in 2019.

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

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

4. In relation to the information required by the present decision, the sample of the substance used for the new tests 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 compositions 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 the substance tested in the new tests 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 tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.