EUROPEAN CHEMICALS AGENCY

Helsinki, 01 April 2020

Addressees
Registrants of JS_27836-01-7 listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
29/01/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Reaction product of [29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32]zinc, sulphuric acid and caustic soda
List number: 939-524-8
CAS number: NS

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

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***7 July 2022***.

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

1. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method EU C.2./OECD TG 202) with the Substance

2. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method EU C.3./OECD TG 201) with the Substance

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

1. In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method OECD TG 473) or in vitro micronucleus study (Annex VIII, Section 8.4.2., test method OECD TG 487) with the Substance

2. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method OECD TG 203) with the Substance

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

1. *In vivo* genotoxicity study to be selected according to the following scenarios:

    a. If the test results of request B.1 are negative:

    In vivo mammalian alkaline comet assay (Annex IX, Section 8.4., column 2; test method OECD TG 489) in rats, oral route, on the following tissues: liver, glandular stomach and duodenum, with the Substance

    OR

Transgenic rodent somatic and germ cell gene mutation assays (Annex IX, Section 8.4., column 2; test method EU B.58./OECD TG 488) in transgenic mice or rats, oral route on the following tissues: liver, glandular stomach, with the Substance; duodenum must be harvested and stored for up to 5 years. The duodenum must be analysed if the results of the glandular stomach and of the liver are negative or inconclusive.

b. If the test results of request B.1 are positive:

In vivo mammalian alkaline comet assay (Annex IX, Section 8.4., column 2; test method OECD TG 489) in rats, oral route, on the following tissues: liver, glandular stomach and duodenum, with the Substance

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

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

4. Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method with the Substance

Conditions to comply with the requests

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

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

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

You must submit the information requested in this decision by the deadline indicated above in an updated registration dossier and also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information. The timeline has been set to allow for sequential testing where relevant.

Appeal

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

Approved[1] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

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

Appendix A: Reasons for the requests to comply with Annex VII of REACH

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

1. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)

Short-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex VII to REACH.

In your dossier, you have provided:

- a key study ([redacted], 1994) conducted according to OECD TG 202 with the Substance;
- a supporting study ([redacted] 1978) conducted according to EPA-660/3-75-009 with the Substance. As this study was not conducted according to a test method referred to in Article 13(3), it is evaluated under the conditions set out in Annex XI, Section 1.1.2 of REACH.

We have assessed this information and identified the following issues:

A. Tests on substances must be conducted in accordance with the OECD test guidelines or other internationally recognised test method (Article 13(3) of REACH). The preferred method for this endpoint is the OECD TG 202[2] which requires that the following cumulative conditions are met (among others):
   1. reliable information on the test material must be available (i.e. adequate description of its composition);
   2. a reliable analytical method for the quantification of the substance must be available and documented (e.g. recovery efficiency, limit of determination and quantification);
   3. analytical monitoring of exposure concentrations must be conducted as a minimum, at the highest and lowest test concentration, at the beginning and end of the test.

   On the study by [redacted] (1994), you provide the following information:
   - The test material is described as containing 9.33% of active ingredient with no additional information (i.e. detailed description of the test material composition);
   - On the analytical method you state that "*concentrations* [were] *determined by spectrophotometry*" with no additional information. You did not provide an estimate of the recovery efficiency or of the sensitivity of the method;
   - You state that the analytical monitoring of exposure concentrations was conducted but you did not report any analytical monitoring data.

   As the cumulative conditions listed above are not met and this study does not comply with the requirements of OECD TG 202.

B. The adaptation rule in Annex XI, Section 1.1.2 imposes a number of cumulative conditions for an adaptation to be valid, in particular existing data must provide an adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3), i.e. OECD TG 202[2]. In this case it includes (among others):

[2] ECHA Guidance R.7b, Section R.7.8.3.1. and Appendix R.7.8-2

- testing on one of the recommended test species (i.e. *Daphnia magna* or other suitable *Daphnia* species);
- using an adequate number of test animals (i.e. at least 20 animals must be used at each test concentration);
- analytical monitoring of exposure concentrations (as a minimum, at the highest and lowest test concentration, at the beginning and end of the test).

However, as regards the study by [redacted] (1978), you indicate that the test species is *Penaeus duorarum* (i.e. not a species from Genus *Daphnia*). You specify that 10 organisms were used per test concentration and that no analytical monitoring of exposure concentrations was conducted.

Consequently this study does not provide adequate and reliable coverage of the key parameters foreseen to be investigated in a short-term toxicity study to aquatic invertebrates and your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

In your comments on the draft decisions, you acknowledged shortcomings in the information provided for this requirement and agreed to perform the requested study.

2. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

Growth inhibition study aquatic plants is a standard information requirement in Annex VII to REACH.

In your dossier, you have provided:

- a key study ([redacted] 2013) conducted according to OECD TG 201 and EU C.3 in combination with the OECD Guidance 23 with the Substance;
- a disregarded study ([redacted] 1994) conducted according to OECD TG 201 with the Substance.

We have assessed this information and identified the following issue:

As already explained in the previous section, tests on substances must be conducted in accordance with the OECD test guidelines or other internationally recognised test method (Article 13(3) of REACH). The preferred method for this endpoint is the OECD TG 201[2] which requires that the following cumulative conditions are met (among others):

- reliable information on the test material must be available (i.e. adequate description of its composition);
- a reliable analytical method for the quantification of the substance must be available and documented (e.g. recovery efficiency, limit of determination and quantification);
- the analytical monitoring of exposure concentrations must be conducted as a minimum, at the highest and lowest test concentration, at the beginning and end of the test. For unstable substances, additional samplings for analysis at 24 hours interval are recommended in order to better define loss of the test substance.

However, as regards the [redacted] (2013) study, you provide the following information:

- The test material is described as being equivalent to the Substance. However, you did not provide a detailed description of this test material (i.e. composition, purity, presence of impurities);

- On the analytical method you state that "*spectrophotometry* [measurements were conducted] *at the start and the end of the exposure*". You did not provide an estimate of the recovery efficiency or of the sensitivity of the method.
- You did not provide detailed reporting of the analytical monitoring data. You report geometric mean measured concentrations which indicate that measured concentrations at the end of the exposure period might have been below the limit of quantification of the analytical method, especially at the lower exposure levels. This suggests that the Substance may be unstable in the test medium.

In your comments on the draft decision, you state regarding the [redacted] (2013) study that "*samples at the start of exposure were taken from an additional replicate without algae. At the end of exposure, test samples were taken directly from the test replicates*". You provide an estimation of the accuracy of the analytical method but without specifying what dilution medium was used and if phytoplankton was present. You consider that this is sufficient to address the concerns identified in the draft decision. However, you have not provided further information on the specificity of the method and on potential measurement biases due to the presence of phytoplankton in the samples analysed at the end of the exposure period. It cannot be excluded that measured concentrations at the end of the test were overestimated due to light absorption by phytoplankton cells. Therefore, you have not demonstrated that a reliable analytical method for the quantification of the substance was used. Finally, you have not reported the raw analytical monitoring data.

On the study by [redacted] (1994), you provide the following information:

- The test material is described as containing 9.33% of active ingredient with no additional information (i.e. detailed description of the test material composition);
- You specify that no analytical determination of exposure concentrations was conducted.

As the cumulative conditions listed above are not met, these studies do not comply with the specifications of OECD TG 201.

Therefore, the information requirement is not fulfilled.

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

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

1. *In vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study (Annex VIII, Section 8.4.2.)

An *In vitro* cytogenicity study in mammalian cells or an *In vitro* micronucleus study is a standard information requirement in Annex VIII to REACH.

You have provided the following studies in your dossier performed with the Substance:

i. Key study: *In vivo* mammalian somatic cell study: cytogenicity / bone marrow chromosome aberration, similar to OECD TG 475 ([redacted] 1989)

We have assessed this information and identified the following issue:

According to Annex VIII, section 8.4.2 Column 2, the *in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study does not need to be conducted if adequate data from an *in vivo* cytogenicity test are available. To fulfil this adaptation, the study must qualify as "*adequate data from an in vivo cytogenicity test*". The *in vivo* study must be either a micronucleus test or a chromosomal aberration test, performed according to OECD TG 474 or 475, respectively[3].

To be considered adequate, the *in vivo* study has to meet the requirements of OECD TG 475, and the key parameters of this test guideline include:

a) Bone marrow samples should be taken at two separate times following single treatments. The first sampling interval should be the time necessary to complete 1.5 normal cell cycle lengths (normally 12-18 hours following the treatment period). Since the time required for uptake and metabolism of the test chemical(s) as well as its effect on cell cycle kinetics can affect the optimum time for chromosomal aberration detection, a later sample collection 24 hours after the first sampling time is recommended.
b) At least 200 metaphases must be analysed for each animal for structural chromosomal aberrations including and excluding gaps.
c) The mitotic index and the mean number of cells with aberrations per group must be reported for each group of animals.

However, the reported data for the *in vivo* study you submitted ([redacted] 1989) did not include:

a) The appropriate exposure duration and collection times of bone marrow samples. Bone marrow cells were arrested in the metaphase and collected 6 or 12 hours after administration.
b) Analysis of the adequate number of metaphases.
c) Reporting of the mitotic index and the mean number of cells with aberrations per group for each group of animals.

[3] ECHA Guidance R.7a, Table R.7.7-3, p.558

Therefore, the provided *in vivo* test is not adequate, and your adaptation is rejected since you have not provided adequate data from an *in vivo* cytogenicity test.

To fulfil the information requirement for the Substance, both *In vitro* cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method OECD TG 473) and *in vitro* micronucleus study (Annex VIII, Section 8.4.2., test method OECD TG 487) are considered suitable.

In your comments on the draft decision, you agreed to perform the *in vitro* micronucleus study as you acknowledged that the *in vivo* chromosome aberration study ([redacted] 1989) you provided has some limitations.

2. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)

Short-term toxicity testing on fish is a standard information requirement in Annex VIII to REACH.

In your dossier, you have provided a key study ([redacted], 1994) conducted according to OECD TG 203 with the Substance.

We have assessed this information and identified the following issue:

Tests on substances must be conducted in accordance with the OECD test guidelines or other internationally recognised test method (Article 13(3) of REACH). The preferred method for this endpoint is the OECD TG 203[2] which requires that the following cumulative conditions are met (among others):

- reliable information on the test material must be available (i.e. adequate description of its composition);
- a reliable analytical method for the quantification of the substance must be available and documented (e.g. recovery efficiency, limit of determination and quantification);
- the analytical monitoring of exposure concentrations must be conducted as a minimum, at the highest and lowest test concentration, at the beginning and end of the test. For unstable substances, additional sampling for analysis at 24 hour intervals are recommended in order to better define losses of the test substance.

As regards the study by [redacted] (1994), you provide the following information:

- The test material is described as containing 9.33% of active ingredient with no additional information (i.e. detailed description of the test material composition);
- On the analytical method you state that "*concentrations* [were] *determined by spectrophotometry*" with no additional information. You did not provide an estimate of the recovery efficiency or of the sensitivity of the method;
- You state that the analytical monitoring of exposure concentrations was conducted but you did not report any analytical monitoring data.

As the cumulative conditions listed above are not met and these studies do not comply with the specifications of OECD TG 203.

Therefore, the information requirement is not fulfilled.

In your comments on the draft decisions, you acknowledged shortcomings in the information provided for this requirement and agreed to perform the requested study.

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

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

1. *In* vivo genotoxicity study (Annex IX, Section 8.4, column 2)

Under Annex IX to REACH, an appropriate *in vivo* somatic cell genotoxicity study is triggered if 1) there is a positive result in any of the *in vitro* genotoxicity studies in Annex VII or VIII to REACH and 2) there are no appropriate results already available from an *in vivo* somatic cell genotoxicity study.

In relation to the first condition, your dossier contains positive results for the *in vitro* gene mutation study in mammalian cells (OECD TG 476; [redacted], 1987), which raise the concern for gene mutation.

In your comments on the draft decision, you refer to genotoxicity data on zinc oxide/CAS 1314-13-2 and on polychloro copper phthalocyanine/ CAS 1328-53-6. More specifically for zinc oxide you indicate that *"zinc salts may cause (false) positive in ML tests"* and that *"zinc salts were not classified as genotoxic in vivo."*. For polychloro copper phthalocyanine you indicate that *"Further it is also known for other phthalocyanine complexes that these complexes do not induce genotoxicity. See e.g. registration of CAS 1328-53-6 (Polychloro copper phthalocyanine)."* and you conclude that *"As our registered substance here is also phthalocyanine, we believe that also this material should be considered negative or false positive in the in vitro mouse lymphoma assay."*.

We have assessed this information and identified the following issue:

ECHA considers the provided argument as an adaptation in order to comply with the REACH information requirements according to Annex XI, Section 1.5.

Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide a justification for the read-across including a hypothesis, explanation of the rationale for the prediction of properties and robust study summary(ies) of the source study(ies).[4]

ECHA notes that in the current dossier of the Substance and in your comments, you did not provide any scientific explanation to substantiate your claims, i.e. no documentation following the read-across approach as described in Annex XI section 1.5, was provided.

Therefore, at present, the elements provided in your comment do not allow ECHA to conclude that the Substance *'should be considered negative or false positive in the in vitro mouse lymphoma assay'*.

In relation to the second condition, your dossier contains the following *in vivo* studies performed with the Substance:

i. Key study: *In vivo* Mammalian Bone Marrow Chromosomal Aberration Test, similar to OECD TG 475 ([redacted] 1989)
ii. Supporting study: Sex-linked Recessive Lethal Test in Drosophila melanogaster,

[4] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.6.1

similar to OECD TG 477 ([redacted], 1981)

We have assessed this information and identified the following issue:

Under ECHA Guidance R.7a, in order to justify that an *in vivo* somatic cell genotoxicity study does not need to be performed in accordance with Annex IX, Section 8.4, column 2, the results of the available *in vivo* study/ies must address the specific concern raised by the *in vitro* positive result.

However, the available *in vivo* studies you submitted do not address the gene mutation concern raised by the positive results for the *in vitro* gene mutation study in mammalian cells (OECD TG 476; [redacted], 1987):

- The Mammalian Bone Marrow Chromosomal Aberration Test (OECD TG 475; [redacted] 1989) can only detect chromosomal aberrations, hence is not an appropriate study to detect gene mutation. In addition, as already specified in section B.1 the study is not adequate.
- The Sex-linked Recessive Lethal Test in Drosophila melanogaster (OECD TG 477; [redacted] 1981) is performed on a non-mammalian test system (flies), hence it is not an adequate in vivo mammalian study.

The provided *in vivo* tests are not appropriate to address the concern identified by the *in vitro* gene mutation studies.

In your comments on the draft decision you consider performing first an in vitro HPRT together with an in vitro MN Test and depending on the outcome of these tests then conduct, if necessary, further tests.

ECHA notes that the *in vitro* gene mutation test ('ML test'), is reported in IUCLID as being of high reliability (reliability 1), and performed according to OECD TG 476 and GLP principles. The results are reported to be positive (significant increase in mutant frequency, dose dependent response), in spite of the fact that no tabulated data were provided. Therefore ECHA considers that there is no need to perform an additional in vitro HPRT assay as the available in vitro gene mutation study in mammalian cells is considered a valid study. In any event, the existing positive result of the existing *in vitro* gene mutation test cannot be disregarded.

Therefore, conditions set out in Annex IX, Section 8.4, column 2 are met and the information requirement for an appropriate *in vivo* somatic cell genotoxicity study is triggered.

Test selection

According to the ECHA Guidance Chapter R.7a[5], the transgenic rodent somatic and germ cell gene mutation assays ("TGR assay", OECD TG 488) and the in vivo mammalian alkaline comet assay ("comet assay", OECD TG 489) are suitable to follow up a positive in vitro result on gene mutation.

Therefore, the TGR and the comet assay are suitable tests to follow up the concern on gene mutation for the Substance.

This decision, however, also requests an *in vitro* test under Annex VIII Section 8.4.2 (see section 1 of Appendix B), which would raise a concern for chromosomal aberration in case of

[5] ECHA Guidance Chapter R.7a, Section R.7.7.6.3

positive results. This concern can be addressed by the comet assay, but not by the TGR assay. Considering the lower costs of the comet assay, the lower number of animals used and costs if one test is conducted rather than two, it is appropriate to wait for the results of the *in vitro* test requested under Annex VIII Section 8.4.2 and, depending on these results, to conduct either (1) the TGR or comet assay, or (2) the comet assay.

Test design

In case you decide to perform the comet assay according to the test method OECD TG 489, the test must be performed in rats. Having considered the anticipated routes of human exposure and adequate exposure of the target tissue(s), performance of the test by the oral route is appropriate.

In line with the OECD TG 489, the test must be performed by analysing tissues from liver, as primary site of xenobiotic metabolism, glandular stomach and duodenum, as sites of contact. There are several expected or possible variables between the glandular stomach and the duodenum (different tissue structure and function, different pH conditions, variable physico-chemical properties and fate of the Substance, and probable different local absorption rates of the Substance and its possible breakdown product(s)). In light of these expected or possible variables, it is necessary to analyse both tissues to ensure a sufficient evaluation of the potential for genotoxicity at the site of contact in the gastro-intestinal tract.

In case the TGR assay is appropriate and you decide to conduct this test, according to the test method EU B.58/OECD TG 488, the test must be performed in transgenic mice or rats and the Substance is usually administered orally.

According to the test method EU B.58/OECD TG 488, the test must be performed by analysing tissues from liver, as slowly proliferating tissue and primary site of xenobiotic metabolism, glandular stomach and duodenum, as rapidly proliferating tissue and site of direct contact. There are several expected or possible variables between the glandular stomach and the duodenum (different tissue structure and function, different pH conditions, variable physico-chemical properties and fate of the Substance, and probable different local absorption rates of the Substance and its possible breakdown product(s)). In light of these expected or possible variables, it is necessary to analyse both tissues to ensure a sufficient evaluation of the potential for mutagenicity at the site of contact in the gastro-intestinal tract. However, duodenum must be stored (at or below −70ºC) until the analysis of the liver and glandular stomach is completed; the duodenum must then be analysed only if the results obtained for the glandular stomach and the liver are negative or inconclusive.

Germ cells:

A subsequent germ cell genotoxicity study (TGR/OECD TG 488, or CA on spermatogonia/OECD TG 483) may still be required under Annex IX of REACH, in case 1) an *in vivo* genotoxicity test on somatic cell is positive, and 2) no clear conclusion can be made on germ cell mutagenicity.

Therefore, in case you decide to perform the comet assay, you may consider to collect the male gonadal cells collected from the seminiferous tubules (as described by e.g. O'Brien *et al.*[6]) in addition to the other aforementioned tissues, as it would optimise the use of animals. You can prepare the slides for male gonadal cells and store them for up

[6] O'Brien, J.M., Beal, M.A., Gingerich, J.D., Soper, L., Douglas, G.R., Yauk, C.L., Marchetti, F. (2014) Transgenic Rodent Assay for Quantifying Male Germ Cell Mutant Frequency. J. Vis. Exp. (90), e51576, doi:10.3791/51576

to 2 months, at room temperature, in dry conditions and protected from light. Following the generation and analysis of data on somatic cells, in accordance to Annex IX, Section 8.4., column 2, you should consider analysing the slides prepared with gonadal cells.

In case you decide to perform the TGR, you may consider to collect the male germ cells at the same time as the other tissues, in order to limit additional animal testing. According to the OECD 488 the tissues (or tissue homogenates) can be stored under specific conditions and used for DNA isolation for up to 5 years (at or below −70 ºC). Following the generation and analysis of data on somatic cells, in accordance to Annex IX, Section 8.4., column 2, you should consider analysing the collected germ cells.

This type of evidence may be relevant for the overall assessment of possible germ cell mutagenicity including classification and labelling according to the CLP Regulation.

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

and

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

Long-term toxicity testing on aquatic invertebrates and on fish are standard information requirements in Annex IX to REACH.

You have adapted these information requirements based on Annex IX, Section 9.1, Column 2 and you have provided the following justification: "*It was proven with an exposure estimation, that all identified uses of the substance are safe (RCR < 1). Furthermore the substance is with high probability acutely not harmful to fish and invertebrates. Otherwise 'zinc phthalocyanine sulfonate' can cause toxic effects to aquatic green algae. Hence algae turned out to be the most sensitive trophic level. Therefore, the chemical safety assessment based on the investigations with aquatic algae. It can be assumed that long-term tests with fish and aquatic invertebrates would not reveal any different findings. Therefore, and for reasons of animal welfare long-term tests on fish as well as on aquatic invertebrates are not required*".

Based on the information provided in your dossier we have identified the following issue:

As specified in Annex IX, Section 9.1., Column 2, long-term toxicity to studies on aquatic invertebrates and fish must be performed unless the Chemical Safety Assessment demonstrates that risks towards the aquatic compartment arising from the use of the Substance are controlled (as per Annex I, section 0.1). The justification must be documented in the Chemical Safety Assessment.

In particular, the Chemical Safety Assessment must take into account the following elements to support that long-term toxicity testing is not required:

- all relevant hazard information from your registration dossier,
- the outcome of the exposure assessment in relation to the uses of the Substance,
- the outcome of the PBT/vPvB assessment including information on relevant degradation products and constituents present in concentration at or above 0.1% (w/w).

As specified in requests A1, A2 and B2, the data on Growth inhibition study aquatic plants and on Short-term toxicity to aquatic invertebrates and to fish are not

compliant. Hence your dossier currently does not include adequate information to characterize the hazardous property of the Substance to aquatic organisms.

Without this information, your Chemical Safety Assessment does not demonstrate that the risks of the Substance are adequately controlled. As a consequence, your adaptation is rejected as it does not meet the specific rules for adaptation of Annex IX, Section 9.1., Column 2.

Therefore, the information requirements of long-term toxicity testing to aquatic invertebrates and to fish are not fulfilled.

In your comments on the draft decision, you indicate that you will re-evaluate the need to conduct long-term toxicity testing on fish and invertebrates once the information requested under section A.1 and B.2 will be available.

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

Identification of the degradation products is a standard information requirement at Annex IX of REACH. Column 2 of Section 9.2.3. of Annex IX further states that the information does not need to be provided if the substance is readily biodegradable.

You have adapted this information requirement based on Annex IX, Section 9.2., Column 2. You have provided the following justification: "*In accordance with Annex VIII, IX and X of Regulation (EC) No. 1907/2006 further biotic degradation tests shall be proposed if the result of the Chemical Safety Assessment indicates the need to investigate further the degradation of the substance and its degradation products. Based on its molecular structure the described substance will probably be persist in the environment. Simulation biodegradation tests in water and sediment are not proposed, since no relevant new findings are expected from such investigations*".

Based on the information provided in your dossier we have identified the following issue:

The Chemical Safety Assessment needs to assess and document that risks arising from the Substance are controlled to demonstrate that there is no need to conduct further testing (Annex 1. Section 0.1; Annex IX, Section 9.2, Column 2).

In particular the following elements need to be included:

- a justification for why there is no need to provide any further information on degradation products to be considered in the hazard assessment and exposure assessment, and
- a PBT/vPvB assessment including information on relevant degradation products.

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

In your dossier you provided a ready biodegradability study according to OECD TG 301B with the Substance. You report that the percentage biodegradation reached 2% after 28 days and you have concluded that the Substance is not readily biodegradable. You have not provided any additional information on the biodegradation of the Substance (e.g. biodegradation simulation study, information on degradation products).

The Substance is not readily biodegradable. Furthermore, you have not supported your general statement above by any (valid and reliable) scientific evidence to demonstrate that this information does not need to be considered in the risk assessment and in the PBT/vPvB assessment. Hence your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

Study selection and design

Regarding the appropriate and suitable test method you are recommended to perform the OECD TG 309 test with water amended with suspended solids/sediment of 0.01 to 1 g/L dry weight ("suspended sediment test"). To overcome the potential analytical limitations in the identification and quantification of major transformation products you may use higher concentrations of the test substance (e.g. >100 µg/L) as specified in the OECD 309 test guideline. You may also use other appropriate and suitable test methods to provide information on the identity of the transformation/degradation products for example by e.g. enhanced screening level degradation test or modelling tools.

There are indications in your dossier that the substance is subject to photolysis. For instance, in the reported key studies for short-term toxicity to fish and aquatic invertebrates you state hat "*because of the photodegradation of the test substance under light, the test was carried out entirely in the dark*". The results reported in the key study for toxicity to aquatic plants also suggest that the test substance was not stable. Therefore you are advised to take due account to the potential formation of abiotic transformation/degradation products.

You will need to provide a scientifically valid justification for the chosen method(s). The provided information should include, identification, stability, behaviour, molar quantity of transformation/degradation products relative to the parent compound. In addition, degradation half-life, log Kow and potential toxicity of the transformation/degradation may be investigated.

Appendix D: Procedural history

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

The compliance check was initiated on 11 March 2019.

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 within 30 days of the notification.

ECHA took into account your comments and did not amend the requests.

You submitted comments concerning a request for a tonnage band change and an indication of a future cease of manufacture. The Agency does not take into account updates of volumes in its decision making (see ECHA's Practical Guide[7]). As these issues do not affect the decision making process of this decision, ECHA has dealt with them in a separate communication.

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

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

[7] ECHA's Practical Guide How to handle dossier evaluation - https://echa.europa.eu/documents/10162/13643/pg_dossier_evaluation_en.pdf/5788b5ee-f6c0-df56-c7ea-c693740acf87)

Appendix E: Observations and technical guidance

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

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

3. Test guidelines, GLP requirements and reporting

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

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

   Under Article 10 (a) (vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide: 'How to report robust study summaries'[8].

4. Test material

   Selection of the test material(s)

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

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

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

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

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

Technical reporting of the test material

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

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers" on the ECHA website[9].

5. List of references of the ECHA Guidance and other guidance/ reference documents[10]

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

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

ECHA Read-across assessment framework (RAAF, March 2017)[11]

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

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

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

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

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

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

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

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

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

OECD Guidance documents[12]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD23.
Guidance Document on Mammalian Reproductive Toxicity Testing and Assessment – No 43, referred to as OECD GD43.

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

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

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

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