~~Confidential~~

Helsinki, 03 June 2024

Addressees
Registrants of JS_DOPO-HCA as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
02 April 2013

Registered substance subject to this decision ("the Substance")
Substance name: 6H-dibenz[c,e][1,2]oxaphosphorin 6-oxide
EC/List number: 252-813-7

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***8 September 2027***.

Requested information must be generated using the Substance unless otherwise specified.

Information required from all the Registrants subject to Annex VIII of REACH

1. *In vitro* micronucleus study (Annex VIII, Section 8.4.2., test method: OECD TG 487). The aneugenic potential of the Substance must be assessed with an additional positive control group for aneugenicity on top of the positive control group for clastogenicity, if the Substance induces an increase in the frequency of micronuclei.

2. Justification for an adaptation of the short-term repeated dose toxicity study (28 days) (Annex VIII, Section 8.6.1., Column 2) based on the request 5 below.

   If the sub-chronic toxicity study (90 days) is not requested:

   Short-term repeated dose toxicity (28 days) (Annex VIII, Section 8.6.1.) by oral route, in rats, to be combined with the screening for reproductive/developmental toxicity requested below.

3. Screening study for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) by oral route, in rats.

4. Hydrolysis as a function of pH (Annex VIII, Section 9.2.2.1.; test method: EU C.7./OECD TG 111).

Information required from all the Registrants subject to Annex IX of REACH

5. Sub-chronic toxicity study (90 days), oral route (Annex IX, Section 8.6.2.; test method: OECD TG 408) in rats.

6. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) by oral route, in one species (rat or rabbit).

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

8. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210).

9. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: EU C.25/OECD TG 309) at a temperature of 12°C.

10. Identification of degradation products (Annex IX, Section 9.2.3.; test method: EU C.25/OECD TG 309)

The reasons for the requests are explained in Appendix 1.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

To comply with your information requirements, you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also **update the chemical safety report, where** relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general requirements for testing and reporting new tests under REACH, see Appendix 4.

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the requests
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[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 for the requests

Reasons related to the information under Annex VIII of REACH

1. *In vitro* micronucleus study

1 An *in vitro* mammalian chromosomal aberration study or an *in vitro* mammalian micronucleus study is an information requirement under Annex VIII, Section 8.4.2.

1.1. Information provided

2 You have provided an *in vitro* cytogenicity study in mammalian cells (1994) with the Substance.

1.2. Assessment of the information provided

1.2.1. The provided study does not meet the specifications of the test guidelines

3 To fulfil the information requirement, the study has to be an *in vitro* chromosomal aberration test or an *in vitro* micronucleus test conducted in mammalian cells. The study must comply with the OECD TG 473 or the OECD TG 487, respectively (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) at least 300 well-spread metaphases are scored per concentration;

b) the positive controls induce responses compatible with those generated in the historical positive control database;

c) the positive controls produce statistically significant increase compared with the negative control;

d) the negative control data is ideally within the 95% control limits of the distribution of the laboratory's historical negative control database;

e) data on the cytotoxicity and the frequency of cells with structural chromosomal aberration(s) for the treated and control cultures is reported;

f) to conclude on a negative outcome, a negative response is obtained in all three experimental conditions described in paragraph 28 of OECD TG 473, using a short-term treatment with and without metabolic activation and long-term treatment without metabolic activation.

4 In the provided study:

a) 100 metaphases (i.e., less than 300 metaphases) were scored per concentration;

b) you have not reported whether the positive control data is compatible with those generated in the historical positive control database;

c) you have not reported whether the positive control produced a statistically significant increase in the induced response when compared with the concurrent negative control;

d) you have not reported whether the negative control showed a response within the historical control range of the laboratory;

e) data on the cytotoxicity for the treated and control cultures were not reported as you only state that "*50% inhibition concentration was 216 µg/mL*";

f) the two experimental conditions described in paragraph 28 of OECD TG 473 (i.e. a short-term treatment with metabolic activation and a short-term

treatment without metabolic activation) are missing to conclude on a negative outcome.

5 The information provided does not cover the specifications required by the OECD TG 473.

6 Therefore, the information requirement is not fulfilled.

1.3. Study design

7 According to the Guidance on IR & CSA, Section R.7.7.6.3., either the *in vitro* mammalian chromosomal aberration ("CA") test (test method OECD TG 473) or the *in vitro* mammalian cell micronucleus ("MN") test (test method OECD TG 487) can be used to investigate chromosomal aberrations *in vitro*. However, while the MN test detects both structural chromosomal aberrations (clastogenicity) and numerical chromosomal aberrations (aneuploidy), the CA test detects only clastogenicity, as OECD TG 473 is not designed to measure aneuploidy (see OECD TG 473, paragraph 2).Therefore, you must perform the MN test (test method OECD TG 487), as it enables a more comprehensive investigation of the chromosome damaging potential in vitro. Moreover, in order to demonstrate the ability of the study to identify clastogens and aneugens, you must include two concurrent positive controls, one known clastogen and one known aneugen [1] (OECD TG 487, paragraphs 33 to 35).

1.3.1. Assessment of aneugenicity potential

8 If the result of the MN test is positive, i.e. your Substance induces an increase in the frequency of micronuclei, you must assess the aneugenic potential of the Substance.

9 In line with the OECD TG 487 (paragraph 4), you should use one of the centromere labelling or hybridisation procedures to determine whether the increase in the number of micronuclei is the result of clastogenic events (i.e. micronuclei contain chromosome fragment(s)) and/or aneugenic events (i.e. micronuclei contain whole chromosome(s)).

[1] According to the TG 487 (2016) "At the present time, no aneugens are known that require metabolic activation for their genotoxic activity" (paragraph 34).

10 In your comments to the draft decision, you agree to perform the requested study.

2. Short-term repeated dose toxicity (28 days)

11 A short-term repeated dose toxicity study (28 days) is an information requirement under Annex VIII, Section 8.6.1. This information may take the form of a study record or a valid adaptation in accordance with either a specific adaptation rule under Column 2 or a general adaptation rule under Annex XI.

2.1. Information provided

12 ECHA understands that you have adapted this information requirement by using Annex VIII, Section 8.6.1., Column 2, although you have not explicitly referred to it. To support the adaptation, you have provided the following information:

(i) a sub-chronic toxicity study (1976) with the Substance.

2.2. Assessment of the information provided

2.2.1. Study not reliable

13 Under Annex VIII, Section 8.6.1., Column 2, Paragraph 1, Indent 1, the study may be omitted if a reliable sub-chronic (90 days) or chronic toxicity study is available or proposed by the registrant.

14 The study (i) is described as a sub-chronic (90 days) toxicity study.

15 However, for the reasons explained in request 5 the study is not reliable.

16 Based on the above, your adaptation is rejected.

17 Therefore, the information requirement is not fulfilled.

2.3. Study design

18 When there is no information available neither for the 28-day repeated dose toxicity (EU B.7, OECD TG 407), nor for the screening study for reproductive/developmental toxicity (OECD TG 421 or TG 422), the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

19 The study design is addressed in request 3.

2.3.1. Justification for an adaptation of the short-term repeated dose toxicity study (Annex VIII, Section 8.6.1., Column 2)

20 The present decision requests the registrants concerned to generate and submit a reliable sub-chronic toxicity study (90 days) (see request 5).

21 According to Annex VIII, Section 8.6.1., Column 2 and to prevent unnecessary animal testing, a short-term toxicity study (28 days) does not need to be conducted. Therefore, to comply with the information requirement in Annex VIII, Section 8.6.1., you are requested to provide a justification for adaptation, as provided in Annex VIII, Section 8.6.1., Column 2.

22 In case the adopted decision no longer contains a request for a 90-day study, you are required to provide a 28-day study.

23 Therefore, you are requested to either submit:

- a justification for the adaptation according to Annex VIII, Section 8.6.1., Column 2, based on request 5; or
- a 28-day study as per the study design described in Section 3.3. in case the 90-day study is not requested in the adopted decision.

24 In your comments to the draft decision, you express your intentions to adapt this information requirement according to Annex VIII, Section 8.6.1., Column 2, based on the request 5 below. As your strategy relies on data (Request 5) which is yet to be generated, no assessment or conclusions on the compliance can currently be made.

3. Screening study for reproductive/developmental toxicity

25 A screening study for reproductive/developmental toxicity study (OECD 421 or OECD 422) is an information requirement under Annex VIII, Section 8.7.1.

3.1. Information provided

26 You have adapted this information requirement and provided the following justification: "*HCA is an intermediate and human exposure is limited by the use of closed batch processes and/or appropriate PPE. Systemic toxicity following single and repeated dose oral exposures is low, therefore, conduct of animal studies to investigate reproduction toxicity are scientifically unjustifiable.*"

3.2. Assessment of the information provided

3.2.1. Your justification to omit the study has no legal basis

27 A registrant may only adapt this information requirement based on the general rules set out in Annex XI or the specific rules set out in Annex VIII, Section 8.7.1., Column 2.

28 Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH or Annex VIII, Section 8.7.1., Column 2 and the legal basis you are relying on for your intended adaptation is not apparent to ECHA.

29 Therefore, you have not demonstrated that this information can be omitted.

30 Minimisation of vertebrate animal testing is not on its own a legal ground for adaptation under the general rules of Annex XI or Annex VIII, Section 8.7.1., Column 2.

31 Therefore, the information requirement is not fulfilled.

3.3. Study design

32 A study according to the test method EU B.63/OECD TG 421 or EU B.64/OECD TG 422 must be performed in rats.

33 As the Substance is a solid, the study must be conducted with oral administration of the Substance (Annex VIII, Section 8.7.1., Column 1).

34 Therefore, the study must be conducted in rats with oral administration of the Substance.

35 In case the adopted decision no longer contains a request for a sub-chronic (90 days) study (e.g. as a result of an overall tonnage band change of the joint submission), a screening study for reproductive/developmental toxicity performed according to the OECD TG 422 is preferred.

36 In your comments to the draft decision, you provide your intention to adapt this information requirement according to Annex VIII, Section 8.7.1., Column 2 and more specifically on the basis of the information from the requested pre-natal developmental toxicity study (request 6 below). As your strategy relies on data which is yet to be generated, no assessment or conclusions on the compliance can currently be made.

4. Hydrolysis as a function of pH

37 Hydrolysis as a function of pH is an information requirement under Annex VIII to REACH (Section 9.2.2.1.).

4.1. Information provided

38 You have adapted this information requirement and provided the following justification: "*substance changes in water to another compound, [2-(2'-hydroxyphenyl) phenyl] phosphonic acid which is stable in acidic and alkaline conditions*".

4.2. Assessment of the information provided

4.2.1. Your justification to omit the study has no legal basis

39 A registrant may only adapt this information requirement based on the general rules set out in Annex XI or the specific rules set out in Annex VIII, Section 9.2.2.1., Column 2.

40 Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH or Annex VIII, Section 9.2.2.1., Column 2 and the legal basis you are relying on for your intended adaptation is not apparent to ECHA.

41 Based on the above, you have not demonstrated that this information can be omitted.

42 Therefore, the information requirement is not fulfilled.

43 In your comments to the draft decision, you agree to perform the requested study.

Reasons related to the information under Annex IX of REACH

5. Sub-chronic toxicity study (90 days)

44 A sub-chronic toxicity study (90 days) is an information requirement under Annex IX, Section 8.6.2.

5.1. Information provided

45 You have provided a sub-chronic toxicity study (1976) with the Substance.

5.2. Assessment of the information provided

5.2.1. The provided study does not meet the specifications of the test guideline

46 To fulfil the information requirement, the sub-chronic toxicity study (90 days) has to meet the requirements of the OECD TG 408. Therefore, the following specifications must be met:

g) clinical signs are observed daily and functional observations (i.e. sensory activity, grip strength and motor activity assessments) are made during week 11 or later;

h) haematological and clinical biochemistry tests are performed;

i) terminal organ weights are measured;

j) gross pathological examinations;

k) full histopathology is performed.

47 In the provided study:

a) clinical signs and functional aspects were not assessed;

b) only limited haematology and clinical biochemistry examinations were performed as platelet count, measure of blood clotting time/potential, sodium, potassium, glucose, total cholesterol, creatinine measurements are missing;

c) limited terminal organ weights were recorded as weight of adrenals, testes, epididymides, uterus, thymus and brain were not measured;

d) limited gross pathology examinations were performed as only as only heart, liver, kidney, spleen, lung, pancreas, seminal vesicle, ovaries, marrow, stomach, small intestine, large intestine and cecum were investigated;

e) the following histopathology items were not studied: brain, spinal cord, pituitary, thyroid, parathyroid, thymus, oesophagus, salivary glands, adrenals, trachea, aorta, gonads, uterus, accessory sex organs, female mammary gland, prostate, urinary bladder, lymph nodes, peripheral nerve, bone marrow, skin and eyes.

48 The information provided does not cover the specifications required by the OECD TG 408.

49 Therefore, the information requirement is not fulfilled.

5.3. Study design

50 Following the criteria provided in Annex IX, Section 8.6.2., Column 2, and considering the Guidance on IRs and CSA, Section R.7.5.6.3.2., the oral route is the most appropriate route of administration to investigate repeated dose toxicity of the Substance.

51 According to the OECD TG 408, the rat is the preferred species.

52 Therefore, the study must be performed in rats according to the OECD TG 408 with oral administration of the Substance.

53 In your comments to the draft decision, you agree to perform the requested study.

6. Pre-natal developmental toxicity study in one species

54 A pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is an information requirement under Annex IX, Section 8.7.2.

6.1. Information provided

55 ECHA understand that you have adapted this information requirement by using Annex IX, Section 8.7., Column 2, although you have not explicitly referred to it. To support the adaptation, you have provided the following information:

(i) "*HCA is an intermediate and human exposure is limited by the use of closed batch processes and/or appropriate PPE. Systemic toxicity following single and repeated dose oral exposures is low, therefore, conduct of animal studies to investigate reproduction toxicity are scientifically unjustifiable*";

(ii) a sub-chronic toxicity study (1976) with the Substance.

6.2. Assessment of the information provided

6.2.1. Criteria for the application of the adaptation for Annex IX, Section 8.7., Column 2 not met

56 Under Annex IX, Section 8.7., Column 2, the study does not need to be conducted if the following criteria are met:

- the substance is of low toxicological activity, demonstrated by a comprehensive and informative dataset showing no toxicity in any of the tests available; and
- that it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure; and
- that there is no or no significant human exposure.

57 However, the information in your dossier does not support these criteria as:

- no reliable repeated dose toxicity studies were provided to demonstrate no toxicity as the study (ii) is not reliable for the reasons explained in request 5; and
- no toxicokinetic data were provided to show that there is no systemic absorption; and
- the uses of the Substance include formulation of epoxy resins and flame retardant with potential for human exposure.

58 Therefore, you have not provided evidence to support the claim for low toxicological activity and lack of systemic absorption. Furthermore, the industrial uses of the Substance indicate human exposure as not all activities are performed in closed batch processes (e.g. PROCs 4, 5, 8a).

59 On this basis, you have not demonstrated that the criteria for this adaptation are fulfilled.

60 Based in the above, your adaptation is rejected.

6.3. Study design

61 A PNDT study according to the test method OECD TG 414 should be performed in rats or rabbits as preferred species.

62 As the Substance is a solid, the study must be conducted with oral administration of the Substance (Annex IX, Section 8.7.2., Column 1).

63 Therefore, the study must be conducted in rats or rabbits with oral administration of the Substance.

64 In your comments to the draft decision, you agree to perform the requested study.

7. Long-term toxicity testing on aquatic invertebrates

65 Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

7.1. Information provided

66 You have adapted this information requirement and provided the following justification: "*The CSA demonstrates that there is no need to investigate further the effects on aquatic organisms. Essentially, direct release to the aquatic environment is very unlikely and indirect exposure is negligible*". In your IUCLID dossier, in the field "Data waiving", you have selected "exposure considerations".

67 We understand that you intend to adapt the standard information on the basis of Annex IX, Section 9.1., Column 2. Furthermore ECHA understands from your statement that you consider that under the foreseen uses of the Substance no exposure to water would occur. The Substance is used in the formulation epoxy resins and flame retardants. For the sake of completeness, ECHA has assessed your justification against the requirements of Annex XI, Section 3.2(b).

7.2. Assessment of the information provided

7.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the study

68 Under Annex IX, Section 9.1., Column 2 is not a basis for omitting information on long-term toxicity to aquatic invertebrates referred to under Column 1, Section 9.1.5.

69 Therefore, the adaptation is rejected.

7.2.2. Substance-tailored exposure-driven testing adaptation rejected

70 A substance-tailored exposure-driven testing adaptation must fulfil the cumulative conditions set out under Annex XI, Sections 3(1) as well as 3(2)(a), (b) or (c).

71 Under Annex XI, Section 3(2)(b), where the substance is not incorporated in an article, it must be demonstrated and documented for all relevant scenarios that throughout the life cycle, strictly controlled conditions as set out in Article 18(4)(a) to (f) apply (see further Guidance on Intermediates and Practical Guide 16).

72 In your IUCLID dossier, you do not claim that the Substance is used under strictly controlled conditions. Your report the following environmental release categories: ERC 5, 6A and 6D with default release factors to water (before STP) of 50%, 2% and 0.005% respectively.

73 Therefore, the use of the Substance under strictly controlled conditions is not demonstrated and the substance-tailored exposure driven testing adaptation under Annex XI, Section 3.2 (b) is rejected.

74 Therefore, the information requirement is not fulfilled.

7.3. Study design

75 The Substance may be difficult to test as fast hydrolysis cannot be excluded based on currently available information (see Request 4).

76 OECD TG 211 specifies that, for difficult to test substances, such as those that rapidly hydrolyse, you must consider the approach described in OECD GD 23.

77 Without reliable hydrolysis data, it cannot be excluded that the Substance is difficult to test due to potential rapid hydrolysis.

78 The outcome of the study requested under request 4 or results of the preliminary stability studies must be used to assess whether the Substance is indeed difficult to test due to rapid hydrolysis (i.e. resulting in a loss of 20% of the initial concentration of parent Substance (OECD GD 23, para. 10), prior to conducting this study. In case rapid hydrolysis is confirmed, the results obtained will also inform whether the parent Substance or its hydrolysis product(s) are more relevant for the aquatic toxicity hazard assessment and, consequently, whether to maximise (and maintain) the parent Substance or its hydrolysis product(s) in the test solution of the currently requested toxicity test.

79 According to OECD GD 23, para. 82, if:

- Half-life is less than one hour:
  - the hydrolysis product(s) are considered more relevant for the aquatic toxicity hazard assessment.
- Half-life is between one hour and three days:
  - before conducting the requested toxicity study, you must determine the relative toxicity between the parent Substance and its degradation product(s), e.g. by preliminary toxicity test(s) or QSARs. Based on that information, you must choose whether the parent Substance or its hydrolysis product(s) are considered more relevant for the aquatic toxicity hazard assessment i.e. the more toxic one should be tested (OECD GD 23, para. 82, second bullet, and 86).
- Half-life is more than three days:
  - the parent Substance is considered more relevant for the aquatic toxicity hazard assessment. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 211.

80 In all cases, appropriate test design and test media preparation methods are required in accordance with section 7.3.2 of OECD GD 23.

81 You must monitor the test concentration(s) of the Substance or the hydrolysis product(s), as applicable, throughout the exposure duration and report the results.

82 In your comments to the draft decision, you agree to perform the requested study.

8. Long-term toxicity testing on fish

83 Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

8.1. Information provided

84 You have adapted this information requirement and provided the same justification as already described under Section 7.1.

8.2. Assessment of the information provided

85 For the reasons already described under Section 7.2., your adaptation is rejected.

86 Therefore, the information requirement is not fulfilled.

8.3. Study design

87 To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (Guidance on IRs and CSA, Section R.7.8.2.).

88 OECD TG 210 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in "Study design" under request 8.

89 In your comments to the draft decision, you agree to perform the requested study.

9. Simulation testing on ultimate degradation in surface water

90 Simulation testing on ultimate degradation in surface water is an information requirement under Annex IX to REACH (Section 9.2.1.2.).

9.1. Information provided

91 You have adapted this information requirement and provided the following justification: "*Direct and indirect exposure to surface water is unlikely*".

9.2. Assessment of information provided

9.2.1. Your justification to omit the study has no legal basis

92 A registrant may only adapt this information requirement based on the general rules set out in Annex XI or the specific rules set out in Annex IX, Section 9.2.1.2., Column 2.

93 It is noted that Column 2 of Annex IX, Section 9.2, does not allow omitting the need to submit information on simulation on ultimate degradation in surface water under Column 1.

94 Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH or Annex IX, Section 9.2.1.2., Column 2 and the legal basis you are relying on for your intended adaptation is not apparent to ECHA.

95 Based on the above, you have not demonstrated that this information can be omitted.

96 Therefore, the information requirement is not fulfilled.

9.3. Study design

97 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1):

(2) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and

(3) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

98 You must perform the test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (Guidance on IRs and CSA, Section R.11.4.1.1.3.).

99 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 309.

100 As specified in Guidance on IRs and CSA, Section R.7.9.4.1., the organic carbon (OC) concentration in surface water simulation tests is typically 2 to 3 orders of magnitude higher than the test material concentration and the formation of non-extractable residues (NERs) may be significant in surface water tests. Paragraph 52 of the OECD TG 309 provides that the "total recovery (mass balance) at the end of the experiment should be between 90% and 110% for radiolabelled substances, whereas the initial recovery at the beginning of the experiment should be between 70% and 110% for non-labelled substances". NERs contribute towards the total recovery. Therefore, the quantity of the (total) NERs must be accounted for the total recovery (mass balance), when relevant, to achieve the objectives of the OECD TG 309 to derive degradation rate and half-life. The reporting of results must include a scientific justification of the used extraction procedures and solvents.

101 For the persistence assessment by default, total NERs is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NERs may be differentiated and quantified as irreversibly bound or as degraded to biogenic NERs, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website (NER - summary 2019 (europa.eu) [1]).

[1] https://echa.europa.eu/documents/10162/13632/bg_note_addressing_non-extractable_residues.pdf/e88d4fc6-a125-efb4-8278-d58b31a5d342

102 Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 309; Guidance on IRs and CSA, Section R.11.4.1.).

103 In your comments to the draft decision, you agree to perform the requested study.

10. Identification of degradation products

104 Identification of abiotic and biotic degradation products is an information requirement under Annex IX to REACH (Section 9.2.3.).

105 You have not submitted any information for this requirement.

106 Therefore, the information requirement is not fulfilled.

10.1. Study design

107 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):

(4) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and

(5) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

108 Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported. In addition, identified transformation/degradation products must be considered in the CSA including PBT assessment.

109 You must obtain this information from the degradation study requested in request 9.

110 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (request 9) must be conducted at 12°C and at a test concentration < 100 µg/L. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline, e.g. 20°C) and at higher application rate (i.e. > 100 µg/L).

111 In your comments to the draft decision, you agree to perform the requested study.

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).
Guidance for monomers and polymers; ECHA (2023).
***Guidance on intermediates*;** ECHA (2010).
All guidance documents are available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF); ECHA (2017).
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs; ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: Procedure

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

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 05 June 2023.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

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

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the request(s).

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.

Appendix 3: Addressees of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third-party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1 Test methods, GLP requirements and reporting

(1) Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.
(2) Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.
(3) 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 on How to report robust study summaries (https://echa.europa.eu/practical-guides).
(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2 Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

(1) Selection of the Test material(s)

The Test Material used to generate the new data must be selected taking into account the following:

- the variation in compositions reported by all members of the joint submission,
- the boundary composition(s) of the Substance,
- 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.

(2) Information on the Test Material needed in the updated dossier

- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- The reported composition must include all constituents of each Test Material and their concentration values.

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers (https://echa.europa.eu/manuals).