~~Confidential~~

Helsinki,23 May 2023

Addressees
Registrant(s) of JS_71735-74-5 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
18/02/2022

Registered substance subject to this decision ("the Substance")
Substance name: Ethyl 3-[[bis(1-methylethoxy)phosphinothioyl]thio]propionate
EC number: 275-965-6

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 ***2 March 2026***.

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 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)

2. Screening 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

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

3. 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)

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

5. 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. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

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

The reasons for the decision(s) 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 request(s)
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 request(s)

Contents

0. Reasons common to several requests

0.1. Read-across adaptation rejected

1 You have adapted the following standard information requirements by using grouping and read-across approach under Annex XI, Section 1.5:

- In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

2 ECHA has considered the scientific and regulatory validity of your read-across approach(es) in general before assessing the specific standard information requirements in the following sections.

3 Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used.

4 Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category.

5 Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

0.1.1. Predictions for toxicological properties

6 You provide a read-across justification document in IUCLID Section 13.

7 You predict the properties of the Substance from information obtained from the following Source Substance:

8 Propanoic acid, 3-[[bis(2-methylpropoxy)phosphinothioyl]thio]-2-methyl-, EC No. 434-070-2, CAS No. 268567-32-4.

9 You provide the following reasoning for the prediction of toxicological properties: analogue approach is based on the structural similarities of the two substances, where the key structural element in both substances is a dithiophosphate, which carries ligands at both oxygen atoms and at the single bonded sulfur atom. The proposed read across approach is further based on similarities in both physico-chemical parameters and toxicological properties.

10 ECHA understands that your read-across hypothesis assumes that different compounds have the same type of effects. You predict the properties of your Substance to be quantitatively equal to those of the Source Substance.

11 We have identified the following issue(s) with the prediction(s) of toxicological properties:

0.1.1.1. Missing supporting information to compare the properties of the substances

12 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 supporting information to scientifically justify the read-across explanation for prediction of properties. The set of supporting information should strengthen the rationale for the read-across in allowing to verify the crucial aspects of the read-across hypothesis and establishing that the properties of the Substance can be predicted from the data on the Source Substance(s) (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

13 As indicated above, your read-across hypothesis is based on the assumption that the structurally similar Source Substance(s) cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the Source Substance(s) is necessary to confirm that the substances cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the Source Substance(s).

14 In order to support your hypothesis that the Substance and the Source Substance have similarities in toxicological properties for the endpoints under consideration, you have provided comparable oral 28-day repeat dose toxicity studies conducted on the Substance and on the Source Substance. To support similarities in genotoxicity properties, you have provided gene mutation studies (gene mutation in bacteria; gene mutation in mammalian cells) conducted on the Substance and a cytogenicity study conducted with the Source Substance.

15 You also provide information on the similarities in physicochemical properties and studies relating to acute toxicity, and irritation properties of the Substance and the Source Substance.

16 The physicochemical properties and studies relating to acute toxicity and irritation properties do not inform on the genotoxicity and reproductive toxicity properties of the Substance and of the Source Substances.

17 For genetic toxicity the gene mutation studies in bacteria and mammalian cells can not be used to support the similarities in the cytogenicity properties of the Substance and the Source Substance as the gene mutation studies do not inform on cytogenicity properties. A cytogenicity study with the Source Substance alone without any bridging data (allowing comparison of studies of comparable design and duration) is not sufficient to support cytogenicity predictions.

18 For reproductive toxicity, the repeated dose toxicity data alone are not sufficient to support reproductive toxicity predictions, since they are missing parameters relevant for sexual function and fertility as well as development.

19 Therefore, you have not provided supporting information to scientifically justify the read-across hypothesis for prediction of properties.

20 In the absence of such information, you have not established that the Substance and the Source Substance(s) are likely to have similar properties. Therefore you have not provided sufficient supporting information to scientifically justify the read-across.

0.1.1. Conclusion on the read-across approach

21 For the reasons above, you have not established that relevant properties of the Substance can be predicted from data on the Source Substance(s). Your read-across approach under Annex XI, Section 1.5. is rejected.

Reasons related to the information under Annex VIII of REACH

1. In vitro cytogenicity study in mammalian cells or In vitro micronucleus study

22 An in vitro cytogenicity study in mammalian cells or an in vitro micronucleus study is an information requirement under Annex VIII, Section 8.4.2.

1.1. Information provided

23 You have adapted this information requirement by using Annex VIII, Section 8.4.2., column 2 combined with a Grouping of substances and read-across approach.

24 To support the adaptation, you have provided the following information:

i. in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus (2000) with the Source Substance - Propanoic acid, 3-[[bis(2-methylpropoxy)phosphinothioyl]thio]-2-methyl-, EC No. 434-070-2, CAS No. 268567-32-4.

1.2. Assessment of the information provided

25 Under Annex VIII, Section 8.4.2., column 2, the study usually does not need to be conducted "if adequate data from an in vivo cytogenicity test are available". The Guidance on IRs and CSA, Section R.7.7.6.3 and Table R.7.7–3 clarifies that the in vivo somatic cell cytogenicity test must be either a micronucleus test or a chromosomal aberration test, performed according to the OECD TG 474 or 475, respectively.

26 You have provided the above mentioned in vivo cytogenicity study (study i) conducted with the Source Substance, applying a grouping of substances and read-across approach.

27 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected. Therefore, the dossier does not contain adequate data from an in vivo cytogenicity test.

28 Based on above, your adaptation is rejected.

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

Specification of the study design

30 To fulfil the information requirement for the Substance, either 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) are considered suitable.

2. Screening for reproductive/developmental toxicity

31 A screening for reproductive/developmental toxicity study (OECD 421 or OECD 422) is an information requirement under Annex VIII, Section 8.7.1., if there is no evidence from analogue substances, QSAR or in vitro methods that the substance may be a developmental toxicant.

2.1. Information provided

32 You have adapted this information requirement by using Annex VIII, Section 8.7., column 2 combined with a Grouping of substances and read-across approach. To support the adaptation, you have provided the following information:

i. Prenatal Developmental Toxicity Study (2013) with the Source Substance - Propanoic acid, 3-[[bis(2-methylpropoxy)phosphinothioyl]thio]-2-methyl-, EC No. 434-070-2, CAS No. 268567-32-4.

2.2. Assessment of the information provided

33 Under Annex VIII, Section 8.7., column 2, the study does not need to be conducted if a pre-natal developmental toxicity study (OECD TG 414) is already available.

34 You have provided the above mentioned pre-natal developmental toxicity study (i) conducted with the Source Substance, applying a grouping of substances and read-across approach.

35 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

36 Therefore, the dossier does not contain adequate data from a pre-natal developmental toxicity study.

37 Based on above, your adaptation based on Annex VIII, Section 8.7., column 2 is rejected.

38 In the comments to the draft decision, you agree with ECHA's assessment, but you note that one of the concerned co-registrants indicates their intention to use the information from the pre-natal developmental toxicity study (Annex IX, Section 8.7.2; OECD TG 414), requested by this decision as request 3, to adapt this information requirement according to Annex VIII, Section 8.7.1, Column 2, first paragraph, fourth indent of REACH.

39 According to Annex VIII, Section 8.7.1, Column 2, first paragraph, fourth indent of REACH, the screening for reproductive/developmental toxicity study does not need to be conducted if a pre-natal developmental toxicity study is available.

40 However, at this point in time, there is no study available. No assessment or conclusions on the compliance of the adaptation can currently be made.

41 Therefore, the data gap remains.

2.3. Specification of the study design

42 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.

43 The study must be conducted with oral administration of the Substance (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

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

Reasons related to the information under Annex IX of REACH

3. Pre-natal developmental toxicity study in one species

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

3.1. Information provided

46 You have adapted this information requirement by using Annex XI, Section 1.5. (Grouping of substances and read-across approach) based on experimental data from the following substances:

(i) Prenatal Developmental Toxicity Study (2013) with the Source Substance - Propanoic acid, 3-[[bis(2-methylpropoxy)phosphinothioyl]thio]-2-methyl-, EC No. 434-070-2, CAS No. 268567-32-4.

3.2. Assessment of the information provided

47 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

48 On this basis, the information requirement is not fulfilled.

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

Specification of the study design

50 A PNDT study according to the test method OECD TG 414 should be performed in rat or rabbit as preferred species.

51 The study must be performed with oral administration of the Substance (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

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

4. Long-term toxicity testing on fish

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

4.1. Information provided

54 You have adapted this information requirement by using Annex XI, Section 3 (substance-tailored exposure-driven testing). To support the adaptation, you have provided the following information:

(i) Testing can be omitted based on Annex XI section 3.1 (substance-tailored exposure-driven testing);
(ii) PNEC can be derived from available test data for the Substance and application of higher Assessment Factor (AF) takes full account of increased uncertainty due to

omission of the study
(iii) Exposure scenarios are available for all uses of the Substance
(iv) Risk characterisation ratios (RCRs) are well below 1 for all uses
(v) Animal testing should be last resort according to Article 25(1)

4.2. Assessment of the information provided

4.2.1. Substance-tailored exposure-driven testing adaptation rejected

55 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).

4.2.1.1. Exposure always well below PNEC not demonstrated

56 The results of the exposure assessment must show that exposures are always well below the PNEC, i.e. RCRs must always be well below 1. This means that a high level of confidence is needed to demonstrate that every RCR is low enough to ensure that the risks are always controlled, under every plausible condition of the manufacture and all identified uses of the Substance. For this purpose, the possible sources of variability and uncertainty must be considered in the assessment of exposure (Guidance on IRs and CSA Chapter R.16, page 68).

57 Uncertainty can be taken into account by carrying out the environmental exposure assessment using conservative assumptions and default values, which are provided in Guidance on IRs and CSA Chapters R.16. (Guidance on IRs and CSA Chapter R.19).

58 When the environmental exposure assessment is not based on these generic assumptions then a stepwise, tiered approach including an uncertainty analysis being either qualitative, deterministic, or probabilistic, must be conducted (Guidance on IRs and CSA Chapter R.19). The results must be provided in the dossier to demonstrate that the application of such tiered uncertainty analysis gives a clear indication that the risk is adequately controlled (e.g. an increased belief that the RCR is less than 1).

59 The registrant subject to this information requirement (see Appendix 3) has provided individual exposure assessments, reporting 11 exposure scenarios (ES) with quantitative exposure assessment and risk characterisation for each of them.

60 The reported exposure assessments are not based on the generic assumptions recommended in Guidance on IRs and CSA Chapter R.16. Instead, less conservative input parameters, in particular for the release factors, have been used.

61 The registrant(s) subject to this information requirement have not provided results of the uncertainty analysis for the environmental exposure assessment ensuring a high level of confidence that the risk is always adequately controlled.

62 Therefore, it is not demonstrated that the exposure assessment is always conservative enough and the RCRs always low enough to cover the possible sources of variability and uncertainty. Thus, exposures cannot be regarded as being always well below the PNEC.

63 In your comments to the draft decision you challenge ECHA's assessment on the following grounds. You generally disagree that an uncertainty analysis would be mandatory, and you claim that the spERCs used in your CSA would represent the most reliable information available and uncertainties are considered minimal and therefore use or spERCs could not be considered as non-default approach.

64 However, there is a particular need for uncertainty analysis in the CSA in cases of exposure based adaptations (or triggering), as it is applicable to your case (see e.g. Guidance in IR and CSA R.5).

65 This is because a study is omitted that would normally improve the understanding of the hazardous properties of a substance and thus the certainty of the CSA conclusion.

66 Therefore, the quantitative justification for omission of testing in accordance with Annex XI 3.2 (a) must address the (un)certainty with which it can be demonstrated that exposure is always well below PNEC considering the lack of this omitted information.

67 As explained above, this can be accomplished by applying conservative default factors in the CSA or, in case non-default factors are used, by providing further justification on the uncertainty this non-default approach bears (see above).

68 Guidance on IRs and CSA, Section 19.3.1.4. states that "(…) *the stepwise approach to uncertainty analysis may begin at Level 1 by treating all uncertainties qualitatively; this may be sufficient (…). Otherwise, those uncertainties which appear critical to the outcome may be analysed".*

69 In this context, Level 1 is understood as the next stage after the "*most basic level"* of standard chemical safety assessment (i.e. Level 0) using default values ("at level 0, a point estimate is derived using agreed conservative assumptions and default values (…)"). Therefore, an uncertainty analysis is required for Level 1 assessments.

70 SpERCs use refined determinants of release factors and therefore cannot be considered default assumptions. Guidance on IR and CSA Section R.16.2.3.1. specifies that default emission factors are those as applied in ERCs.

71 The use of ERCs in the CSA represents a Tier 1 (i.e. Level 0) assessment. Section R.16.6. further outlines that, in contrast to the use of ERCs understood as *default* assessment, a *refined* assessment includes refinement of those determinants, as it is the case when applying spERCs (see also Table R16-6).

72 In sum, spERC based release factors

(1) are not considered as default Level 0 parameters and thus

(2) must be supported by an uncertainty analysis,

(3) this is in particular necessary when such assessment is used for adaptation under Annex XI, 3.2 (a), as the exposure assessment must show that exposures are always well below the PNEC.

73 For all these reasons, the information does not meet the requirements for adaptation.

74 When the conditions for an adaptation are not met and there is a data gap, ECHA has the duty to request the missing study, which is a standard information requirement and ECHA does not breach the principle of testing as last resort in Article 25(1) of the REACH Regulation by requesting the study.

75 Therefore, the information requirement is not fulfilled.

4.3. Study design and test specifications

76 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.).

77 The Substance is difficult to test due to the low water solubility (16.7 mg/L). OECD TG 210 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance.

78 In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations.

79 Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. 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 210.

80 In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

5. Simulation testing on ultimate degradation in surface water

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

5.1. Information provided

82 You have adapted this information requirement and provided a justification based on the following:

(i) Testing does not appear scientifically necessary according to Annex XI, Section 1;

(ii) Based on QSAR prediction the Substance was found to be not readily biodegradable;

(iii) Further biotic degradation testing shall be proposed if the CSA according to Annex I indicates the need to investigate further degradation of the Substance.

5.2. Assessment of the information provided

5.2.1. Regarding (i) and (ii):Your justification to omit the study has no legal basis

83 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.

84 Your justification to omit this information refers to Annex XI Section 1, however, you did not provide further documentation to support your adaptation and you did not specify which rule of Annex XI Section 1 you intend to apply.

85 Your conclusion that the Substance is not readily biodegradable is not a valid basis to omit the study.

86 Moreover, the QSAR prediction based on which you draw that conclusion is rejected as explained under request 6.

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

5.2.2. Regarding (iii): Annex IX, Section 9.2., Column 2 is not a valid basis to omit the study

88 ECHA notes that you may have intended an adaptation based on Annex IX, Section 9.2., Column 2.

89 However, we point out that Annex IX, Section 9.2., Column 2 provides that "further" biodegradation testing must be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. That provision allows a registrant to propose, or ECHA to require, biotic degradation testing not covered by the information on degradation listed under Annex IX, section 9.2., Column 1. This provision cannot be used as a justification for omitting the submission of information on simulation testing on ultimate degradation in surface water required under Annex IX, Section 9.2.1.2, Column 1.

90 Therefore, your adaption is rejected.

91 On this basis, the information requirement is not fulfilled.

5.3. Study design and test specifications

92 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.

93 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.).

94 In the comments to the draft decision you argue that instead of using the pelagic test option the suspended sediment option, including increased bacteria cell density, should be used.

95 You base this claim on the following arguments:

- it would be closer to environmentally relevant conditions
- it could produce better (higher) biodegradation rates
- it would increase robustness of the outcome

96 Guidance on IRs and CSA, Section R.11.4.1.1.3. specifies that the pelagic option should be used as:

- it well reflects environmental conditions, relevant for EU fresh water
- enhanced biodegration due to use of suspended sediment is not recommended as it might overestimate the degradation kinetics and thus underestimates P/vP properties of the Substance
- suspended sediment approach will with high probability increase NER formation

97 Therefore, the pelagic option is the preferred option.

98 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.

99 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.

100 Therefore, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents. By default, total NER is regarded as non-degraded Substance.

101 However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, 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.).

102 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.

103 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.).

6. Identification of Degradation Products

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

6.1. Information provided

105 You have adapted this information requirement by using Annex XI, Section 1.3. (Qualitative or Quantitative Structure-Activity Relationships ((Q)SARs). To support the adaptation, you have provided the following information:

(i) a prediction from CATALOGIC 301C v.10.14 with the Substance.

6.2. Assessment of the information provided

6.2.1. (Q)SAR adaptation rejected

6.2.1.1. The substance is outside the applicability domain of the model

106 Under ECHA Guidance R.6.1.5.3., a substance must fall within the applicability domain specified by the model developer.

107 The applicability domain of the model you used does not include dithiophoshpate fragments.

108 The Substance used as input for the prediction contains up to 28% unknown fragments in its structure, i.e. dithiophosphate fragments.

109 The Substance used as input for the prediction is out of the applicability domain as the oxidative desulfuration of the dithiophosphate fragment cannot be predicted with certainty because this fragement is not known by the model.

110 You have not demonstrated that the Substance falls within the applicability domain of the model.

111 Therefore, your QSAR adaptation under Annex XI, Section 1.3. is rejected.

112 Therefore, the information requirement is not fulfilled.

6.3. Study design and test specifications

113 Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported.

114 In addition, degradation half-life, log K_{ow} and potential toxicity of the transformation/degradation need to be investigated. You must obtain this information from the degradation study requested in request 5 or by some other measure.

115 In the comments to the draft decision, you indicate your intention to identify degradation products by conducting an OECD TG 309 study, which ECHA agrees to be an adequate method. As clarified by ECHA's Board of Appeal's decision in case A-005-2021, the information must be generated through the applicable studies under under Column 1 of Section 9.2.1.2. of AnnexIX.

116 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (request 5) must be conducted at 12°C and at a test concentration < 100 µg/L.

117 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).

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 (2012).
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 14 January 2022.

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.

In the comments on the draft decision, you requested an extension of the deadline from 30 to 36 months from the date of adoption of the decision.

You considered that the extension of 6 months is needed to allow for sequential testing as well as expected lab capacity issues due to Covid-19-pandemic.

The timeline set in this decision allows for generating the required data on the Substance as a result of incompliances identified. It takes into account tiered testing where relevant.

Furthermore, as explained above, it also takes into account the current longer lead times in contract research organisations and has already been exceptionally extended on this basis.

You have not provided any further arguments as to why the timeline requires further extension.

On this basis, ECHA has not modified the deadline.

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]

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[2].

(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 and other parameters relevant for the property to be tested.

This information is needed to assess 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[3].

[2] https://echa.europa.eu/practical-guides
[3] https://echa.europa.eu/manuals