~~Confidential~~

Helsinki, 5 May 2022

Addressees
Registrants of JS_629-11-8_Hexane-1,6-diol as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
26/04/2016

Registered substance subject to this decision ("the Substance")
Substance name: Hexane-1,6-diol
EC number: 211-074-0

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 the deadline of ***10 February 2025***.

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

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

1. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: OECD TG 471, 2020) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102

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

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

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

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

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

5. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: OECD TG 414) by oral route, in a second species (rabbit)

6. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: OECD TG 443) by oral route, in rats, specified as follows:

- Ten weeks premating exposure duration for the parental (P0) generation;
- The highest dose level in P0 animals must be determined based on clear evidence of an adverse effect on sexual function and fertility without severe suffering or

deaths in P0 animals as specified further in Appendix 1, or follow the limit dose concept. The reporting of the study must provide the justification for the setting of the dose levels;
- Cohort 1A (Reproductive toxicity); and
- Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation.

You must report the study performed according to the above specifications. Any expansion of the study must be scientifically justified.

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 decision
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 decision

Contents

Reasons related to the information under Annex VII of REACH

1. In vitro gene mutation study in bacteria

1 An in vitro gene mutation study in bacteria is an information requirement under Annex VII to REACH (Section 8.4.1.).

1.1. Information provided

2 You have provided:

i. *In vitro* gene mutation study in bacteria (1988) with the Substance.

1.2. Assessment of the information provided

3 We have assessed this information and identified the following issue(s):

1.2.1. Study not adequate for the information requirement

4 To fulfil the information requirement, the study must meet the requirements of OECD TG 471 (2020). Therefore, the following specifications must be:

ii. The test must be performed with 5 strains: four strains of *S. typhimurium* (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101)

5 The study i. is described as in vitro gene mutation study in bacteria. However, the following specifications are not according to the requirements of OECD TG 471 (2020):

i. results for the required fifth strain, S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101).

6 The information provided does not cover one of the key parameters required by OECD TG 471.

7 Therefore, the information requirement is not fulfilled.

1.3. Specification of the study design

8 To fulfil the information requirement for the Substance, the in vitro gene mutation study in bacteria (OECD TG 471, 2020) should be performed using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102.

2. Growth inhibition study aquatic plants

9 Growth inhibition study aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2.).

2.1. Information provided

10 You have provided a key study according to German standard DIN 38 412, part 9, on species Desmodesmus subspicatus, with the Substance.

2.2. Assessment of the information provided

11 We have assessed this information and identified the following issues:

12 To fulfil the information requirement, a study must comply with OECD TG 201 (Article 13(3) of REACH). Therefore, the following specifications must be met:

13 Validity criteria

i. exponential growth in the control cultures is observed over the entire duration of the test;

ii. at least 16-fold increase in biomass is observed in the control cultures by the end of the test;

iii. the mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures is ≤ 35%;

iv. the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is ≤ 7% in tests for species Desmodesmus subspicatus.

14 Technical specifications impacting the sensitivity/reliability of the test

v. three replicates at each test concentration and at least three replicates for controls (including solvent controls, if applicable) are included;

vi. at least 6 treatment replicates are included if a limit test (at 100 mg/L or at the limit of solubility of the test substance) is conducted;

vii. one of the two alternative growth medium (i.e. the OECD or the AAP medium) is used. Any deviations from recommended test media must be described and justified;

viii. for *Desmodesmus subspicatus* the initial cell density is 2-5 x10^3 cells/mL cells/mL;

ix. the test concentrations are arranged in a geometric series with a spacing factor ≤ 3.2, unless a higher factor is justified by a flat concentration response curve.

15 Characterisation of exposure

x. a reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range must be available. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided;

xi. the test media prepared specifically for analysis of exposure concentrations during the test is treated identically to those used for testing (i.e. inoculated with algae and incubated under identical conditions);

xii. the concentrations of the test material are measured at least at the beginning and end of the test:

xiii. at the highest, and

xiv. at the lowest test concentration, and

xv. at a concentration around the expected EC50.

xvi. the results can be based on nominal or measured initial concentration only if the concentration of the test material has been maintained within 20 % of the nominal or measured initial concentration throughout the test.

16 Your registration dossier provides a study showing the following issues:

17 Validity criteria

18 No information is provided on:

i. the section-by-section growth rates in the control cultures;

ii. the initial biomass and the biomass in the control at the end of the test;

iii. the mean coefficient of variation for section-by-section specific growth in the control;

iv. the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures.

19 Technical specifications impacting the sensitivity/reliability of the test

20 No information is provided on:

v. the number of replicates;

vi. the test medium;

vii. the initial cell density;

viii. the test concentrations.

21 Characterisation of exposure

22 No information is provided on whether an analytical monitoring of exposure was conducted.

23 Based on the above, you have not provided an adequate and reliable documentation of the study. The reporting of the study is not sufficient to conduct an independent assessment of its validity and reliability.

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

Reasons related to the information under Annex IX of REACH

3. Long-term toxicity testing on aquatic invertebrates

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

3.1. Information provided

26 You have provided a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2.:

27 "In Annex IX of Regulation (EC) No 1907/2006, it is laid down that chronic tests shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on aquatic invertebrates. According to Annex I of this regulation, the chemical safety assessment triggers further action when the substance or the preparation meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB. The hazard assessment of Hexane-1,6-diol reveals neither a need to classify the substance as dangerous to the environment, nor is it a PBT or vPvB substance, nor are there any further indications that the substance may be hazardous to the environment. Therefore, a chronic test in aquatic invertebrates is not provided".

3.2. Assessment of the information provided

28 We have assessed this information and identified the following issue:

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

29 Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to aquatic invertebrates under Column 1. It must be understood as a trigger for providing further information on aquatic invertebrates if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

30 Your adaptation is therefore rejected.

4. Long-term toxicity testing on fish

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

4.1. Information provided

32 You have provided a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2.:

33 "In Annex IX of Regulation (EC) No 1907/2006, it is laid down that chronic tests shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on fish. According to Annex I of this regulation, the chemical safety assessment triggers further action when the substance or the preparation meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB. The hazard assessment of Hexane-1,6-diol reveals neither a need to classify the substance as dangerous to the environment, nor is it a PBT or vPvB substance, nor are there any further indications that the substance may be

hazardous to the environment. Therefore, and for reasons of animal welfare, a chronic test in fish is not provided".

4.2. Assessment of the information provided

34 We have assessed this information and identified the following issues:

4.2.1. Your interpretation of the legal basis used in your justification is incorrect

35 Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

4.2.2. Animal welfare is not a legal basis to omit the required information

36 Animal welfare does not constitute as such a valid justification to omit the standard information requirements of Annexes VII – X or a valid adaptation to these information requirements.

37 Therefore, your adaptation is rejected and the information requirement is not fulfilled.

4.3. Study design and test specifications

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.).

Reasons related to the information under Annex X of REACH

5. Pre-natal developmental toxicity study in a second species

38 Pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is an information requirement under Annex X to REACH (Section 8.7.2.).

5.1. Information provided

39 You have not specifically claimed an adaptation but you have provided a justification which can be interpreted as an intention to adapt this information requirement by using Column 2 of Annex X, Section 8.7. To support the adaptation, you have provided following information:

i. Justification: "*According to the results of an OECD 421 reprotoxicity screening study 1,6-hexanediol is not reprotoxic. There was no effect at the limit dose of 1000 mg/kg bw/day. No effects have been observed in a prenatal developmental toxicity study with rats according to OECD 414 up to the limit dose of 1000 mg/kg/d. Taken together and according to REACH Article 25, the available data do not provide any hint that the test substance might affect reproduction. Thus, it is unlikely that the conduction of another vertebrate study will add new information with respect to risk assessment. Based on animal welfare, the registrant hence concludes that the study is scientifically not justified*."

ii. Reproductive/developmental screening study with the Substance (1995)

iii. Pre-natal developmental toxicity study in rat with the Substance (2014)

5.2. Assessment of the information provided

40 We have assessed this information and identified the following issue(s):

5.2.1. Animal welfare is not a legal basis to omit the required information

41 Animal welfare does not constitute as such a valid justification to omit the standard information requirements of Annexes VII – X or a valid adaptation to these information requirements.

42 Therefore, your adaptation is rejected and the information requirement is not fulfilled.

5.2.2. Adaptation criteria not met

43 Under Section 8.7., column 2 of Annex IX to REACH, the study does not need to be conducted if the substance is of low toxicological activity. This needs to be demonstrated with three concomitant criteria, namely

i. that there is no evidence of toxicity seen in any of the tests available; and

ii. that it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure; and

iii. that there is no or no significant human exposure.

44 The studies ii. and iii. do not show any signs of toxicity.

45 No toxicokinetic data on systemic absorption are provided.

46 In your dossier, PROCs 8a, 8b and 9 are reported for industrial uses, and PROCs 1, 2 and 3 for manufacture.

47 You have not provided toxicokinetic data to show that there is no systemic absorption. The uses of the Substance indicate that significant human exposure cannot be excluded as you have not specified the level of exposure. In addition, you have not demonstrated no or no significant human exposure since you have not performed an exposure assessment in your provided CSR. Therefore, you have not demonstrated the absence of (significant) human exposure.

48 Therefore, your adaptation is rejected.

5.2.3. Study not adequate for the information requirement

49 (Eco)toxicological studies must comply with a recognised test method (Art. 13(3) of REACH), in this case OECD TG 414 and must cover a second species. Such study must cover the key parameters of the corresponding OECD test guideline (Art. 13(3) of REACH). Therefore, the following specifications must be met:

i. 20 female animals with implantation sites for each test and control group;

ii. examination of the foetuses for sex and body weight/external, skeletal and soft tissue alterations (variations and malformations)/number of resorptions and or live foetuses/ measurement of anogenital distance in live rodent foetuses.

50 The study ii. is described as reproduction/developmental screening study. This study has been conducted using OECD TG 421 which is a screening tests rather than a conclusive developmental toxicity study. In any case, that study does not cover the key parameters of the OECD TG 414 such as:

i. a statistical power equivalent to the OECD TG 414, as the study provided has 10 animals in each group

ii. skeletal and soft tissue alterations (variations and malformations).

51 Study iii. provides information on a first species.

52 The studies are not adequate for the information requirement and is therefore rejected.

5.3. Specification of the study design

53 A PNDT study according to the test method OECD TG 414 should be performed in rat or rabbit as preferred species. The study in the first species was carried out by using a rodent species (rat).

54 Therefore, a PNDT study in a second species must be performed in the rabbit as preferred non-rodent species.

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

56 Based on the above, the study must be conducted in rabbits with oral exposure of the Substance.

6. Extended one-generation reproductive toxicity study

57 An extended one-generation reproductive toxicity (EOGRT) study (OECD TG 443) is an information requirement under Annex X to REACH (Section 8.7.3.).

6.1. Information provided

58 You have not specifically claimed an adaptation but you have provided a justification which can be interpreted as an intention to adapt this information requirement by using Column 2 of Annex X, Section 8.7. To support the adaptation, you have provided following information:

i. "*According to the results of an OECD 421 reprotoxicity screening study 1,6-hexanediol is not reprotoxic. There was no effect at the limit dose of 1000 mg/kg bw/day. Recently, a 90-day repeated dose toxicty study has been performed in which, amongst other, the estrous cycle and sperm parameters (sperm motility, sperm morphology, sperm head count (testis and cauda epididymis)) were analyzed in detail. No effects have been observed up to the limit dose of 1000 mg/kg/d. Taken together and according to REACH Article 25, the available data from a 90-day repeated dose toxicity and reproduction screening study do not provide any hint that the test substance might affect reproduction. Thus, it is unlikely that the conduction of another vertebrate study will add new information with respect to risk assessment. Based on animal welfare, the registrant hence concludes that the study is scientifically not justified*."

ii. Reproductive/developmental screening study with the Substance (1995)

6.2. Assessment of the information provided

59 We have assessed this information and identified the following issue(s):

6.2.1. Animal welfare is not a legal basis to omit the required information

60 Animal welfare does not constitute as such a valid justification to omit the standard information requirements of Annexes VII – X or a valid adaptation to these information requirements.

61 Therefore, your adaptation is rejected and the information requirement is not fulfilled.

6.2.2. Adaptation criteria not met

62 Under Section 8.7., column 2 of Annex IX to REACH, the study does not need to be conducted if the substance is of low toxicological activity. This needs to be demonstrated with three concomitant criteria, namely

i. that there is no evidence of toxicity seen in any of the tests available; and

ii. that it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure; and

iii. that there is no or no significant human exposure.

63 The studies ii. and iii. do not show show any signs of toxicity.

64 No toxicokinetic data on systemic absorption are provided.

65 In your dossier, PROCs 8a, 8b and 9 are reported for industrial uses, and PROCs 1, 2 and 3 for manufacture.

66 In addition, you have not provided toxicokinetic data to show that there is no systemic absorption. The uses of the Substance indicate that significant human exposure cannot be excluded as you have not specified the level of exposure. In addition, you have not demonstrated no or no significant human exposure since you have not performed an exposure assessment in your provided CSR. Therefore, you have not demonstrated the absence of (significant) human exposure.

67 Therefore, your adaptation is rejected.

6.2.3. Study not adequate for the information requirement

68 (Eco)toxicological studies must comply with a recognised test method (Art. 13(3) of REACH), in this case OECD TG 443. Such study must cover the key parameters of the corresponding OECD test guideline (Art. 13(3) of REACH). Therefore, the following specifications must be met:

i. 20 pregnant females for each test and control group;

ii. Examinations of relevant life stages, including the extensive postnatal investigations of the fully exposed F1 generation up to the adulthood.

69 The study ii. is described as reproduction/developmental screening study. This study has been conducted using OECD TG 421 which is a screening test rather than a conclusive test for toxicity to reproduction. In any case, that study does not cover the key parameters of the OECD TG 443 such as:

i. A statistical power equivalent to the OECD TG 443, as the study provided has 10 animals in each group example

ii. Extensive postnatal investigations of the fully exposed F1 generation up to adulthood are not included.

70 The study is not adequate for the information requirement and is therefore rejected.

6.3. Specification of the study design

6.3.1. Species and route selection

71 A study according to the test method OECD TG 443 must be performed in rats with oral administration of the Substance (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

6.3.2. Pre-mating exposure duration

72 The length of pre-mating exposure period must be ten weeks to cover the full spermatogenesis and folliculogenesis before the mating, allowing meaningful assessment of the effects on fertility.

73 Ten weeks pre-mating exposure duration is required to obtain results adequate for classification and labelling and/or risk assessment. There is no substance specific information in the dossier supporting shorter premating exposure duration (Guidance on IRs and CSA, Section R.7.6.).

74 Therefore, the requested pre-mating exposure duration is ten weeks.

6.3.3. Dose-level setting

75 The aim of the requested test must be to demonstrate whether the classification criteria of the most severe hazard category for sexual function and fertility (Repr. 1B; H360F) and

developmental toxicity (Repr. 1B; H360D) under the CLP Regulation apply for the Substance (OECD TG 443, para. 22; OECD GD 151, para. 28; Annex I Section 1.0.1. of REACH and Recital 7, Regulation 2015/282), and whether the Substance meets the criteria for a Substance of very high concern regarding endocrine disruption according to Art.57(f) of REACH as well as supporting the identification of appropriate risk management measures in the chemical safety assessment.

76 To investigate the properties of the Substance for these purposes, the highest dose level must be set on the basis of clear evidence of an adverse effect on sexual function and fertility, but no deaths (i.e., no more than 10% mortality; Section 3.7.2.4.4 of Annex I to the CLP Regulation) or severe suffering such as persistent pain and distress (OECD GD 19, para. 18) in the P0 animals.

77 In case there are no clear evidence of an adverse effect on sexual function and fertility, the limit dose of at least 1000 mg/kg bw/day or the highest possible dose level not causing severe suffering or deaths in P0 must be used as the highest dose level. A descending sequence of dose levels should be selected to demonstrate any dose-related effect and aiming to establish the lowest dose level as a NOAEL.

78 In summary: Unless limited by the physical/chemical nature of the Substance, the highest dose level in P0 animals must be as follows:

i. in case of clear evidence of an adverse effect on sexual function and fertility without severe suffering or deaths in P0 animals, the highest dose level in P0 animals must be determined based on such clear evidence, or

ii. (2 in the absence of such clear evidence, the highest dose level in P0 animals must be set to be the highest possible dose not causing severe suffering or death, or

iii. if there is such clear evidence but the highest dose level set on that basis would cause severe suffering or death, the highest dose level in P0 animals must be set to be the highest possible dose not causing severe suffering or death, or

iv. the highest dose level in P0 animals must follow the limit dose concept.

79 You have to provide a justification with your study results demonstrating that the dose level selection meets the conditions described above.

80 Numerical results (i.e. incidences and magnitudes) and description of the severity of effects at all dose levels from the dose range-finding study/ies must be reported to facilitate the assessment of the dose level section and interpretation of the results of the main study.

6.3.4. Cohorts 1A and 1B

81 Cohorts 1A and 1B belong to the basic study design and must be included.

6.3.4.1. Histopathological investigations in Cohorts 1A and 1B

82 In addition to histopathological investigations of cohorts 1A, organs and tissues of Cohort 1B animals processed to block stage, including those of identified target organs, must be subjected to histopathological investigations (according to OECD TG 443, para. 67 and 72) if

i. the results from Cohort 1A are equivocal,

ii. the test substance is a suspected reproductive toxicant or

iii. the test substance is a suspected endocrine toxicant.

6.3.4.2. Splenic lymphocyte subpopulation analysis

83 Splenic lymphocyte subpopulation analysis must be conducted in Cohort 1A (OECD TG 443, para. 66; OECD GD 151, Annex Table 1.3).

6.3.4.3. Investigations of sexual maturation

84 To improve the ability to detect rare or low-incidence effects, all F1 animals must be maintained until sexual maturation to ensure that sufficient animals (3/sex/litter/dose) are available for evaluation of balano-preputial separation or vaginal patency (OECD GD 151, para. 12 in conjunction with OECD TG 443, para. 47). For statistical analyses, data on sexual maturation from all evaluated animals/sex/dose must be combined to maximise the statistical power of the study.

6.4. Further expansion of the study design

85 The conditions to include the extension of Cohort 1B are currently not met. Furthermore, no triggers for the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) and Cohort 3 (developmental immunotoxicity) were identified. However, you may expand the study by including the extension of Cohort 1B, Cohorts 2A and 2B and/or Cohort 3 if relevant information becomes available from other studies or during conduct of this study. Inclusion is justified if the available information meets the criteria and conditions which are described in Column 2, Section 8.7.3., Annex IX/X. You may also expand the study due to other scientific reasons in order to avoid a conduct of a new study. The study design, including any added expansions, must be fully justified and documented. Further detailed guidance on study design and triggers is provided in Guidance on IRs & CSA, Section R.7.6.

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).

All Guidance on REACH is 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 4 March 2021.

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

ECHA did not receive any comments within the commenting period.

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
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[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
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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].

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