~~Confidential~~

Helsinki, 18 April 2023

Addressees
Registrant(s) of JS-Cyclohexyl salicylate as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
21/05/2013

Registered substance subject to this decision ("the Substance")
Substance name: cyclohexyl salicylate
EC/List number: 400-410-3

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 ***23 January 2026***.

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

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

1. Skin sensitisation (Annex VII, Section 8.3.)
   i. *in vitro/in chemico* skin sensitisation information on molecular interactions with skin proteins (OECD TG 442C), inflammatory response in keratinocytes (OECD TG 442D) and activation of dendritic cells (OECD TG 442E)(Annex VII, Section 8.3.1.); and
   ii. Only if the *in vitro/in chemico* test methods specified under point i.) above are not applicable for the Substance or the results obtained are not adequate for classification and risk assessment, *in vivo* skin sensitisation (Annex VII, Section 8.3.2.; test method: EU B.42./OECD TG 429);

2. 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

3. 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 VIII of REACH

4. Justification for an adaptation of a Short-term repeated dose toxicity (28 days) based on the results of the Sub-chronic toxicity study (90 days) requested below (Annex VIII, Section 8.6.1.)

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

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

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

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Reasons related to the information under Annex VII of REACH

1. Skin sensitisation

1 Skin sensitisation is an information requirement under Annex VII, Section 8.3. Under Section 8.3., Column 1, the registrants must submit information allowing (1) a conclusion whether the substance is a skin sensitiser and (2) whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A).

1.1. Information provided

2 You have provided:

i. an *in vivo* Guinea Pig Maximization test (1984) 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. Assessment whether the Substance causes skin sensitisation

1.2.1.1. The provided study does not meet the specifications of the test guideline(s)

4 To fulfil the information requirement, and to enable concluding whether the Substance causes skin sensitisation, a study must comply with the EU Method B.6/OECD TG 406 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) a dose level selection rationale is provided;
b) the induction concentration is the highest causing mild-to-moderate irritation to the skin;
c) positive controls are included to establish the sensitivity and reliability of the experimental technique.

5 Study (i) is described as a Guinea Pig Maximisation Test. However, the following specifications are not according to the requirements of OECD TG 406:

a) no dose level selection rationale was provided;
b) the concentration used for induction did not cause mild-to-moderate irritation;
c) no information on positive control group was provided.

6 The information provided does not cover the specification(s) required by OECD TG 406 and does not allow to make a conclusion whether the Substance causes skin sensitisation.

1.2.2. No assessment of potency

7 To be considered compliant and enable a conclusion in cases where the substance is considered to cause skin sensitisation, the information provided must also allow a conclusion whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A).

8 As the currently available data does not allow to conclude whether the Substance causes skin sensitisation (see section 1.2.1above), this condition cannot be assessed.

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

10 In the comments to the draft decision you agree with the request.

1.3. Specification of the study design

11 To fulfil the information requirement for the Substance, information on molecular interaction with skin proteins and inflammatory response in keratinocytes and activation of dendritic cells (OECD TG 442C and OECD TG 442D and OECD TG 442E) must be provided. Furthermore an appropriate risk assessment is required if a classification of the Substance as a skin sensitiser (Cat 1A or 1B) is warranted.

12 In case no conclusion on the skin sensitisation potency can be made for the Substance based on the existing data or newly generated in vitro/in chemico data, in vivo skin sensitisation study must be performed and the murine local lymph node assay (EU Method B.42/OECD TG 429) is considered as the appropriate study for the potency estimation.

2. In vitro gene mutation study in bacteria

13 An in vitro gene mutation study in bacteria is an information requirement under Annex VII, Section 8.4.1.

2.1. Information provided

14 You have provided:

i. An *in vitro* gene mutation test in bacteria (1990) with the Substance.

2.2. Assessment of the information provided

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

2.2.1. The provided study does not meet the information requirement

16 To fulfil the information requirement, a study must comply with OECD TG 471 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) the test is 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).

17 The study (i) is described as an in vitro gene mutation study on bacteria.

18 However, the following specifications are not according to the requirements of the OECD TG 471:

a) the test was performed with the following strains: S. typhimurium TA 1535, TA 1537, TA 98 and TA 100 and TA 1538 (i.e., one of the strains S*. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101); is missing).

19 The information provided does not cover the specification required by the OECD TG 471.

20 In the comments to the draft decision you disagree to perform the requested study. You propose to use the results of an in vivo micronucleus study (OECD 474) on the substance which will be submitted in an updated dossier.

21 While the micronucleous study can detect both structural chromosomal aberrations (clastogenicity) and numerical chromosomal aberrations (aneuploidy), the study is not suitable to detect gene mutations. Therefore, updating the dossier with the above mentioned data will not fulfil the information requirement for the 5th strain in the gene mutation study in bacteria. Therefore, the information requirement is not fulfilled.

2.3. Specification of the study design

22 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.

3. Growth inhibition study aquatic plants

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

3.1. Information provided

24 You have provided an algae growth inhibition test (1985), according to OECD TG 201, with the Substance.

3.2. Assessment of the information provided

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

3.2.1. The provided study does not meet the information requirement

26 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:

27 Validity criteria

a) exponential growth in the control cultures is observed over the entire duration of the test;
b) at least 16-fold increase in biomass is observed in the control cultures by the end of the test;
c) 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%;
d) the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is ≤ 7% in tests with *Desmodesmus subspicatus*;

28 Characterisation of exposure

e) analytical monitoring must be conducted. Adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations is provided. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided;
f) 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;

29 Reporting of the methodology and results

g) the test design is reported (*e.g.*, number of replicates, number of test concentrations and geometric progression used);
h) the test conditions are reported (*e.g.*, composition of the test medium, test temperature, test species, biomass density at the beginning of the test);
i) the method for determination of biomass and evidence of correlation between the measured parameter and dry weight are reported;
j) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;
k) microscopic observation performed to verify a normal and healthy appearance of the inoculum culture are reported. Any abnormal appearance of the algae at the end of the test is reported.

30 Your registration dossier provides an OECD TG 201 study showing the following:

31 Validity criteria

a) no information on whether exponential growth occurred over the entire duration of the test in the control cultures;
b) no information on whether the biomass increased by at least a factor 16-in the control cultures;
c) no information on whether the mean coefficient of variation for section-by-section specific growth in the control was ≤ 35%;
d) no information on whether the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures was ≤ 7%;

32 Characterisation of exposure

e) no analytical monitoring of exposure was conducted;
f) you have expressed the effect values based on nominal concentrations;

33 Reporting of the methodology and results

g) on the test design, you have not specified the number of replicates, the test concentrations;
h) on the test conditions, you have not specified the composition of the test medium, the test temperature, the biomass density at the beginning of the test;
i) the method used to determine algal biomass is not reported;
j) tabulated data on the algal biomass determined daily for each treatment group and control are not reported;
k) microscopic observations to verify a normal and healthy appearance of the inoculum culture are not reported.

34 Based on the above, the reporting of the study is not sufficient to conduct an independent assessment of its reliability. In particular, the validity criteria of OECD TG 201 cannot be verified. Furthermore, no analytical monitoring of the test concentrations was performed. Based on the analytical monitoring reported for the studies on fish and for the long-term study on Daphnia, losses of the Substance much higher than 20% of the nominal concentrations cannot be excluded. Still, you have expressed the effect values based on nominal concentrations.

35 Therefore, the requirements of OECD TG 201 are not met.

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

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

Reasons related to the information under Annex VIII of REACH

4. Justification for an adaptation of a Short-term repeated dose toxicity (28 days) based on the results of the Sub-chronic toxicity study (90 days)

38 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 of Annex VIII or a general adaptation rule under Annex XI.

4.1. Information provided

39 You have provided:

i. a Short term repeated dose toxicity study (1984), Directive 79/831/EEC, Annex V, Part B) with the Substance;
ii. a Subchronic repeated dose toxicity study (1995), OECD TG 408 with the Substance;
iii. a One-generation reproduction toxicity study (1995), OECD TG 415 with the Substance.

4.2. Assessment of the information provided

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

4.2.1. The provided studies do not meet the information requirement

41 To fulfil the information requirement, a study must comply with the OECD TG 407 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a. highest dose level should aim to induce toxicity or reach the limit dose.
b. full histopathology, including incidence and severity, as specified in paragraphs 47-49 of the test guideline.

42 The study (i) is described as a Short term repeated dose toxicity study.

43 However, the following specifications are not according to the requirements of the OECD TG 407:

a. no justification for the dose setting while the highest dose levels tested was 250 or 500 mg/kg bw/d (no explanation available), which is below the limit dose of the test guideline, and no adverse effects were observed(or not described).

44 The study (ii) is described as a Subchronic repeated dose toxicity study.

45 However, the following specifications are not according to the requirements of the OECD TG 407:

a. no justification for the dose setting while the highest dose levels tested was 360 mg/kg bw/d , which is below the limit dose of the test guideline, and no adverse effects were observed.

46 The study (iii) is described as a One-generation reproduction toxicity study.

47 However, the following specifications are not according to the requirements of the OECD TG 407:

b. data on histopathology findings are missing: incidence and severity

48 The information provided does not cover the specification(s) required by the OECD TG 407.

49 Therefore, the information requirement is not fulfilled.

50 In the comments to the draft decision, you agree with the data gap and you propose to adapt this standard information requirement under Column 2 of Annex VIII, Section 8.6.1 of the REACH regulation. You further indicate that the lead registrant will update the dossier accordingly.

51 ECHA acknowledges your intention and points out that when the subchronic (90 days) or chronic toxicity study is available, you may adapt this information requirement according to Annex VIII, Section 8.6.1, Column 2, first paragraph, first indent of REACH *("a reliable sub-chronic (90 days) or chronic toxicity study is available, provided that an appropriate species, dosage, solvent and route of administration were used,…*"). However, at this point in time, the study is still to be conducted or to be uploaded to the dossier and therefore, no conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline.

4.3. Specification of the study design

52 Annex VIII, Section 8.6.1., Column 2 provides that an experimental study for this information requirement is not needed if a reliable sub-chronic (90 days) or chronic toxicity study is available.

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

54 Because you still must comply with the information requirement in Annex VIII, Section 8.6.1., you are requested to submit a justification for the adaptation provided in Column 2 of that provision.

Reasons related to the information under Annex IX of REACH

5. Sub-chronic toxicity study (90-day)

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

5.1. Information provided

56 You have provided:

i. a Short term repeated dose toxicity study (1984), Directive 79/831/EEC, Annex V, Part B) with the Substance;
ii. a Subchronic repeated dose toxicity study (1995), OECD TG 408) with the Substance;
iii. a One-generation reproduction toxicity study (1995), OECD TG 415) with the Substance.

5.2. Assessment of the information provided

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

5.2.1. Study not adequate for the information requirement

58 To fulfil the information requirement, a study must comply with the OECD TG 408 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a. highest dose level should aim to induce toxicity or reach the limit dose;
b. dosing of the Substance daily for a minimum of 90 days;
c. terminal organ and body weights;
d. full histopathology as specified in paragraphs 47-49 of the test guideline.

59 In study (i), the following specifications are not according to the requirements of the OECD TG 408:

a. no justification for the dose setting while the highest dose levels tested was 250 or 500 mg/kg bw/d (no explanation available), which is below the limit dose of the test guideline, and no adverse effects were observed;
b. dosing of the Substance for a minimum of 90 days, as an exposure duration of 28 days was reported.

60 In study (ii), the following specifications are not according to the requirements of the OECD TG 408:

a. no justification for the dose setting while the highest dose levels tested was 360 mg/kg bw/day, which is below the limit dose of the test guideline, and no adverse effects were observed.
b. dosing of the Substance for a minimum of 90 days, as only 5 days per week was reported.

61 In study (iii), the following specifications are not according to the requirements of the OECD TG 408:

c. data on terminal organ weights and organ/body weight ratios are reported only

on some organs (For males, organ weights are reported on: prostate, testis, seminal vesicles, liver and epididymis, and for females liver only);

d. data on histopathology findings are missing.

62 The information provided does not cover the specification(s) required by the OECD TG 408.

63 In the comments to the draft decision you indicate that further information on the existing studies is available and will be submitted in order to fulfil the information requirement. You indicate that the *"lead registrant will buy these reports, where the rationale for the dose levels is given, based on the results of toxicological examinations*".

64 However, as the information is currently not available in your registration dossier, no conclusion on the compliance of the studies can be made and the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set out in the decision.

65 Therefore, the information requirement is not fulfilled.

5.3. Specification of the study design

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

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

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

6. Pre-natal developmental toxicity study in one species

69 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

You have provided :

i. a one-generation reproductive toxicity (1995) with the Substance.
ii. a pre-natal developmental toxicity study (1996) with the Substance.

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

6.2. Assessment of the information provided

6.2.1. The provided studies do not meet the information requirement

71 To fulfil the information requirement, a study must comply with OECD TG 414 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) the highest dose level aims to induce toxicity or aims to reach the limit dose;
b) the exposure duration is at least from implantation until one day prior to scheduled caesarean section;
c) the foetuses are examined for body weight, number and percent of live and dead foetuses and resorptions, sex ratio, external, skeletal and soft tissue alterations

(variations and malformations), measurement of anogenital distance in all live rodent foetuses.

72 The study (i) is described as a one-generation reproductive toxicity.

73 However, the following specifications are not according to the requirements of the OECD TG 414:

b) the exposure duration was not at least from implantation until one day prior to scheduled caesarean section as no caesarean section was conducted;
c) data on the examination of the foetuses, including incidence and severity, are missing; In particular, the following investigations are missing: external, skeletal and soft tissue alterations (variations and malformations) and the anogenital distance has not been measured in live foetuses.

74 The study (ii) is described as a pre-natal developmental toxicity study.

75 However, the following specifications are not according to the requirements of the OECD TG 414:

a) the highest dose levels tested was 360 mg/kg bw/d which is below the limit dose of the test guideline, and no adverse effect were observed, and no justification for the dose setting was provided.

76 Based on the above, the information you provided do not fulfil the information requirement.

77 In the comments to the draft decision you indicate that further information on the existing studies is available and will be submitted in order to fulfil the information requirement. You indicate that the "*lead registrant will buy these reports, where the rationale for the dose levels is given, based on the results of toxicological examinations*".

78 However, as the information is currently not available in your registration dossier, no conclusion on the compliance of the study can be made and the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set out in the decision."

6.3. Specification of the study design

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

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

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

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 05 July 2021.

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

In your comments, you requested an extension of deadline. The deadline of the draft decision was 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 took into account your comments and did not amend the request(s) but amended 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]
[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[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