~~Confidential~~

Helsinki, 04 May 2023

Addressee(s)
Registrant of JS-gamma undecalactone as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
02/07/2019

Registered substance subject to this decision ("the Substance")
Substance name: Undecan-4-olide
EC/List number: 203-225-4

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 ***11 November 2026***.

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

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

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

2. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: OECD TG 443) in rats, oral route, 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 request(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.

In addition, the studies relating to biodegradation and bioaccumulation are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency and bioaccumulation of the Substance you should consider the sequence in which these tests are performed and other conditions described in this Appendix.

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. Weight of evidence adaptation rejected

1 You have adapted the following standard information requirements by using Annex XI, Section 1.2. (weight of evidence):

- Pre-natal developmental toxicity study in a second species (Annex X, Section 8.7.2.)
- Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.)

2 Annex XI, Section 1.2. states that there may be sufficient weight of evidence from several independent sources of information enabling, through a reasoned justification, a conclusion on the information requirement, while the information from each single source alone is insufficient to fulfil the information requirement.

3 The justification must have regard to the information that would otherwise be obtained from the study that must normally be performed for this information requirement.

4 According to ECHA Guidance R.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude on the corresponding information requirement.

5 The application of these conditions to your registration dossier are analysed under Sections 1 and 2 below.

Reasons related to the information under Annex X of REACH

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

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

1.1. Information provided

7 You have adapted this information requirement by using Annex XI, Section 1.2. (weight of evidence) based on the following:

(i) Developmental toxicity study in rat with the analogue substance hexan-4-olide, EC 211-778-8.
(ii) A combined repeated dose toxicity with the reproduction / developmental toxicity screening test in rat with the analogue substance δ-valerolactone, EC 208-807-1

8 To support your adaptation, you have also provided the following statements:

(iii) Statement 1; "*The absence of developmental and reproductive toxicity effects at any dose in the high quality relevant studies performed in rats on the analogue substances, γ-caprolactone and δ-valerolactone, indicates that there is no concern for developmental toxicity for γ-undecalactone."*
(iv) Statement 2; "*…published data demonstrated that for substances of low concern for developmental toxicity there is no value in the performance of a study in a second species*"
(v) Statement 3;"*…the forty-ninth joint FAO/WHO Expert Committee on Food Additives evaluated a group of aliphatic lactones used as flavouring substances in food and all the data indicated no safety concern associated with intake of γ-nonalactone, γ-decalactone, γ-undecalactone and γ-caprolactone (JECFA, Aliphatic lactones. WHO food additives series 40, 1998)"*
(vi)Statement 4. "*The metabolic steps involved in the metabolism of the substance are common to most animals and therefore significant species differences are not expected, that is, the rabbit is predicted to have very similar metabolites and rate of metabolism to the rat*."

9 The statements (iii to vi) cannot be taken into account in the assessment of your weight of evidence adaptation because the studies they refer to are not actual sources of information in the form of robust study summaries, as required under Section 1.2 of Annex XI to the REACH Regulation.

1.2. Assessment of the information provided

10 As explained under Reasons common to several requests in Section 0. the weight of evidence adaptation must fulfil the information requirement based on relevant and reliable sources of information. These sources of information must provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

11 Relevant information that can be used to support weight of evidence adaptation for the information requirement of Annex X, Section 8.7.2. includes similar information that is produced by the OECD TG 414 in a second species. OECD TG 414 requires the study to investigate the following key elements:

- structural gross, visceral and skeletal malformations and variations are investigated in two species.

12 The sources of information (i) and (ii) may provide relevant information on prenatal developmental toxicity.

13 However, none of the information sources, alone or together, provide any information on prenatal developmental toxicity on a second species.

14 In summary, the sources of information (i) to (vi) provide no relevant information on pre-natal developmental toxicity in a second species.

15 It is not possible to conclude, based on any source of information alone or considered together, on the information requirement for pre-natal developmental toxicity in a second species.

16 Based on the above, your adaptation is rejected.

17 Therefore, the information requirement is not fulfilled.

1.3. Comments on the draft decision

18 In your comments to the draft decision you point out a contradiction related to sources of information (iii) to (vi):" *On the one hand ECHA states that these sources of information cannot be taken into account in the assessment, and later ECHA states that the sources of information (i) to (vi) provide no relevant information. It is not clear how ECHA can reach this conclusion on studies (iii) to (vi) if they were not assessed."*

19 ECHA agrees that it would have been more correct to conclude that sources (i) and (ii) do not provide relevant information on pre-natal developmental toxicity in a second species. The outcome of the evaluation remains however the same.

20 You furthermore agree to provide information in an update to the dossier that is adequate to meet the information requirement.

1.4. Specification of the study design

21 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).

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

23 As the Substance is a liquid, the study must be conducted with oral administration of the Substance (Annex X, Section 8.7.2, Column 1).

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

2. Extended one-generation reproductive toxicity study

25 An extended one-generation reproductive toxicity (EOGRT) study (OECD TG 443) is an information requirement under Annex X, Section 8.7.3. Furthermore Column 2 defines the conditions under which the study design needs to be expanded.

2.1. Information provided

26 You have adapted this information requirement by using Annex XI, Section 1.2. (weight of evidence) based on the following:

(i) Repeated dose toxicity study (28d) in rat with the analogue substance hexan-4-olide, EC 211-778-8.
(ii) Repeated dose toxicity study (90d) in mouse with the analogue substance gamma-butyrolactone, EC 202-509-5.
(iii) Repeated dose toxicity study (90d) in rat with the analogue substance gamma-butyrolactone, EC 202-509-5.
(iv) Developmental toxicity study in rat with the analogue substance hexan-4-olide, EC 211-778-8.
(v) A combined repeated dose toxicity with the reproduction / developmental toxicity screening test in rat with the analogue substance δ-valerolactone, EC 208-807-1

27 To support your adaptation, you have also provided the following statements:

(vi) Statement 1 *"…..the forty-ninth joint FAO/WHO Expert Committee on Food Additives evaluated a group of aliphatic lactones used as flavouring substances in food and all the data indicated no safety concern associated with intake of γ-nonalactone, γ-decalactone, γ-undecalactone and γ-caprolactone (JECFA, Aliphatic lactones. WHO food additives series 40, 1998)".*

28 The statement (vi) cannot be taken into account in the assessment of your weight of evidence adaptation because the studies it refers to are not actual sources of information in the form of robust study summaries, as required under Section 1.2 of Annex XI to the REACH Regulation.

2.2. Assessment of the information provided

29 As explained under Reasons common to several requests in Section 0. the weight of evidence adaptation must fulfil the information requirement based on relevant and reliable sources of information. These sources of information must provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

30 Relevant information that can be used to support weight of evidence adaptation for the information requirement of Annex X, Section 8.7.3 includes similar information that is produced by the OECD TG 443. OECD TG 443 requires the study to investigate the following key elements:

(1) sexual function and fertility,
(2) toxicity to offspring, and
(3) systemic toxicity

2.2.1. Sexual function and fertility

31 Sexual function and fertility on both sexes must include information on mating, fertility, gestation (length), maintenance of pregnancy (abortions, total resorptions), parturition, lactation, organ weights and histopathology of reproductive organs and tissues, oestrous cyclicity, sperm count, sperm analysis, hormone levels, litter sizes, nursing performance and other potential aspects of sexual function and fertility.

32 The source of information (v) may provide relevant information on sexual function and fertility. Source (iv) contains some information on this key element, namely on maintenance of pregnancy (abortions, total resorptions). Studies (i) to (iii) do not contain any relevant information on sexual function and fertility as the animals were not mated.

33 However, the reliability of sources of information (iv) and (v) is significantly affected by the following deficiency:

34 Information on sexual function and fertility (functional fertility and histopathology of reproductive organs and tissues) must be investigated in parental P0 animals as indicated in OECD TG 443 after at least ten weeks premating exposure duration if extension of Cohort 1B is not included[2] to ensure the exposure of full spermatogenesis and folliculogenesis before mating.

35 In the case of your Substance, the conditions to include the extension of Cohort 1B are currently not met. The source of information (v) investigates sexual function and fertility with the premating exposure duration of two weeks for the parental P0 animals. The other source (iv) does not have any premating exposure.

36 Neither sources of information investigate the sexual function and fertility in the P0 generation with sufficient premating exposure duration to ensure the coverage of full spermatogenesis and folliculogenesis before mating.

37 In the absence of information on the sexual function and fertility after exposure to the Substance over a pre-mating period of 10 weeks, no conclusion can be drawn on sexual function and fertility as required by the information requirement.

38 Therefore the provided sources of information cannot be considered a reliable sources of information that could contribute to the conclusion on this key element investigated by the required study.

2.2.2. Toxicity to the offspring

39 Toxicity to offspring must cover information on deaths before, during or after birth, growth, external malformations, clinical signs, sexual maturity, oestrous cyclicity, organ weights and histopathology of reproductive organs and tissues in adulthood and other potential aspects of toxicity to offspring.

40 The source of information (v) provides some information on toxicity to the offpsring up to post-natal day 4. Source (iv) informs on *in utero* development of offspring. Neither the sources of information (iv) nor (v) inform on toxicity to the offspring up to adulthood. Sources of information (i) to (iii) do not provide information on toxicity to the offspring.

41 Information provided on toxicity to offspring is limited and does not cover all relevant and essential aspects as defined above. Therefore, no conclusion can be drawn on toxicity to the offspring as required by the information requirement.

2.2.1. Systemic toxicity

42 Systemic toxicity must include information on clinical signs, survival, body weights, food consumption, haematology (full-scale), clinical chemistry (full-scale), organ weights and histopathology of non-reproductive organs and tissues (full-scale) and other potential aspects of systemic toxicity in the parental P and F1 generation up to adulthood.

43 Sources of information (i to v) provide relevant information on systemic toxicity in animalsexposed as adults

44 Information provided on systemic toxicity does not cover all relevant and essential aspects as defined above. In particular, there is no information on systemic toxicity from F1 generation. Therefore, the information on systemic toxicity does not cover the required aspect on systemic toxicity.

2.3. Conclusion

[2] ECHA Guidance R.7a, Section R.7.6

45 In summary, the sources of information (i) to (v) provide limited relevant information on sexual function and fertility, toxicity to the offspring and systemic toxicity. However, in particular information on toxicity to the offspring up to adulthood is missing, and information on sexual function and fertility is not reliable.

46 It is not possible to conclude, based on any source of information alone or considered together, on the information requirement for extended one-generation reproductive toxicity study.

47 Based on the above, your adaptation is rejected.

48 Therefore, the information requirement is not fulfilled.

2.4. Comments on the draft decision

49 In your comments to the draft decision you agree to provide information in an update to the dossier that is adequate to meet the information requirement.

2.5. Specification of the study design

2.5.1. Species and route selection

50 As the Substance is a liquid, the study must be conducted with oral administration of the Substance (Annex X, Section 8.7.3, Column 1).

2.5.2. Pre-mating exposure duration

51 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.

52 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.).

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

2.5.3. Dose-level setting

54 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, paragraph 22; OECD GD 151, paragraph 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.

55 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; Annex I, Section 3.7.2.4.4. of the CLP Regulation) or severe suffering such as persistent pain and distress (OECD GD 19, paragraph 18) in the P0 animals.

56 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.

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

(1) 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

(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

(3) 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

(4) the highest dose level in P0 animals must follow the limit dose concept.

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

59 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.

2.5.4. Cohorts 1A and 1B

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

2.5.4.1. Histopathological investigations in Cohorts 1A and 1B

61 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, paragraph 67 and 72) if

- the results from Cohort 1A are equivocal,
- the test substance is a suspected reproductive toxicant or
- the test substance is a suspected endocrine toxicant.

2.5.4.2. Splenic lymphocyte subpopulation analysis

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

2.5.4.3. Investigations of sexual maturation

63 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, paragraph 12 in conjunction with OECD TG 443, paragraph 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.

2.5.5. Further expansion of the study design

64 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 Annex IX/X, Section 8.7.3., Column 2. 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).
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 17 November 2021.

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

ECHA took into account your comments and did not amend the request(s) or the deadline.

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

ECHA notified 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: Addressee(s) 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]

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[3].

(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2. Test material

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

(1) Selection of the Test material(s)

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

- the variation in compositions reported by all members of the joint submission,
- the boundary composition(s) of the Substance,
- the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

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

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

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

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

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