~~Confidential~~

Helsinki, 12 October 2022

Addressee
Registrant of JS_Oleoylsarkosin as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
27 April 2021

Registered substance subject to this decision ("the Substance")
Substance name: N-methyl-N-[C18-(unsaturated)alkanoyl]glycine
EC number: 701-177-3

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

DECISION ON TESTING PROPOSAL(S)

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***20 October 2025***.

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

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

1. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: EU B.56./OECD TG 443) by oral route, in rats, specified as follows:

   - At least two 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 effects 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);
   - Cohort 1B (Reproductive toxicity) with extension to mate Cohort 1B animals to produce the F2 generation which shall be followed to weaning;
   - Cohorts 2A and 2B (Developmental neurotoxicity); and
   - Investigations on learning and memory function as described in paragraph 37 of the OECD TG 426.

You must report the study performed according to the above specifications. Any expansions of the study design 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 for the decision(s) related to the information under Annex X of REACH

1. Extended one-generation reproductive toxicity study

1 The basic test design of an extended one-generation reproductive toxicity study (EOGRTS) is a standard information requirement under Annex X to the REACH Regulation. Furthermore, column 2 of Section 8.7.3. defines when the study design needs to be expanded.

1.1. Information provided to fulfil the information requirement

2 You have submitted a testing proposal for an EOGRTS according to OECD TG 443 by the oral route in rats with a 10-week premating exposure duration, with the Substance.

3 ECHA requested your considerations for alternative methods to fulfil the information requirement for Toxicity to reproduction. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

4 ECHA agrees that an EOGRTS is necessary.

1.2. Specification of the study design

1.2.1. Species and route selection

5 You proposed testing in the rat. ECHA agrees with your proposal because the rat is the species preferred by OECD TG 443.

6 You proposed testing by oral route. ECHA agrees with your proposal.

1.2.2. Pre-mating exposure duration

7 You proposed ten weeks pre-mating exposure duration. However, a minimum of 2-week pre-mating exposure duration for P0 animals is required because the full spectrum of parameters on sexual function and fertility will be covered in the F1 animals (Guidance on IRs & CSA, Appendix R.7.6-3).

1.2.3. Dose-level setting

8 You proposed that the dose level setting shall aim to induce some toxicity at the highest dose level. Furthermore, you note that in the available OECD TG 408 and OECD TG 414 studies in rats, substantial (maternal) toxicity was seen at 1000 and 750 mg/kg bw/day. ECHA notes that in the OECD TG 421 study, 1000 mg/kg bw/d was tolerated.

9 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.

10 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.

11 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.

12 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.

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

14 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.

1.2.4. Cohorts 1A and 1B

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

16 <u>Splenic lymphocyte subpopulation analysis</u>

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

18 <u>Investigations of sexual maturation</u>

19 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.

1.2.5. Extension of Cohort 1B

20 If the Column 2 conditions of 8.7.3. are met, Cohort 1B must be extended by mating the Cohort 1B animals to produce the F2 generation.

21 The extension is required, among others, if the use of the Substance is leading to significant exposure of consumers and professionals (column 2, first para., point (a) of Section 8.7.3.) and if there are indications of one or more relevant modes of action related to endocrine disruption from available *in vivo* studies or non-animal approaches (column 2, first para., point (b), third indent of Section 8.7.3.).

22 The use of the Substance reported in your dossier is leading to significant exposure of consumers and professionals because the Substance is used by professionals, e.g. as fuel, lubricant, in washing, cleaning and disinfecting products, in hairdressing services, in agrochemicals (PROCs 1, 2, 3, 4, 5, 6, 8a, 8b, 9, 9a, 10, 13, 14, 15, 17, 18, 19, 20) and by consumers, e.g. in cosmetic/personal care products and fragrances, in washing and cleaning products, in polishes and wax blends and in biocidal products.

23 In your comments, you agree with the significant exposure to consumers and professionals. You express an intention to update your dossier and to remove certain exposure scenarios, such as professional use in hairdressing services and consumer uses in cosmetics and biocidal products. ECHA acknowledges this intention but notes that the remaining exposure scenarios still indicate significant exposure of consumers and professionals.

24 Furthermore, there are indications of one or more modes of action related to endocrine disruption because changes in organs/parameters sensitive to endocrine activity are observed. More specifically, the available studies show:

- Dose-dependent decreases of T3 and T4 serum levels, reaching statistical significance at the mid and high dose levels, in the presence of dose-dependent increases of TSH serum levels in dams (OECD TG 414, 2020). According to OECD GD 150, the above-mentioned effects are indicative of thyroid disruption.

25 In your comments, you note that all dams in the high dose group of OECD TG 414 study demonstrated clear signs of toxicity. You also acknowledge that statistically significant decreases in T3 and T4 levels were observed in the mid dose group without any clinical signs of toxicity. You expect that the toxicity induces hepatic enzyme induction, and consider that this will occur to a certain extent in all treatment groups. You refer to the thyroid hormone homeostasis in rodents which is sensitive to xenobiotic metabolism in liver, and that hepatic enzyme induction may increase depletion of thyroid hormones. In this context, you refer to species differences and consider that '*the relevance of findings from rodent studies for humans needs to be very cautiously evaluated'*. You also refer to OECD GD 150 which advises that endocrine effects observed in the presence of clear systemic toxicity should be interpreted with caution as they may be secondary effects.

26 To support your considerations, you refer to the OECD TG 408 study which showed no effect on T3 or TSH. You consider that the increased T4 values observed in treated females can be explained by the exceptionally low T4 values in control animals, making the change in T4 observed in mid and high dose females just a statistical artefact. You conclude that there was no test item-related effect in T4 in females in the OECD TG 408 study. However, you note that some liver weight increases as well as increased liver enzyme activities were observed. In conclusion, you consider that '*the observed decreases in T3 and T4 in the OECD TG 414 study addressed by ECHA are interpreted as a secondary effect in consequence of an adaptation of xenobiotic metabolic capacities in the liver, i.e. induction of hepatic enzymes and increased turnover of thyroid hormones, and not as a direct effect on the endocrine system.'* You emphasise that the decreases of T3 and T4 in the OECD TG 414 study were well within the historical control data and observed in the absence of any apical effects.

27 ECHA agrees that there was toxicity at the high dose level in the OECD TG 414 study. However, ECHA notes that the decreases of T3 and T4, as well as the increase of TSH, were observed in all dose levels in a dose-dependent manner, and that there was no clear systemic toxicity at the low and mid dose levels. Therefore, ECHA considers that these changes in thyroid hormone levels are not secondary to systemic toxicity.

28 According to the ECHA/EFSA Guidance[2] for the identification of endocrine disruptors, '*In the absence of substance-specific data which provide proof of the contrary, humans and rodents are considered to be equally sensitive to thyroid-disruption (including cases where liver enzyme induction is responsible for increased TH clearance).*'. You have not provided substance-specific data which would provide proof that the observed thyroid-related effects would not be relevant to humans.

29 ECHA further notes that an OECD TG 414 study investigates pregnant animals, whereas OECD TG 408 study investigates adult, non-pregnant animals. As animals are exposed during different physiological states, the results of these two type of studies should be compared with caution. Due to the significant physiological changes associated with pregnancy, indications of thyroid disruption may be observed in pregnant animals even if such effects would not be observed in non-pregnant animals. Therefore, lack of thyroid hormone changes in an OECD TG 408 study does not negate the findings observed in an OECD TG 414 study.

30 ECHA agrees that the thyroid hormone changes observed in the OECD TG 414 study are within the historical control ranges but notes that the primary reference point should be the concurrent control data (OECD GD 43, paragraph 67). Dose-dependent changes in T3, T4 and TSH were observed when compared to the concurrent control.

31 In the context of OECD TG 414 study, the OECD GD 150 explains that '*"apical" endpoints are developmental parameters (including anogenital distance, genital abnormalities and sex ratio). "Indicators of hormonal activity" are hormones (including T4, TSH).*'. Furthermore, it clarifies that '*Anogenital distance (AGD), appearance of external genitalia and sex ratio are examples of apical endpoints that may be affected by via estrogen- or androgen-mediated activity. T4 and TSH may be affected by disturbance of the thyroid hormonal system*.' ECHA agrees that the OECD TG 414 study did not show any effects in the above-mentioned apical endpoints but notes that those are mediated via estrogen- or androgen-mediated activity. Lack of effects in estrogen- or androgen-mediated endpoints does not negate findings related to disturbance of the thyroid hormonal system.

32 In conclusion, ECHA considers that the effects in thyroid hormone levels in the OECD TG 414 study are relevant and indicative of thyroid disruption.

33 You have proposed not to include an extension of Cohort 1B.

34 For the reasons stated above, ECHA considers that Cohort 1B must be extended.

35 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) because there is a concern for

[2] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5311
ECHA emphasises that even though the ECHA/EFSA Guidance was developed for hazard identitification for endocrine-disrupting properties for other regulatory purposes, the same scientific principles apply also under the REACH Regulation.

reproductive toxicity/endocrine activity indicated by the toxicity-triggers to extend the Cohort 1B.

36 The F2 generation must be followed to weaning allowing assessment of nursing and lactation of the F1 parents and postnatal development of F2 offspring. Investigations for F2 pups must be similar to those requested for F1 pups in OECD TG 443 and described in OECD GD 151.

37 In your comments you also question the benefit of producing the F2 generation. You refer to OECD GD 117[3] which discusses the limited parameters being assessed in the F2 generation. ECHA notes that e.g. thyroid hormone measurements (T4 and TSH) are performed in F2 animals (OECD GD 151) and therefore the F2 generation will provide relevant information in the context of the observed indication of thyroid hormone disturbance. Furthermore, there will be information on fertility on two generations.

1.2.6. Cohorts 2A and 2B

38 The developmental neurotoxicity Cohorts 2A and 2B must be conducted in case of a particular concern on (developmental) neurotoxicity.

39 Existing information on the Substance itself derived from available *in vivo* study (OECD TG 414, 2020) shows evidence of thyroid disruption as explained above, in Section 1.2.5.

40 Changes in thyroid hormone levels, observed in pregnant animals, indicate a concern for neurodevelopment (Guidance on IRs & CSA, Appendix R.7.6-2).

41 Furthermore, according to the ECHA/EFSA Guidance for the identification of endocrine disruptors, "*substances that alter the circulating levels of T3 and/or T4 without histopathological findings would still present a potential concern for neurodevelopment*".

42 You proposed not to include Cohort 2A and 2B.

43 In your comments, you question the relevance of findings related to thyroid hormone levels, and therefore consider that the request for Cohorts 2A and 2B is not justified. ECHA has addressed your comments under Section 1.2.5.

44 For the reasons stated above, ECHA however considers that the developmental neurotoxicity Cohorts 2A and 2B must be conducted.

1.2.6.1. Cognitive functions: learning and memory

45 Paragraph 51 of OECD 443 provides that, "If existing information indicates the need for other functional testing (e.g. sensory, social, cognitive), these should be integrated without compromising the integrity of the other evaluations conducted in the study."

46 The Substance caused changes in thyroid hormone (T3, T4 and TSH) levels in an OECD TG 414 study, and so perturbs thyroid hormone signalling. It is known that perturbation of thyroid hormone signalling in offspring affects spatial cognitive abilities (learning and memory) [1-3].

47 Therefore, it is necessary to conduct spatial learning and memory tests for F1 animals. The spatial learning and memory tests must be performed in accordance

[3] Guidance document 117 on the current implementation of internal triggers in test guideline 443 for an extended one-generation reproductive toxicity study, in the United States and Canada https://www.oecd.org/chemicalsafety/testing/48516094.pdf

with OECD 426 paragraph 37, i.e. at adolescence (e.g. PND 25±2 days) and young adulthood (PND 60 and older).

48 In your comments, you question the relevance of findings related to thyroid hormone levels, and therefore consider that the request for assessment of learning and memory is not justified. ECHA has addressed your arguments under Section 1.2.5.

[1] Axelstad *et al*. (2008) Developmental neurotoxicity of Propylthiouracil (PTU) in rats: Relationship between transient hypothyroxinemia during development and long-lasting behavioural and functional changes. *Toxicol. Appl. Pharmacol.* 232, 1-13.

[2] van Wijk *et al*. (2008) Perinatal and chronic hypothyroidism impair behavioural development in male and female rats. *Exp. Physiol.* 93, 1199-1209.

[3] Amano *et al.* (2018) Effects of Mild Perinatal Hypothyroidism on Cognitive Function of Adult Male Offspring. *Endocrinol.* 159(4), 1910-1921.

1.2.6.2. Observations for the spatial learning and memory testing

49 OECD TG 426, paragraph 37 presents examples of test methods for different types of associative learning and memory. Among the tests given in OECD TG 426, paragraph 37, you should conduct the Morris water maze test or Radial arm maze test at one time point, and the Cincinnati water maze test at the other time point to investigate spatial learning and memory, as these appear to be the most sensitive tests [4-7].

50 Investigations of spatial learning and memory should not compromise the integrity of the study. In OECD TG 443 adverse effects on sexual function and fertility may limit the number of offspring available for developmental investigations. Dosing must be based on the considerations provided above ('Dose-level setting'), and dosing must not be lowered in order to get a sufficient number of offspring. The priority of the OECD TG 443 test is to identify potential effects on sexual function and fertility.

51 Taking into account the practical aspects of conducting the OECD TG 443 study, as an alternative to Cohort 2A, the investigations on spatial learning and memory may also be conducted in Cohort 1A animals which can be allocated to two sets of animals, 10 males and 10 females in both; the first set of animals to be tested at adolescence and the other set of animals at young adulthood.

[4] Levin E. (2015) Learning about cognition risk with the radial-arm maze in the developmental neurotoxicology battery. *Neurotoxicol Teratol.* 52, 88-92.

[5] Vorhees and Williams (2015) Reprint of "Value of water mazes for assessing spatial and egocentric learning and memory in rodent basic research and regulatory studies". *Neurotoxicol Teratol.* 52, 93-108.

[6] Vorhees and Makris (2015) Assessment of learning, memory, and attention in developmental neurotoxicity regulatory studies: synthesis, commentary, and recommendations. *Neurotoxicol Teratol.* 52, 109-115.

[7] Vorhees and Williams (2016) Cincinnati water maze: A review of the development, methods, and evidence as a test of egocentric learning and memory. *Neurotoxicol Teratol*. 57, 1-19.

1.3. Outcome

52 Under Article 40(3)(b) your testing proposal is accepted under modified conditions and you are requested to conduct the test with the Substance, as specified above.

Further expansion of the study design

53 No triggers for the inclusion of Cohort 3 (developmental immunotoxicity) were identified. However, you may expand the study by including the extension of 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).

Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009; ECHA/EFSA (2018)
Available online: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5311

Appendix 2: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 30 April 2021.

ECHA held a third party consultation for the testing proposal(s) from 21 October 2021 until 7 December 2021. ECHA did not receive information from third parties.

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

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) but amended 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 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 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[4].

(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

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

a) the boundary composition(s) of the Substance,
b) 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.

Information on the Test Material needed in the updated dossier

a) 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.
b) The reported composition must include the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as far as possible as well as their concentration. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical method.

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance.

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)

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