~~Confidential~~

Helsinki, 25 February 2022

Addressees
Registrant(s) of JS_Oxooil LS9 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
26/05/2020

Registered substance subject to this decision ("the Substance")
Substance name: Octene, hydroformylation products, low-boiling
EC number: 273-110-1
CAS number: 68938-03-4

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 the deadline of ***2 September 2024***.

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

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

1. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210)

Reasons for the request(s) are explained in the following appendix:

i. Appendix entitled "Reasons to request information required under Annex IX of REACH".

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

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 testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

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

[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 A: Reasons to request information required under Annex IX of REACH

1. Long-term toxicity testing on fish

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

You have adapted this information requirement based on Annex IX, Section 9.1., Column 2 and provided the following information:

i. a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you provided the following justification: *Oxooil LS9 is not acutely harmful to fish (LC 50 > 100 mg/l). A long-term study on fish is not available. In a first step, the PNEC for the aquatic environment is derived from short-term toxicity tests with a conservative assessment factor. The risk assessment according to Annex I of the REACh regulation (EC) No 1907/2006, based on the result from the short-term tests, reveals an acceptable risk (PEC/PNEC <1) of Oxooil LS9 on aquatic organisms. Therefore, the effect of Oxooil LS9 on aquatic organism does not need to be investigated further and a long-term test with fish is not required.*

ii. Information on short-term toxicity to fish

We have assessed this information and identified the following issues:

i. Rejection of adaptation based on Annex IX, Section 9.1., Column 2

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

In your comments to the initial draft decision, you have provided further information why you believe that the chemical safety assessment does not indicate the need for further investigation. However, as mentioned above, there is no legal basis to adapt this information requirement for the reasons set above.

Your adaptation is therefore rejected.

ii. Information on short-term toxicity

Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests does not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has, or constituents have, a water solubility below 1 mg/l or below the detection limit of the analytical method of the test material (ECHA Guidance R.7.8.5).

You have provided information which indicates that the Substance includes constituents that are poorly water soluble. In section 4.8 of the IUCLID dossier you conclude that the water solubility of the constituents of the Substance ranges from 0.87 to 1887.7 mg/l at 25°C, with a weighted mean of 16.2 mg/l.

Therefore, the short-term studies must be rejected with no further use of their result values for PNEC calculation and/or Classification and information on long-term toxicity on fish must be provided.

In your comments to the initial draft decision, you have provided two adaptations:

a. Adaptation as set out in Annex XI, Section 1.
b. Adaptation under Annex XI, Section 2.

Adaptation as set out in Annex XI, Section 1.

In your comments to the initial draft decision, you state your intention to submit an adaptation(s) to comply with the general rules of adaptation as set out in Annex XI, Section 1. You explicitly mention the adaptation of Annex XI, Section 1.5 (Grouping and read-across approach). However you do not provide any information to substantiate these statements of intent.

The acceptability of the adaptation will be conditional to the acceptability of the predicted properties. Please note that this decision does not consider updates of the registration dossiers after the date on which you were notified of the draft decision according to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation). You remain responsible for complying with this decision by the set deadline.

Adaptation under Annex XI, Section 2.

ECHA understands that you submit an adaptation under Annex XI, Section 2.

Under that provision, testing for a specific endpoint may be omitted, if it is technically not possible to conduct the study as a consequence of the properties of the substance: e.g. very volatile, highly reactive or unstable substances cannot be used, mixing of the substance with water may cause danger of fire or explosion or the radio-labelling of the substance required in certain studies may not be possible. The guidance given in the test methods referred to in Article 13(3), more specifically on the technical limitations of a specific method, shall always be respected.

You outline a number of arguments why you will find the testing of the long term aquatic toxicity testing on fish will be difficult:

- You state "According to the registration dossier, the water solubility of the constituents of the UVCB substance has been estimated to range from 0.87 mg/L to 1887.7 mg/L. Thus, the substance contains constituents with low water solubility and constituents, which are sufficiently water soluble. The short-term toxicity data with fish covers at least the constituents with higher solubility as the equilibrium will be achieved in a short-term test".
  - As stated above, as your Substance contains constituents with low water solubility and as these constituents do not reach a steady state by the duration of the short-term test, this invalids the whole test as the validity criteria cannot be met, the organisms are not being exposed to all the whole Substance.
- You state "The wide range of solubility implies that the study design of an aquatic long-term toxicity study will be challenging. If the substance is solved in water, the ratio of the constituents in water will be distorted and constituents with good solubility could be overrepresented. The guidance document OECD No. 23 could help to encounter these problems. However, due to the volatility of the substance, the achievement of an equilibrium for constituents with a poor solubility and a stable exposure concentration is still complex for a long-term test (which are 30 to 60 days, species dependent according to the OECD TG 210)". Additionally, the nature of the substance needs to be considered for the analytical monitoring. The registered substance is a UVCB substance and is

a complex combination of C9 olefins and paraffins and C9 alcohols. Although, the constituents are well characterized, the number of constituents leads to challenges in the analytical detection of the substance in the requested study.

Based on the performance of a long term Daphnia study, long term aquatic testing is possible for this Substance. Also, further more precise analytical technology has been developed since the performance of the long term Daphnia study.

You do not claim that testing is impossible, only difficult.

Therefore your adaptations are rejected.

On this basis, the information requirement is not fulfilled.

Study design

To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (ECHA Guidance R.7.8.2.).

OECD TG 210 specifies that for difficult to test substances OECD GD 23 must be followed. The Substance is difficult to test due to its UVCB nature, the low water solubility (of some constituents), volatility and adsorptive properties (log Koc = 3.2). OECD TG 210 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 210. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solutions.

For multi-constituents/UVCBs, the analytical method must be adequate to monitor qualitative and quantitative changes in exposure to the dissolved fraction of the test material during the test (e.g. by comparing mass spectral full-scan GC or HPLC chromatogram peak areas or by using targeted measures of key constituents and/or groups of constituents).

If you decide to use the Water Accommodated Fraction (WAF) approach, in addition to the above, you must:

- use loading rates that are sufficiently low to be in the solubility range of most constituents (or that are consistent with the PEC value). This condition is mandatory to provide relevant information for the hazard and risk assessment (ECHA Guidance, Appendix R.7.8.1-1, Table R.7.8-3);
- provide a full description of the method used to prepare the WAF (including, among others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique);
- prepare WAFs separately for each dose level (i.e. loading rate) and in a consistent manner.

Appendix B: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. 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].

B. Test material

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 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.

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

Appendix C: General recommendations when conducting and reporting new tests for REACH purposes

A. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in ECHA Guidance R.11 (Section R.11.4.2.2), you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthesize its relevant constituents and/or fractions.

Appendix D: 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 12 August 2020.

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

Change of a Deadline:

In your comments on the draft decision, you requested an extension of the deadline to provide information from 18 to 24 months from the date of adoption of the decision.

You justify the extension by stating

- In your comments to the initial draft decision, you state your intention to submit an adaptation(s) to comply with the general rules of adaptation as set out in Annex XI, Section 1. You explicitly mention the adaptation of Annex XI, Section 1.5 (Grouping and read-across approach). Due to the complexity of establishing similar UVCB substances, you request extra time.
- "The test capacity at the contracted research organization will be limited and could lead to a backlog of studies for the following years. Thus, the registrant likes to ask for consideration of the situation and kindly requests a prolongation from 18 months to 24 months."

Due to the foreseen reduced laboratory capacity, an extension is granted.

The deadline to provide the requested information was amended to 30 months, to align with other decisions for related substances.

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 E: List of references - ECHA Guidance[4] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[5]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[6]
Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

[4] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[5] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[6] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

Appendix F: Addressees of this decision and their corresponding information requirements

You must provide the information requested in this decision for all REACH Annexes applicable to you.

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.