~~Confidential~~

Helsinki, 12 January 2023

Addressee
Registrant of JS_Acetylsalicylic acid as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
02/04/2013

Registered substance subject to this decision ("the Substance")
Substance name: O-acetylsalicylic acid
EC number: 200-064-1

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 ***20 January 2025***.

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

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

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

2. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: EU C.4. A/B/C/D/E/F/OECD TG 301A/B/C/D/E/F or EU C.29./OECD TG 310)

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

3. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: EU C.1./OECD TG 203)

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

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

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 addressee of the decision and its corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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 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

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Reasons related to the information under Annex VII of REACH

1. Growth inhibition study aquatic plants

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

1.1. Information provided

(i) You have provided an OECD 201 study

1.2. Assessment of the information provided

2 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:

3 Characterisation of exposure

a) analytical monitoring must be conducted. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided;
b) the concentrations of the test material are measured at least at the beginning and end of the test:
   - at the highest, and
   - at the lowest test concentration, and
   - at a concentration around the expected EC_{50}.

4 Reporting of the methodology and results

c) the test design is reported (*e.g.*, number of replicates, number of test concentrations and geometric progression used);
d) the test conditions are reported (*e.g.*, composition of the test medium, test temperature, test species, biomass density at the beginning of the test);
e) the method for determination of biomass and evidence of correlation between the measured parameter and dry weight are reported
f) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;
g) 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.

5 In study (i) described as growth inhibition study on aquatic plants/algae:

a) no analytical monitoring of exposure was conducted;
b) the concentration of the test material was not determined at least at the beginning and end of the test:
   - at the highest, and
   - at the lowest test concentration, and
   - at a concentration around the expected EC_{50}.

6 Reporting of the methodology and results:

c) no information on the test design
d) no information on the test conditions
e) no information on how the algal biomass was determined
f) tabulated data on the algal biomass determined daily for each treatment group and

control are not reported;
g) microscopic observations to verify a normal and healthy appearance of the inoculum culture are not reported.

7 Based on the above the information provided d the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, in the absence of so many missing pieces of information it is not possible to assess coverage of key parameters and compliance with OECD TG.

8 Therefore, the requirements of OECD TG 201 are not met and the information requirement is not fulfilled.

2. Ready biodegradability

9 Ready biodegradability is an information requirement in Annex VII to REACH (Section 9.2.1.1.).

2.1. Information provided

(i) You provided an experimental study according to ISO 7827 (Evaluation in an Aqueous Medium of the "Ultimate" Aerobic Biodegradability of Organic Compounds - Method by Analysis of Dissolved Organic Carbon (DOC)) from 1993

2.1. Assessment of the information provided

10 To fulfil the information requirement, a study must comply with the OECD TG 301 or 310 (Article 13(3) of REACH). Therefore, for a study according to OECD TG 301, the following requirements must be met:

11 Reporting of the methodology and results

a) the source of the inoculum, its concentration in the test and any pre-conditioning treatment are reported;
b) the test temperature is reported;
c) the methods of preparation of test solutions/suspensions is reported;
d) the results of measurements at each sampling point in each replicate is reported in a tabular form;
e) any observed inhibition phenomena and/or abiotic degradation are reported;
f) the calculation of the $ThCO_2$ is described and justified;
g) the inorganic carbon content (IC) and total carbon content (TC) of the test material suspension in the mineral medium at the beginning of the test is reported;
h) information on the 10-day window to assess the level of biodegradability
i) information on the validity criteria and technical specifications of the test.

12 In study (i) described as a study on ready biodegradability:

13 Reporting of the methodology and results

a) The concentration of the inoculum in the test and any pre-conditioning treatment are not reported;
b) the test temperature is not reported;
c) the methods of preparation of test solutionsis not reported;
d) the results of measurements at each sampling point in each replicate is not reported in a tabular form;
e) no information is provided on inhibition phenomena and/or abiotic degradation (if

any);

f) the calculation of the $ThCO_2$ is not described;
g) the inorganic carbon content (IC) and total carbon content (TC) of the test material suspension in the mineral medium at the beginning of the test is not reported;
h) no information is reported on the 10-day window to assess the level of biodegradability
i) no information is given on validity criteria and technical specifications.

14 The reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, in the absence of so many missing pieces of information it is not possible to assess coverage of key parameters and compliance with OECD TG.

15 Therefore, the requirements of OECD TG 301 are not met and the information requirement is not fulfilled.

Reasons related to the information under Annex VIII of REACH

3. Short-term toxicity testing on fish

16 Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.).

3.1. Information provided

17 You have provided two studies:

(i) One 48h study in *Leuciscus idus* equivalent or similar to OECD 203

(ii) One 96h limit test by USEPA

3.2. Assessment of the information provided

18 To fulfil the information requirement, a study must comply with OECD TG 203 (Article 13(3) of REACH). Therefore, the following specifications must be met:

19 Characterisation of exposure

a) analytical monitoring must be conducted. A reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range must be available.

20 Reporting of the methodology and results

a) the test design is reported (*e.g.* static, semi-static or flow-through, number of test animals);
b) the test procedure is reported (*e.g.* composition of the test medium, fish loading);
c) in static tests, the results of at least daily measurements of dissolved oxygen, pH, salinity (if relevant) and temperature measured daily in each test vessel are reported. The results of hardness and TOC determinations at the beginning of the exposure in the dilution water are reported;
d) mortalities and sub-lethal effects (*e.g.* with regard to equilibrium, appearance, ventilator and swimming behaviour) are reported. The frequency of observations includes at least 2 observations within the first 24 hours and at least two observations per day from day 2 to 4.

21 In studies (i, ii) described as a short-term toxicity study on fish:

22 Characterisation of exposure

a) no analytical monitoring of exposure was conducted;

23 Reporting of the methodology and results:

a) no information on the test design is reported
b) no information on the test procedure is reported
c) the dissolved oxygen and pH measured are not reported;
d) tabulated data on mortalities and sub-lethal effects (*e.g.* with regard to equilibrium, appearance, ventilator and swimming behaviour) obtained on at least 2 observations within the first 24 hours and at least two observations per day from day 2 to 4 for each treatment group and control are not reported.

24 Based on the above, the information provided is not sufficient to conduct an independent assessment of its reliability. More specifically, in the absence of so many missing pieces of information it is not possible to assess coverage of key parameters and compliance with OECD TG.

25 Therefore, the requirements of OECD TG 203 are not met and the information requirement is not fulfilled.

Reasons related to the information under Annex IX of REACH

4. Long-term toxicity testing on aquatic invertebrates

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

4.1. Information provided

27 You have provided two studies:

(i) One OECD 211 study

(ii) One study 'standard methods used by USEPA'

4.2. Assessment of the information provided

28 To fulfil the information requirement, a study must comply with the OECD TG 211 (Article 13(3) of REACH). Therefore, the following specifications must be met:

29 Validity criteria

a) the mean number of living offspring produced per surviving parent animal in the control is ≥ 60 at the end of the test.

30 Characterisation of exposure

a) analytical monitoring must be conducted. A reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range must be available.

31 Reporting of the methodology and results

a) the test design is reported (*e.g.* semi-static or flow-through, number of replicates, number of parents per replicate);
b) the test procedure is reported (*e.g.* loading in number of *Daphnia* per litre, test medium composition);
c) the methods used to prepare stock and test solutions
d) report adequate information on the final test medium composition
e) detailed information on feeding, including amount (in mgC/daphnia/day) and schedule is reported;
f) the nominal test concentrations and the results of all analyses to determine the concentration of the test substance in the test vessels are reported;
g) water quality monitoring within the test vessels (*i.e.* pH, temperature and dissolved oxygen concentration, and TOC and/or COD and hardness where applicable) is reported;
h) the full record of the daily production of living offspring during the test by each parent animal is provided;
i) the number of deaths among the parent animals (if any) and the day on which they occurred is reported;
j) the coefficient of variation for control reproductive output is reported.

32 In study (i):

33 Validity criteria

a) the mean number of living offspring produced per parent animal surviving at the end of the test was *'not equal or above 60'*.

34 Characterisation of exposure

a) no analytical monitoring of exposure was conducted.

35 In study (ii):

36 You reported only a 'chronic EC50 value with citation only, but data published by USEPA.'

37 Reporting of the methodology and results

a) on the test design, you have only specified that it is a semi-static system but no other information
b) no information on the test procedure
c) the methods used to prepare stock and test solutions is not reported;
d) you have not provided adequate information on the final test medium composition
e) information on feeding rate is not provided;
f) no information is reported if the study contains analytical monitoring
g) water quality monitoring within the test vessels are not reported;
h) the full record of the daily production of living offspring during the test [by each parent animal is not provided;
i) the number of deaths among the parent animals (if any) and the day on which they occurred is not reported;
j) the coefficient of variation for control reproductive output is not reported;

38 Based on the above for study (i) the validity criteria of OECD TG 211 are not met and for study (ii) the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, in the absence of so many missing pieces of information it is not possible to assess coverage of key parameters and compliance with OECD TG.

39 Therefore, the requirements of OECD TG 211 are not met and the information requirement is not fulfilled.

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 14 September 2021.

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

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the request(s).

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]

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

(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 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.

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