EUROPEAN CHEMICALS AGENCY

Helsinki, 21 January 2021

Addressees
Registrant(s) of JS_Sodium benzoate as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
05/11/2019

Registered substance subject to this decision ("the Substance")
Substance name: Sodium benzoate
EC number: 208-534-8
CAS number: 532-32-1

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 the deadline of ***26 October 2022***.

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

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

1. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202)

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

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

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

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

2. 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 appendices:

- Appendices entitled "Reasons to request information required under Annexes VII to IX of REACH", respectively.

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 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.

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 testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil 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 Christel Schilliger-Musset, 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 VII of REACH

1. Short-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex VII to REACH.

You have provided a key study with the Substance in your dossier:

i. Key study (1986), no testing guideline followed, no GLP. reliability score 2;

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

Although you do not explicitly claim an adaptation, ECHA understands that the information provided was submitted in order to meet the required information by way of adaptation under Annex, Section XI 1.1.2. This adaptation rule enables registrants to claim that the data from experiments not carried out according to GLP or the test methods referred to in Article 13(3) can be considered equivalent to data generated by those test methods where a number of cumulative conditions are met, in particular:

Adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3), in this case, an OECD TG 202 which include;

- fulfilment of validity criteria as set up in the test guideline: dissolved oxygen concentrations at the end of the test ≥3 mg/l in all control and test vessels,
- Analytical monitoring to verify initial concentrations and maintenance of these concentrations throughout the test as required in guideline,
- If test concentrations are not maintained within 20% of initial measured concentrations throughout testing, effect concentrations must be reported based on measured values (see ECHA Guidance R7b, section R.7.8.4.1),
- Young daphnids, aged less than 24 hours at the start of the test are used.

You have provided a key study showing the following:

- You only stated that "Disolved oxygen starting level was not reported. If the dissolved oxygen concentration fell below 40% of the starting level, the test was repeated with 0.5 L/min aeration",
- Analytical monitoring was not performed,
- You state that juveniles were used, but exact age of daphnid is not provided,

The following was reported for the provided algal growth inhibition study:

- The measured concentrations decreased below the limit of detection (LOD; <0.004 mg/L) in the three lowest test concentrations (10-32 mg/L) during the first 24-hour test period.
- After 72 hours of exposure all measured concentrations had decreased below the LOD.

You have not demonstrated compliance with the above validity criterion.

With regards to the analytical monitoring, the Substance degrades in the test system (the Substance is readily biodegradable). Therefore it is expected that considerable losses will occur during the exposure period, as confirmed by the provided algal growth inhibition study.

For the key study, you did not provide any analytical monitoring of exposure concentrations and did not demonstrate that the test concentration during the test was maintained within the required 20% of the measured initial concentrations.

In your comment to the draft decision, you agree with ECHA's assessment that both key and supporting studies lack details needed to fulfil the information requirement. You state that you have no objection to conduct the requested study. Furthermore, you also acknowledge the fact that the Substance is readily biodegradable and agreed to reflect this in the study design.

Based on above, the information provided does not demonstrate adequate and reliable coverage of the key parameters and therefore information provided is rejected.

Appendix B: Reasons to request information required under Annex VIII of REACH

1. Short-term toxicity testing on fish

Short-term toxicity testing on fish is a standard information requirement in Annex VII to REACH.

You have provided a key study and supporting study with the Substance in your dossier:

i. Key study (1985), conducted according to EPA OPP 72-1, no GLP, reliability score 2;
ii. Supporting study (1986), conducted according to OECD TG 203, GLP, reliability score 2.

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

Although you do not explicitly claim an adaptation, ECHA understands that the information provided was submitted in order to meet the required information by way of adaptation under Annex, Section XI 1.1.2. This adaptation rule enables registrants to claim that the data from experiments not carried out according to GLP or the test methods referred to in Article 13(3) can be considered equivalent to data generated by those test methods where a number of cumulative conditions are met, in particular:

Adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3), in this case, an OECD TG 203 which require;

- The analytical measurement of test concentrations must be conducted,
- If test concentrations are not maintained within 20% of initial measured concentrations throughout testing, effect concentrations must be reported based on measured values (see ECHA Guidance R7b, section R.7.8.4.1),
- Validity criterion: dissolved oxygen must be at least 60% of air saturation value
- at least 7 fish must be used at each concentration and in the controls,

You have provided a key study showing the following:

- You provided mean measured concentrations for each replicate but you did not provide nominal concentration, and you did not specify how the effect concentrations are derived,
- Dissolved oxygen measurement as 7 without any unit,
- You did not provide the number of fish used for the study.

You have provided a supporting study (OECD TG 203) showing the following:

- Analytical monitoring was not performed,
- You only state that if the dissolved oxygen concentration fell below 40% of the starting level and the test was repeated with 0.05 L/min aeration.

In your comments to the draft decision, you provide the following additional information on the key study (1985):

- The analytical monitoring was performed by using HPLC at 24, 48, 72, and 96 hours,
- The raw data on the measured concentrations, average concentrations, standard deviation, coefficient of variation and corrected average (Table 1),
- The actual measured oxygen concentration was 7 mg/L and it was >60 % of

saturation.

- The number of fish used in the study was 20 fish/replicatewith 2 replicates/dose(40 fish total/dose).
- Regarding the nominal concentration, in your comments to the draft decision, you provide justifications for the lack of nominal concentration and initial measured concentrations. They may be summerised as below;The study was performed by using flow through system,
- The study was conducted in duplicate and analytical monitoring was performed at four time points (24, 48, 72 and 96hrs),
- The measured concentrations between 24-96 hours remained stable (provided in Table 1),
- Lack of mortality during the first 24 hrs at all test concentrations (raw data provided in Table 2),
- The effect concentrations are reported based on the measured concentrations.

In your comments to draft decision, you indicate your intention to update the technical dossier with the information outlined above.

ECHA has assessed the provided information and consider that the submitted information on the key study is sufficient to fulfil the information requirement. However, as you remain responsible for complying with this decision by the set deadline, you must provide the information in your updated dossier by the set deadline of this decision.

Based on above, the information provided does not demonstrate adequate and reliable coverage of the key parameters and therefore information provided is rejected.

Appendix C: Reasons to request information required under Annex IX of REACH

1. Long-term toxicity testing on aquatic invertebrates

Long-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex IX to the REACH Regulation.

You have provided adaptation for long-term toxicity testing on aquatic invertebrates based on column 2 by stating that "the Substance is readily biodegradable, and has low bioaccumulation potential and low acute toxicity to aquatic organisms" and "all RCRs are below 1" thus concluding that there is no need to further investigate the effects on aquatic organisms.

We have assessed this information and identified the following issue(s):
As specified in Annex IX, Section 9.1., Column 2, a long-term toxicity to study on aquatic invertebrates must be performed unless the Chemical Safety Assessment demonstrates that risks towards the aquatic compartment arising from the use of the Substance are controlled (as per Annex I, section 0.1). The justification must be documented in the Chemical Safety Assessment.

In particular, the Chemical Safety Assessment must take into account the following elements to support that long-term toxicity testing is not required:
- all relevant hazard information from your registration dossier,
- the outcome of the exposure assessment in relation to the uses of the Substance,

You rely on the availability of acute aquatic toxicity and long-term fish toxicity data, as well as the PNEC derived from these studies to demonstrate that risks towards the aquatic compartment arising from the use of the Substane are controlled.

As specified in requests A-1, B-2 above as well as C-2 below, the data on short-term daphnia and fish, as well as, long-term fish are not compliant with the REACH requirements. Hence your dossier currently does not include adequate information to characterize the hazard property of the Substance.

Without this information your Chemical Safety Assessment does not demonstrate that the risks of the Substance are adequately controlled. As a consequence, your adaptation is rejected as it does not meet the specific rules for adaptation of Annex IX, Section 9.1., Column 2.

In your comments on the draft decision you propose a tiered approach to fulfil the data gaps for this endpoint according to the integrated testing strategy. You agree to perform the short-term study on daphnia (request A-1 above). Successively, you would update the CSA and determine whether the long-term *Daphnia* and the long-term fish studies requested in this decision are needed.

If the CSA shows that further investigation of effects on aquatic organisms is required, you indicate to use read-across data to fulfil the data gaps for long-term aquatic toxicity studies. In case no read-across is possible, you indicate that you will perform long-term toxicity test on daphnia (OECD TG 211) unless there is any evidence to suggest that fish are significantly more sensitive to the Substance than daphnia.

ECHA notes that following the recent Boad of Appeal case (A-011-2018), column 2 is no longer applicable for aquatic toxicity testing and long-term studies are information requirements under Annex IX.

While you indicate to apply a read-across in case long-term studies are required after OECD TG 202 study and subsequent CSA update, you have not provided a read-across adaptation and ECHA cannot currently assess whether your proposal to use read-across adaptations for the long-term aquatic toxicity endpoints would be acceptable. ECHA will evaluate your information after the set deadline of this decision according to the specific rules of adaptation(s) according to Annex XI. It is in your discretion to generate and provide the necessary supporting information in order to justify your read-across adaptation. If you do so, you are responsible for demonstrating the fulfilment of the requirements of Section 1.5 of Annex XI to REACH. If it fails and the resulting data does not support, or even contradict, your read-across hypothesis, you remain responsible for complying with this decision by the set deadline.

Consequently, the provided information is rejected.

2. Long-term toxicity testing on fish

Long-term toxicity testing on fish is a standard information requirement in Annex IX to the REACH Regulation.

You have provided a key study with the Substance in your dossier:

i. Key study (2007), no testing guideline followed, reliability score 2;

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

Although you do not explicitly claim an adaptation, ECHA understands that the information provided was submitted in order to meet the required information by way of adaptation under Annex, Section XI 1.1.2. This adaptation rule enables registrants to claim that the data from experiments not carried out according to GLP or the test methods referred to in Article 13(3) can be considered equivalent to data generated by those test methods where a number of cumulative conditions are met, in particular:

1. Adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3), in this case OECD TG 210, which include;
    - Investigation of stage of embryonic development; Hatching and survival of embryos and larvae; Survival of juvenile fish; Abnormal appearance; Abnormal behaviour; Weight at the end of the test; Length at the end of the test;
    - Monitoring of test substance concentrations;
    - The dissolved oxygen concentration must be >60% of the air saturation value throughout the test,
2. Exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3); in this case OECD TG 210, which requires 32 days exposure duration for Danio rerio;

You have provided key study (2007) showing the following:

- Test conducted at the test concentration up to 2000 ppm with the exposure duration of 24 hr.
- Only at the test concentration of 1000 ppm, the exposure period was extended for 144 hours.
- No analytical monitoring was conducted during the test duration.

- No investigation of weight at the end of the test or length at the end of the test and no reporting of any investigation on hatching (e.g., days of hatch) or mortality (eg, mortality at each stage);
- No information on test conditions (e.g. dissolved oxygen and temperature).

On this basis, you have not demonstrated that the provided study has an adequate and reliable coverage of the required key parameters.

In your comments to the draft decision you state that you agree with ECHA's assessment and that achknowledge that the key study does not provide information to conclude on the chronic toxicity of the Substance to fish.

In your comments on the draft decision you propose a tiered approach to fulfil the data gaps for this endpoint and for long-term toxicity testing on daphnia (request C-1 above) according to the integrated testing strategy.

As explained in the request C-1 above, column 2 is not a legal basis to adapt this information requirement. ECHA will evaluate your information after the deadline of this decision according to the specific rules of adaptation(s) according to Annex XI. It is in your discretion to generate and provide the necessary supporting information in order to justify your read-across adaptation. If you do so, you are responsible for demonstrating the fulfilment of the requirements of Section 1.5 of Annex XI to REACH. If it fails and the resulting data does not support, or even contradict, your read-across hypothesis, you remain responsible for complying with this decision by the set deadline.

Therefore, your adaptation is rejected and the information requirement is not fulfilled.

Appendix D: 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

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

1. Selection of the Test material(s)

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

2. Information on the Test Material needed in the updated dossier
   - You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
   - The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[3].

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

Appendix E: 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 9 July 2019.

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).

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 F: 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)[6]

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.

[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] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316

OECD Guidance documents[7]

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

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.

[7] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix G: Addressees of this decision and the corresponding information requirements applicable to them

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
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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.