~~Confidential~~

Helsinki, 24 June 2021

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

Date of submission of the dossier subject to this decision
04/11/2019

Registered substance subject to this decision ("the Substance")
Substance name: Potassium hydrogen tartrate
EC number: 212-769-1
CAS number: 868-14-4

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 in A.1., A.2. and B.2. below by ***29 September 2022*** and the other information listed below by ***2 April 2024***.

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)

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

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

1. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) by oral route, in rats

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

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

- Appendix entitled "Reasons common to several requests";
- Appendices entitled "Reasons to request information required under Annexes VII to VIII 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 Annexes VII and VIII to REACH, for registration at 10-100 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". 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 on Reasons common to several requests

1. **Assessment of your Weight of Evidence adaptation under Annex XI, Section 1.2**

You have adapted the following standard information requirements by applying weight of evidence (WoE) adaptation in accordance with Annex XI, section 1.2:

- Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)
- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)
- Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)

Your weight of evidence adaptation raises the same deficiencies irrespective of the information requirement for which it is invoked. Accordingly, ECHA addressed these deficiencies in the present Appendix, before assessing the specific standard information requirements in the following appendices.

Annex XI, Section 1.2 states that there may be sufficient weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion.

According to ECHA Guidance R.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude that the Substance has or has not the (dangerous) property investigated by the required study.

Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence approach.

However, for each relevant information requirement, you have not submitted any explanation why the sources of information provide sufficient weight of evidence leading to the conclusion/assumption that the Substance has or has not a particular dangerous property.

In spite of this critical deficiency, ECHA has have nevertheless assessed the validity of your adaptation.

The issue identified below is relevant for all the environmental information requirements in which you invoked a weight of evidence.

QSAR predictions rejected

Section 2 of the present Appendix identifies deficiencies of the information based on application of (quantitative) structure-activity relationships (QSAR) submitted under your weight of evidence adaptations.

Your weight of evidence approach has deficiencies that that are specific for these information requirements individually. The specific deficiencies are set out under the information requirement concerned in the Appendices below.

2. Assessment of (quantitative) structure-activity relationships estimations

You have provided information based on application of (quantitative) structure-activity relationships (QSAR) for the following standard information requirements:

1. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)
2. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)
3. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)

Information generated by application of various QSARs applied by you raises the same deficiencies irrespective of the information requirement for which it is invoked. Accordingly, ECHA addressed these deficiencies in the present Appendix, before assessing the specific standard information requirements in the following appendices.

Annex XI, Section 1.3. states that results obtained from valid QSAR models may be used instead of testing when several cumulative conditions are met, in particular:

1. results are derived from a QSAR model whose scientific validity has been established;
2. the substance falls within the applicability domain of the QSAR model;
3. adequate and reliable documentation of the applied method is provided; and
4. the results are adequate for classification and labelling and/or risk assessment.

You have provided QSAR predictions by Danish National Food Institute (MultiCASE platform) for the aquatic toxicity endpoints listed above in order to comply with the REACH information requirements.

Inadequate documentation of the model (QMRF)

Under Appendix C of the OECD Guidance document on the validation of (Q)SAR models (ENV/JM/MONO(2007)2) and ECHA Guidance R.6.1.6.3., adequate and reliable documentation must include a (Q)SAR Model Reporting Format document (QMRF) which reports, among others, the following information:

- the predicted endpoint, including information on experimental protocol and data quality for the data used to develop the model;
- an unambiguous definition of the algorithm, the descriptor(s) of the model and its applicability domain,
- an estimate of the goodness-of-fit and of the predictivity of the model, including information on training set and validation statistics.

You have provided in the dossier document describing the model applied, i.e. QSAR Model Reporting Format (QMRF). For the algorithm definition you note in this document that "*details available on request*".

Thus, the information in the QMRF is not sufficient to conclude on the unambiguous algorithm. In absence of such information, ECHA cannot establish that the model can be used to meet this information requirement.

Lack of documentation of the prediction (QPRF)

ECHA Guidance R.6.1.6.3 states that the information specified in or equivalent to the (Q)SAR Prediction Reporting Format document (QPRF) must be provided to have adequate and reliable documentation of the applied method. For a QPRF this includes, among others:

- the model prediction(s), including the endpoint,
- a precise identification of the substance modelled,
- the relationship between the modelled substance and the defined applicability domain,

- the identities of close analogues, including considerations on how predicted and experimental data for analogues support the prediction.

You have not provided information about the prediction.

In absence of such information, ECHA cannot establish that the prediction can be used to meet this information requirement.

Summarising, you have provided in the dossier document describing the model applied, i.e. QSAR Model Reporting Format (QMRF). However, you have not provided sufficient documentation for the QSAR predictions for any of the endpoints listed above. In particular, you have not included QSAR Prediction Reporting Format (QPRF) in your technical dossier and the information in the QMRF is not sufficient to conclude on the unambiguous algorithm.

Consequently, ECHA cannot verify that the cumulative conditions of Annex XI, Section 1.3 listed above are met. Therefore, provided information based on application of QSARs is rejected.

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 an information requirement under Annex VII to REACH (Section 9.1.1.).

You have adapted this information requirement by using a WoE adaptation in accordance with Annex XI, section 1.2.
You have provided the following information:

i. OECD TG 202 study with the analogue substance tartaric acid (EC 201-766-0).
ii. Prediction of effect concentration to daphnids by MultiCASE.

As explained under Appendix on Reasons common to several requests, Section 1, the weight of evidence adaptation must fulfil the information requirement based on relevant and reliable sources of information. These sources of information must provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

To fulfil the information requirement, normally a study performed according to OECD TG 202 must be provided. OECD TG 202 requires the study to investigate the following key parameter:

- the concentration of the test material leading to the immobilisation of 50% of daphnids at the end of the test is estimated.

Coverage of key investigations

All provided sources of information may provide information on the immobilization of daphnids.

However, the reliability of these sources of information is significantly affected by the deficiencies identified under Appendix on Reasons common to several requests, Section 1.

In addition, the reliability of these sources of information is significantly affected by the following deficiencies:

Reliability of the experimental study

To fulfil the information requirement, normally a study according to OECD TG 202 must be provided. The specifications of this test include:

- the test duration is 48 hours or longer;
- the concentrations of the test material are measured at least at the highest and lowest test concentration, at the beginning and end of the test;
- the effect values can only be based on nominal or measured initial concentration if the concentration of the test material has been satisfactorily maintained within 20 % of the nominal or measured initial concentration throughout the test (see also ECHA Guidance R.7b, Section R.7.8.4.1);
- the test design (*e.g.* static or semi-static test, number of replicates) and the test procedure (*e.g.* composition of the test medium, loading in number of *Daphnia* per test vessel) are reported.

Your registration dossier provides following information for the experimental study:

- the test duration was 24 hours;
- no information about analytical monitoring of exposure concentrations throughout

the test duration;
- information on the test design and procedure is missing from the registration dossier.

Based on the above, the listed above specifications are not met for the provided experimental study. Thus, there are critical methodological deficiencies significantly affecting its reliability.

As a conclusion, sources of information as indicated above, provide information on the immobilization of daphnids, but provided information is not reliable.

Based on the assessment above, it is not possible to conclude, based on any source of information alone or considered together, whether your Substance has or has not the particular dangerous property foreseen to be investigated in an OECD TG 202 study. Therefore, your adaptation is rejected and the information requirement is not fulfilled.

There is a parallel dossier evaluation process to request the joint submission registrants concerned to generate and submit a long-term toxicity study on aquatic invertebrates. Unnecessary animal testing must be avoided. Therefore, to fulfil the information requirement covered by this endpoint, a justification for an adaptation based on column 2 of the present information requirement should be considered instead of the standard test.

2. Growth inhibition study aquatic plants

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

You have adapted this information requirement by using a WoE adaptation in accordance with Annex XI, section 1.2.
You have provided the following information:

i. Experimental study where "*tartaric acid solution was used as solvent and it was tested to assess its toxicity (negative control). A concentration of 0.06% tartaric acid was resulted in no or little growth inhibition among all the strains tested: the highest value for inhibition was 11.3% for I. galbana.*)".
ii. Prediction of effect concentration to algae by MultiCASE (flagged by you as weight of evidence).

As explained in the Appendix on Reasons common to several requests, Section 1, the weight of evidence adaptation must fulfil the information requirement based on relevant and reliable sources of information. These sources of information must provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

To fulfil the information requirement, normally a study performed according to OECD TG 201 must be provided. OECD TG 201 requires the study to investigate the following key investigations:

- the concentrations of the test material leading to a 50 % and 0% (or 10%) inhibition of growth at the end of the test are estimated.

Coverage of key investigations

All provided sources of information may provide information on the inhibition of growth of algae.

However, the reliability of these sources of information is significantly affected by the deficiencies identified under Appendix on Reasons common to several requests, Section 1.

In addition,, the relevance and reliability of these sources of information is significantly affected by the following deficiencies:

Reliability of experimental study

To fulfil the information requirement, normally a study according to OECD TG 201 must be provided. The specifications of this test include:

- the concentrations of the test material are measured at least at the beginning and end of the test:
  1) at the highest, and
  2) at the lowest test concentration, and
  3) at a concentration around the expected EC_{50}.
- the results can be based on nominal or measured initial concentration only if the concentration of the test material has been maintained within 20 % of the nominal or measured initial concentration throughout the test;
- information on the test design (e.g., number of replicates etc.), test conditions (e.g., biomass density at the beginning of the test) and biological results are reported.

Your registration dossier indicates that no analytical monitoring of exposure concentrations throughout the test duration was conducted and does not provide information on the test design (e.g., number of replicates etc.), test conditions (e.g., biomass density at the beginning of the test) and biological results for the provided study.

Based on the above, the listed above specifications are not met for the provided experimental study. Thus, there are critical methodological deficiencies significantly affecting its reliability.

As a conclusion, sources of information as indicated above, provide information on the inhibition of growth of algae, but provided information is not reliable.

Based on the assessment above, it is not possible to conclude, based on any source of information alone or considered together, whether your Substance has or has not the particular dangerous property foreseen to be investigated in an OECD TG 201 study. Therefore, your adaptation is rejected and the information requirement is not fulfilled.

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

1. Screening for reproductive/developmental toxicity

Screening for reproductive/developmental toxicity is a standard information requirement under Annex VIII to REACH. This information may take the form of a study record or a valid adaptation in accordance with either a specific adaptation rule under Column 2 of Annex VIII or a general adaptation rule under Annex XI.

We understand that you have provided an adaptation according to Annex IX, Section 8.7., Column 2, by stating that the study does not need to be conducted because the substance is of low toxicological activity, no systemic absorption occurs via relevant routes of exposure, and there is no or no significant human exposure. However, Screening for reproductive/developmental toxicity is an information requirement under Annex VIII to REACH and we have to assess it accordingly under this Annex.

Assessment of the Column 2 adaptation under Annex VIII, Section 8.7.

According to Annex VIII, Section 8.7.1, Column 2, first paragraph, third intent, the corresponding study does not need to be conducted if relevant human exposure can be excluded in accordance with Annex XI section 3.

In your dossier you identified uses for manufacture, for formulation and repacking, at industrial sites, for professionals and consumers. For professional workers you identified eight uses e.g. in metal and surface treatments, metal working fluids, polishes and wax blends and textile dyes and impregnating products. For these uses process categories (PROC) like e.g. PROC 3, 4, 7, 8a, 9, 10 and 13 were included. You identified five consumer uses: ink and toners, perfumes and fragrances, pharmaceuticals, washing and cleaning products and cosmetics and personal care products. No other information than the use names and process or product categories were given for the identified uses and related human exposure.

ECHA notes that having professional and consumer uses means that human exposure is likely. Also, as no details on exposure scenarios, conditions of use and/or exposure estimates are included in the dossier or CSR, the information provided cannot be considered as proof of excluding relevant human exposure.

ECHA notes that in order to justify the omission of the standard information requirement, the human exposure assessment should be in accordance with Annex XI section 3. According to Annex XI sections 3.1 and 3.2 testing may be omitted based on the exposure scenarios developed in the Chemical Safety Report and in all cases adequate justification and documentation shall be provided based on a thorough and rigorous exposure assessment in accordance with section 5 of Annex I. All this information is missing from your dossier.

Based on the above, your adaptation is rejected.

Therefore, the information you provided does not fulfil the information requirement.

Information on study design

A study according to the test method EU B.63/OECD TG 421 or EU B.64/OECD TG 422 must be performed in rats with oral[2] administration of the Substance.

[2] ECHA Guidance R.7a, Section R.7.6.2.3.2.

2. Short-term toxicity testing on fish

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

You have adapted this information requirement by using a WoE adaptation in accordance with Annex XI, section 1.2.

You have provided the following information:

i. Prediction of effect concentration to fish by MultiCASE.

As explained in the Appendix on Reasons common to several requests, Section 1, the weight of evidence adaptation must fulfil the information requirement based on relevant and reliable sources of information. These sources of information must provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

Information from a single source alone is insufficient to support weight of evidence leading to the conclusion/assumption that the Substance has or has not a particular dangerous property. However, you have provided information from the single source in the registration dossier.

In spite of these critical deficiencies, ECHA has nevertheless assessed the reliability and relevance of the source of information provided.

To fulfil the information requirement, normally a study performed according to OECD TG 203 must be provided. OECD TG 203 requires the study to investigate the following key parameter:

- the concentration of the test material leading to the mortality of 50% of the juvenile fish at the end of the test is estimated.

Coverage of key investigations

The provided source of information may provide information on the mortality of fish.

However, the reliability of these sources of information is significantly affected by the deficiencies identified under Appendix on Reasons common to several requests, Section 1.

As a conclusion, source of information as indicated above, provide information on the mortality of fish, but provided information is not relevant and/or reliable.

Based on the assessment above, it is not possible to conclude, based on the source of information alone, whether your Substance has or has not the particular dangerous property foreseen to be investigated in an OECD TG 203 study. Therefore, your adaptation is rejected and the information requirement is not fulfilled.

There is a parallel dossier evaluation process to request the joint submission registrants concerned to generate and submit a long-term toxicity study on fish. Unnecessary animal testing must be avoided. Therefore, to fulfil the information requirement covered by this endpoint, a justification for an adaptation based on column 2 of the present information requirement should be considered instead of the standard test.

Appendix C: 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[3].

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[4].

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

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 10 March 2020.

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

ECHA did not receive any comments within the 30-day notification period.

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[5] 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)[6]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[7]

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[8]

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

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.

Appendix F: 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
[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.