Helsinki, 01 September 2020

Addressees
Registrant of JS_2EOBPADMA as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
12/09/2019

Registered substance subject to this decision ("the Substance")
Substance name: Reaction mass of (1-methylethylidene)bis(4,1-phenyleneoxy-2,1-ethanediyl) bismethacrylate and 2-{4-[2-(4-{2-[2-(methacryloyloxy)ethoxy]ethoxy}phenyl)propan-2-yl]phenoxy}ethyl methacrylate
List number: 939-702-5
CAS number: NS

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 ***8 December 2021***.

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. Skin sensitisation (Annex VII, Section 8.3.):

   i) *in vitro/in chemico* skin sensitisation information on molecular interactions with skin proteins (OECD TG 442C), inflammatory response in keratinocytes (OECD TG 442D) and activation of dendritic cells (OECD TG 442E) (Annex VII, Section 8.3.1.); and

   ii) *in vivo* skin sensitisation (Annex VII, Section 8.3.2.; test method: EU B.42./OECD TG 429), in case the *in vitro/in chemico* test methods specified under point i) are not applicable for the Substance or the results obtained are not adequate for classification and risk assessment;

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

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

1. Hydrolysis as a function of pH (Annex VIII, Section 9.2.2.1.; test method: EU C.7./OECD TG 111)

Reasons for the request(s) are explained in the following appendices entitled "Reasons to request information required under Annexes VII and 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, VIII and IX to REACH, for registration at 100-1000 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". 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 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. Skin sensitisation

Skin sensitisation is an information requirement under Annex VII to REACH (Section 8.3.). Column 1 of Section 8.3. requires the registrants to submit information allowing a conclusion A) whether the substance is a skin sensitiser and B) whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A), and risk assessment, where required.

You have provided the following information in the technical dossier:

i. *in vivo* Guinea Pig Maximization test (key study, method as described by [redacted] 1970, non-GLP, 1978).

You have submitted an adaptation under Annex VII, Section 8.3., column 2 adaptation for not performing the *in vitro* studies, *i.e.* you claim that adequate data from an *in vivo* skin sensitisation study is available.

We have assessed this information and identified the following issues:

A) Assessment whether the Substance causes skin sensitisation:

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 XI, Section 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. Adequacy for the purpose of classification and labelling and/or risk assessment;
2. 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 the OECD TG 406/ EU Method B.6. Therefore, the following requirements must be met:
   - a dose level selection rationale is provided;
   - the challenge dose must be the highest dose causing no irritation (OECD TG 406, paragraph 14);
   - positive and negative controls to establish the sensitivity and reliability of the experimental technique are included (OECD TG 406, paragraph 11).
3. Exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3);
4. Adequate and reliable documentation of the study is provided;

For the study in your dossier:

- no dose level selection rationale was provided;
- no dermal irritation was noted following the topical application of undiluted test substance, therefore the selected concentration of 25% for challenge was not the highest dose causing no irritation;
- no information on positive and negative control groups were provided.

Therefore the study does not fulfil the requirements of method B.6/OECD TG 406 and does not allow to make a conclusion whether or not the Substance causes skin

sensitisation. On this basis, your adaptation is rejected and the information requirement is not fulfilled.

B) Assessment whether the Substance can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A)

As the currently available data does not allow to conclude whether the Substance causes skin sensitisation, this condition cannot be assessed.

Therefore the information requirement is not fulfilled.

In your comments on the draft decision, you agreed to conduct the requested study on the Substance.

Study design

To fulfil the information requirement *in vitro/in chemico* studies (OECD TG 442C, 442D and 442E) may be suitable. In case *in vitro/in chemico* methods are not suitable for the Substance or the results cannot be used for classification and risk assessment an *in vivo* skin sensitisation study must be performed and the murine local lymph node assay (LLNA) (OEDC TG 429) is considered appropriate.

2. Ready biodegradability

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

You have provided:

i. a key study ([redacted], 2013) according to the OECD TG 301F with the Substance showing 65.1% biodegradation after 28 days;
ii. a supporting study ([redacted], 2005) according to the OECD TG 301D with the Substance showing 4% biodegradation after 28 days.

We have assessed this information and identified the following issue:

To comply with this information requirement, a study must fulfil the requirements of the corresponding OECD test guideline or EU method (Article 13(3) of REACH), in this case OECD TG 301/EU Method C.4. Therefore, the following requirements must be met:

- An inoculum blank control must be included;
- The test substance is the nominal sole source of added organic carbon;
- If a solvent or emulsifying agent is used to increase the homogeneity of test solutions, it must not be biodegraded;
- Low solubility substances must be added directly to the test medium;
- The theoretical oxygen demand (ThOD) used in the calculation is representative of the test substance;
- In OECD TG 301F, the concentration of the inoculum is set to reach a bacterial cell density of 10^7 to 10^8 cells/L in the test vessel. The suspended solid concentration is ≤ 30 mg/L;
- In OECD TG 301D, the oxygen depletion in the inoculum blank is ≤ 1.5 mg dissolved oxygen/L after 28 days;
- The results of measurements at each sampling point in each replicate is reported in a tabular form;

For study i. above you report the following:

- The test material was tested with addition of a surface active agent (Synperonic P103) *"in order to have a stable and homogeneous suspension"*;
- *"A surface agent control flask"* was included in the test design but the results are not reported;
- The parent solution was heated at ~ 40°C and subject to strong magnetic shaking for two days before being used to conduct the test;
- *"The calculated theoretical oxygen demand of the test item is 2.2826 mg O2/mg"*;
- You have not reported the concentration of the inoculum in the test vessels;
- You have not provided the results of measurements of oxygen consumption at each sampling point in each replicate in a tabular form.

In your comments on the draft decision, you have provided the full study report for study i. which shows the following:

- a surface active agent control was included in the study design showing an oxygen consumption of 21.55 mg O_2/L by day 28. No inoculum blank control was included in the study design;
- the report does not specify if the surface active agent stock solution was subject to the same physical treatment as the parent test solution (i.e. heated at ~ 40°C and subject to strong magnetic shaking for two days);
- the theoretical oxygen demand of the test item was determined based on CHN analysis;
- the report specifies that the inoculum density was *"30 mg/L"* but does not provide information on the inoculum density as cells/L;
- the test report includes the results of measurements of oxygen consumption at each sampling point in each replicate in a tabular form.

For study ii. above you report the following:

- *"Ammonium chloride was omitted from the medium to prevent nitrification"*;
- You have only provided the results of the inoculum control until 14 days. However, you have provided the results of an inoculum control with evaporated silica gel showing an oxygen depletion of 2.2 mg dissolved oxygen/L after 28 days;

Based on the above, we identified the following deficiencies for study i.:

- The test substance was not the nominal sole source of added organic carbon as an organic surface agent was used to prepare test solution. You have provided the results of the surface agent control flask. However, as the study design did not include an inoculum blank control and as it is not specified if the surface active agent stock solution was subject to the same physical treatment as the parent test solution (which include the surface active agent), the results of the surface active agent control cannot be interpreted. Therefore, it remains unclear whether the presence of the surface active agent has biased the results;
- According to the data in your dossier the test substance is a poorly soluble (36.4 µg/L based on a modified OECD TG 105 method) liquid but the test substance was not added directly to the test medium. You have not provided any justification that the physical treatment (*i.e.* shaking for 2 days at 40°C) did not lead to abiotic degradation (*e.g.* hydrolysis) which could have biased the results of the study. In your comments on the draft decision, you acknowledge that no justification was provided on the potential impact of this procedure on the results of the study. You consider that hydrolysis of the parent substance would not have biased the results as it would have *"no significant impact on BOD"*. However, it may be expected that the degradation kinetics of the parent substance and of its hydrolysis products may differ and that it may have had on impact on the study results. We note that you have provided no

justification that this is not the case;

- The reported theoretical oxygen demand (ThOD) is the value for the main constituent (69.6%) of the Substance. However, you have not justified that it does not underestimate the ThOD of the test material used to conduct the study. In your comments on the draft decision, you have clarified that the ThOD was determined based on CHN analysis of the test material and that it therefore represents the whole UVCB;
- As you have not provided information on the concentration of the inoculum in the test vessels and the results of an inoculum blank control, it is not possible to verify the adequacy of the test conditions and whether or not the validity criteria of the test guideline were fulfilled.

With regard to study ii., the information you have provided indicate that the validity criteria of OECD TG 301D were not met. The oxygen depletion in the inoculum control with evaporated silica gel was > 1.5 mg dissolved oxygen/L after 28 days. Furthermore the reported value likely underestimates the value that would have been obtained under the standard conditions of OECD TG 301D as you specify that nitrification was prevented by omitting ammonium chloride from the test medium.

Therefore, none of these studies meets the requirement of OECD TG 301 and the information requirement is not fulfilled.

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

1. Hydrolysis as a function of pH

Hydrolysis as a function of pH is an information requirement under Annex VIII to REACH (Section 9.2.2.1.).

You have adapted the information according to Annex VIII, Section 9.2.2.1., Column 2 with the following justification: "*The test substance being a complex reaction product with a low water solubility (0.0364 mg/L according to an OECD 105 test; <1 mg/L), the assessment of hydrolysis as function of pH was thus not conducted*".

We have assessed this information and identified the following issues:

A. Under Section 9.2.2.1., Column 2, first indent, Annex VIII to REACH, the study may be omitted if the substance is readily biodegradable.

   As explained under request A.1, the information provided on ready biodegradability is not compliant. Therefore you have not demonstrated that the Substance is readily biodegradable.

B. Under Section 9.2.2.1., Column 2, second indent, Annex VIII to REACH, the study may be omitted if the substance is highly insoluble in water. A substance is considered highly insoluble if the recommended OECD test guideline or EU method (Article 13(3) of REACH), in this case OECD TG 111, is not technically feasible. The test guideline is generally applicable to any chemical substances (unlabelled or labelled) for which an analytical method with sufficient accuracy and sensitivity is available. In this context, the analytical method is considered sufficiently sensitive if the test substance concentrations can be quantified down to 10 % or less of the initial

   In section 4.8 of your dossier you report a water solubility estimate of 36.4 µg/L based on a modified OECD TG 105 method. In Section 6.1.4 of your dossier, you report a recent long-term toxicity study to aquatic invertebrates (Chastenet, 2018) with a limit of quantification (LoQ) of 2 µg/L for the test substance.

   While the Substance has low water solubility, the information in your dossier support that it can be quantified down to 10 % or less of its saturation in water. Therefore, you have not demonstrated that the Substance is highly insoluble, *i.e.* too insoluble to conduct an OECD TG 111.

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

In your comments on the draft decision, you state that, if ECHA confirms that the information requirement for ready biodegradability is not fulfilled, you intend to first conduct a new ready biodegradability study as requested under A.2 above. If the Substance is found to be readily biodegradable, you intend to adapt the information requirement for Hydrolysis as a function of pH based under Section 9.2.2.1., Column 2, first indent, Annex VIII to REACH.

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[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 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

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 11 November 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 requests but amended the deadline for the reasons explained below.

The timeline indicated in the draft decision to provide the information requested is 12 months from the date of adoption of the decision.

In your comments on the draft decision, you requested an extension of the timeline to 18 months. You justified your request stating that:

- if ECHA confirms the need to generate further data on ready biodegradability, you intend to conduct a sequential testing by first conducting a ready biodegradability study and then deciding whether an adaptation under first indent of Section 9.2.2.1, column 2 of Annex VIII to REACH may be applicable or if a hydrolysis study needs to be conducted;
- you consider the Substance difficult to test as it is a UVCB with low water solubility.

We note that the deadline of 12 months already allows conducting sequential testing for most substances. We further note that a sensitive analytical method has already been developed in the context of aquatic toxicity testing and that the identity of potential hydrolysis products can be anticipated with a good level of confidence based on the structure. However, we acknowledge that the Substance has low solubility which may pose some technical challenges when conducting a hydrolysis study. Therefore, we granted an extra 3 months to account for a potential need to further refine the analytical method to conduct the hydrolysis test requested in the decision.

Hence, ECHA has only partially granted the request and set the deadline to 15 months.

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)[5]

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

OECD Guidance documents[6]

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.

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

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.