~~Confidential~~

Helsinki, 26 October 2023

**Addressee(s)**
Registrant(s) of JS_SPG_Spiroglycol as listed in Appendix 3 of this decision

**Date of submission of the dossier subject to this decision**
15 August 2022

**Registered substance subject to this decision ("the Substance")**
Substance name: 3,9-bis(1,1-dimethyl-2-hydroxy ethyl)-2,4,8,10-tetraoxaspiro[5,5]undecane
EC/List number: 485-230-3

**Decision number:** Please refer to the REACH-IT message which delivered this communication (in format TPE-D-XXXXXXXXXX-XX-XX/F)

## DECISION ON TESTING PROPOSAL(S)

Under Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***3 August 2026***.

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

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

1. Dissociation constant (Annex IX, Section 7.16.; test method OECD TG 112);

2. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: OECD TG 408) by oral route, in rats.

3. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) by oral route, in one species (rat or rabbit)

4. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: EU C.25./OECD TG 309) at a temperature of 12°C.

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(s) of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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 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 decision
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 decision

### Contents

**Appendix 1: Reasons for the decision ..... 3**

**Reasons for the decision(s) related to the information under Annex IX of REACH ..... 4**

1. Dissociation constant ..... 4
2. Sub-chronic toxicity study (90-days) ..... 4
3. Pre-natal developmental toxicity study ..... 6
4. Simulation testing on ultimate degradation in surface water ..... 6

**References ..... 9**

**Appendix 2: Procedure ..... 10**

**Appendix 3: Addressee(s) of this decision and their corresponding information requirements ..... 11**

**Appendix 4: Conducting and reporting new tests for REACH purposes ..... 12**

**Reasons for the decision(s) related to the information under Annex IX of REACH**

## 1. Dissociation constant

1 Dissociation constant is an information requirement under Annex IX to REACH (Section 7.16.).

### *1.1. Information provided to fulfil the information requirement*

2 You have submitted a testing proposal for a Dissociation constants in water test (test method: OECD TG 112) on the Substance.

3 Your registration dossier does not include any information on Dissociation constant.

4 ECHA agrees that an appropriate study on Dissociation constant is needed.

### *1.2. Test selection and study specifications*

5 The proposed Dissociation constants in water test (test method: OECD TG 112) is appropriate to cover the information requirement on Dissociation constant (ECHA Guidance R.7.1.17.3.).

### *1.3. Outcome*

6 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

## 2. Sub-chronic toxicity study (90-days)

7 A sub-chronic toxicity study (90 day) is an information requirement under Annex IX, Section 8.6.2.

### *2.1. Information provided to fulfil the information requirement*

8 You have submitted a testing proposal for a Sub-chronic toxicity study (90 day) according to OECD TG 408 with the Substance.

9 ECHA requested your considerations for alternative methods to fulfil the information requirement for Repeated dose toxicity. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

10 ECHA received third party information concerning the testing proposal during the third-party consultation.

11 A third party has indicated that the existing 28-day repeated dose toxicity study (OECD TG 407) with the Substance reports a NOAEL of 1000 mg/kg bw/day and therefore the Substance appears to meet the definition of a 'low toxicity substance' and a 90-day study is not justified.

12 Although not explicitly stated, ECHA understands that the third party comment refers to the adaptation possibility under Annex IX, Section 8.6.2., column 2, first paragraph, fourth indent. This adaptation possibility specifies that a sub-chronic toxicity study (90-day) does not need to be conducted if "*the substance is unreactive, insoluble and not inhalable and*

*there is no evidence of absorption and no evidence of toxicity in a 28-day study, particularly if such a pattern is coupled with limited human exposure*". ECHA notes that all criteria need to be met.

13 ECHA observes that the third party comments addressed only the criterion concerning "no evidence of toxicity". The third party did not submit information regarding the other cumulative criteria under Annex IX, Section 8.6.2., column 2, first paragraph, fourth indent.

14 Therefore, based on the information submitted by the third party the cumulative criteria listed in Annex IX, section 8.6.2., column 2, first paragraph fourth indent are not met. ECHA notes that it is your responsibility to consider and justify in the registration dossier any adaptation of the information requirements in accordance with Annex IX, Section 8.6.2., column 2, first paragraph, fourth indent.

15 ECHA agrees that a 90-day study is necessary.

### *2.2. Specification of the study design*

16 You proposed testing in the rat. ECHA agrees with your proposal because the rat is the preferred species according to the OECD TG 408. Therefore, the study must be conducted in the rat.

17 You proposed testing by the oral route. ECHA agrees with your proposal because this route of administration is appropriate to investigate systemic toxicity (Guidance on IRs and CSA, Section R.7.5.4.3.2.)

18 In the comments to the draft decision, you indicate your intention to adapt this information requirement based on the adaptation possibility under Annex IX, Section 8.6.2, column 2, first paragraph, fourth indent. As already indicated in Section 2.1., this adaptation possibility specifies that a sub-chronic toxicity study (90-day) does not need to be conducted if "*the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day study, particularly if such a pattern is coupled with limited human exposure*". ECHA notes that all criteria need to be met to omit the study.

19 In your comments, you consider the Substance to be unreactive. However, you note that the Substance is '*likely to be converted to the acid and/or conjugated with glucuronic acid or sulphate*'. ECHA considers that this indicates reactivity of the Substance.

20 Further, you acknowledge that the Substance has '*some*' water solubility. Therefore, ECHA considers that the Substance is not insoluble. You further specified that the particle size distribution of the Substance is below 100 µm, which ECHA considers as an inhalable size (Guidance on IRs and CSA, Section R.7.5.6.3.4).

21 ECHA notes that the legal requirement regarding '*no evidence of absorption*' requires that there has to be evidence of the lack of absorption of the substance in order to omit the study (Guidance on IRs and CSA, Section R.7.5.4.3.4). There is no such evidence available in your registration dossier. In fact, you acknowledge that the Substance '*is likely to be absorbed orally and through the skin*. You also describe that the Substance and its metabolites are likely to '*be excreted in the bile*' or '*in urine*'.

22 You indicate that the Substance appears to be non-toxic. ECHA acknowledges there is no evidence of toxicity in the available 28-day study.

23 Finally, you indicate that the Substance is predominantly used under industrial conditions with effective protective measures in the production of polymers. ECHA notes there is no exposure assessment performed or risk management measures specified in the CSR to estimate and minimise exposure of workers to the Substance.

24 Since all the cumulative criteria listed in Annex IX, section 8.6.2., column 2, first paragraph fourth indent are not met, the sub-chronic study (90 days) must be conducted.

*2.3. Outcome*

25 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test, as specified above.

## 3. Pre-natal developmental toxicity study

26 A pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is an information requirement under Annex IX, Section 8.7.2.

*3.1. Information provided to fulfil the information requirement*

27 You have submitted a testing proposal for a PNDT study according to the OECD TG 414 by the oral route with the Substance.

28 ECHA requested your considerations for alternative methods to fulfil the information requirement for Developmental toxicity. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

29 ECHA agrees that a PNDT study in a first species is necessary.

*3.2. Specification of the study design*

30 You proposed testing in the rat as a first species. You may select between the rat or the rabbit because both are preferred species under the OECD TG 414 (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

31 You proposed testing by the oral route. ECHA agrees with your proposal because this route of administration is the most appropriate to investigate reproductive toxicity (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

*3.3. Outcome*

32 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test, as specified above.

## 4. Simulation testing on ultimate degradation in surface water

33 Simulation testing on ultimate degradation in surface water is an information requirement under Annex IX to REACH (Section 9.2.1.2.).

34 Simulation testing on ultimate degradation in surface water does not need to be conducted if the substance is highly insoluble in water or is readily biodegradable (Annex IX, Section 9.2.1.2, column 2).

35 In your technical dossier, you have provided that

- the Substance is well soluble (water solubility 168 mg/L based on EU method A.6)

- the Substance is not readily biodegradable (38 % biodegradation after 28 days based on OECD TG 301B)

36 Therefore, the Substance is considered to be well soluble and not readily biodegradable and information on Simulation testing on ultimate degradation in surface water must be provided.

*4.1. Information provided to fulfil the information requirement*

37 You have submitted a testing proposal for an Aerobic mineralisation in Surface Water – Simulation biodegradation test (test method: EU C.25/OECD TG 309).

38 Your registration dossier does not include any information on aerobic transformation in aquatic surface water systems.

39 ECHA agrees that an appropriate degradation simulation study in surface water is needed.

*4.2. Test selection and study specifications*

40 The proposed Aerobic mineralisation in Surface Water – Simulation biodegradation test (test method: EU C.25/OECD TG 309) is appropriate to cover the information requirement for degradation/biodegradation (Guidance on IRs and CSA, Section R.7.9.4.1).

41 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):

1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

42 You must perform the test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (Guidance on IRs and CSA, Section R.11.4.1.1.3.).

43 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Section R.16, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 309.

44 As specified in Guidance on IRs and CSA, Section R.7.9.4.1., the organic carbon (OC) concentration in surface water simulation tests is typically 2 to 3 orders of magnitude higher than the test substance concentration and the formation of non-extractable residues (NERs) may be significant in surface water tests. Paragraph 52 of the OECD TG 309 provides that the "*total recovery (mass balance) at the end of the experiment should be between 90% and 110% for radiolabelled substances, whereas the initial recovery at the beginning of the experiment should be between 70% and 110% for non-labelled substances*". NERs contribute towards the total recovery. Therefore, the quantity of the (total) NERs must be accounted for the total recovery (mass balance), when relevant, to achieve the objectives of the OECD TG 309 to derive degradation rate and half-life. The reporting of results must include a scientific justification of the used extraction procedures and solvents.

45 For the persistence assessment by default, total NERs is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NERs may be differentiated and quantified as irreversibly bound or as degraded to biogenic NERs, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in

regulatory persistence assessment available on the ECHA website (NER - summary 2019 (europa.eu)).

46 Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 309; Guidance on IRs and CSA, Section R.11.4.1.).

### *4.3. Outcome*

47 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test, as specified above.

## 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**

ECHA received your testing proposal(s) on 23 August 2022 and started the testing proposal evaluation in accordance with Article 40(1).

ECHA held a third-party consultation for the testing proposal(s) from 28 November 2022 until 12 January 2023. ECHA received information from third parties (see corresponding Appendix/Appendices)

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

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.

In the comments to the draft decision, ECHA understands that you request an extension of the deadline, but you have not provided any documentary evidence of a CRO. As explained above, the deadline has already been extended to account for longer lead times in contract research laboratories. Therefore, ECHA has not granted you an additional extension.

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) and the deadline.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

## Appendix 3: Addressee(s) 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 Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;

| Registrant Name | Registration number | Highest REACH Annex applicable to you |
|---|---|---|
| [redacted] | [redacted] | [redacted] |
| [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

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.

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

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. General recommendations for conducting and reporting new tests

References to Guidance on REACH and other supporting documents can be found in Appendix 1.

[3] https://echa.europa.eu/manuals