~~Confidential~~

Helsinki, 23 June 2022

Addressees
Registrant(s) of JS_Pt(IV)N as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
11/05/2021

Registered substance subject to this decision ("the Substance")
Substance name: platinum(IV) nitrate/nitric acid solution
EC number: 432-400-1

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)

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), **the testing proposal listed below is rejected**:

Testing proposal(s) under Annex VIII to REACH

1. In vivo mammalian alkaline comet assay (OECD TG 489) combined with the in vivo mammalian erythrocyte micronucleus test (OECD TG 474) and toxicokinetic study using the analogue substance platinum(IV) aqua hydroxo nitrato complexes (EC no. 701-319-4).

Reasons for the rejection are explained in Appendix 1.

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.

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

[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

Reasons for the decision related to the information under Annex VIII of REACH

1 This decision is based on the examination of the testing proposal you submitted.

2 In the testing proposal examination, ECHA has only assessed the need for the test. This assessment resulted in the rejection of the testing proposal.

1. In vivo mammalian alkaline comet assay combined with in vivo mammalian erythrocyte micronucleus test

3 Appropriate in vivo mutagenicity studies must be considered under Annex VIII to REACH (Section 8.4., Column 2) in case of a positive result in any of the in vitro genotoxicity studies under Annex VII or VIII to REACH. The generation of new information should be tailored to real information needs, and unnecessary animal testing should be avoided.

1.1. Information provided

4 You have submitted a testing proposal for an In vivo mammalian alkaline comet assay combined with an in vivo mammalian erythrocyte micronucleus test and a toxicokinetic study, to be performed with the analogue substance platinum(IV) aqua hydroxo nitrato complexes, (EC no. 701-319-4).

5 Your dossier contains positive results in the following studies performed with the analogue substance platinum(IV) aqua hydroxo nitrato complexes (EC no. 701-319-4): in vitro gene mutation study in bacteria (OECD TG 471; 1999) and in vitro gene mutation study in mammalian cells (OECD TG 476; 2000).

6 We have assessed the information you provided and identified the following issue:

1.2. Grouping and read-across approach

7 Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

8 Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6. and related documents[2,3].

1.2.1. Absence of read-across documentation

9 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide a justification for the read-across including a hypothesis, explanation of the rationale for the prediction of properties and robust study summary(ies) of the study(ies) on the source substance(s) (Guidance on IRs and CSA, Section R.6.2.6.1.).

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[2] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)

[3] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://doi.org/10.2823/794394

10 For the in vitro mutagenicity studies (OECD TG 471 and 476), you have only provided data with a substance other than the registered Substance itself. However, you have not provided documentation as to why this information is relevant for the Substance.

11 In the absence of such documentation, the properties of the Substance cannot be reliably predicted from the data on the source substance(s).

1.2.2. Conclusions on the read-across approach

12 As explained above, you have not established that relevant properties of the Substance can be predicted from data on the analogue substance.

1.3. Conclusions

13 On the basis of read-across rejection and the information in your dossier, in particular the absence of positive in vitro mutagenicity results with your Substance, ECHA considers that, at this point in time, no further in vivo study needs to be performed, to further investigate the mutagenic properties of the Substance.

14 Your testing proposal is rejected under Article 40(3)(d) of REACH.

15 In your comments on the draft decision, you agreed that the dossier does not contain adequate information or justification for a read-across approach to genetic toxicity.

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).

All Guidance on REACH is available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF), ECHA (2017)
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs), ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: Procedure

This decision does not prevent ECHA from initiating a compliance check on the present dossier at a later stage.

ECHA received your testing proposal(s) on 11 May 2021 and started the testing proposal evaluation in accordance with Article 40(1).

ECHA held a third party consultation for the testing proposal(s) from 26 August 2021 until 11 October 2021. ECHA did not receive information from third parties.

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

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

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

> In your comments to the draft decision, you indicated that you would update your dossier with an improved read-across argumentation. For the purposes of this decision-making process there is no need for ECHA to assess any improved read-across of your substance as the present decision is not requesting you to perform a study. This is because at the time the draft evaluation decision was sent for your comments there was no information available in your dossier triggering the proposed test. Moreover, ECHA notes that the information contained therein is not substantial new information, as the information could have been provided earlier.
>
> Furthermore, ECHA notes that the registrants of the analogue substance have been requested to perform the study by 21 August 2023. Therefore, you will always be able to include the study with the analogue substance in your dossier after it has been completed by the registrants of that substance. ECHA may however assess the validity of your adaptations for the mutagenicity information requirements in a subsequent compliance check.

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

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

Appendix 3: Addressees of this decision

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 and VIII to REACH, for registration at 10-100 tpa.

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

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.