Helsinki, 30 July 2020

Addressees
Registrants of JS2245838 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
18/11/2019

Registered substance subject to this decision ("the Substance")
Substance name: 2,2'-azobis[2,4-dimethylvaleronitrile]
EC number: 224-583-8
CAS number: 4419-11-8

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

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 ***4 November 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) with the Substance;

i. *In vitro* skin sensitisation information on activation of dendritic cells (test method: EU B.71/OECD TG 442E)(Annex VII, Section 8.3.1.); and

ii. Only if the *in vitro* test methods specified under point 1 i.) are not applicable for the Substance, or the results obtained are not adequate for classification and risk assessment, *in vivo* skin sensitisation (Annex VII, Section 8.3.2.; test method: EU B.42./OECD TG 429).

2. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: EU B.13/14. / OECD TG 471)

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

4. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: [EU C.3./OECD TG 201 // EU C.26./OECD TG 221])

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

1. If negative results are obtained in tests performed for the information requirement of Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2. then: In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or OECD TG 490), with the Substance;

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 entitled "Reasons to request information required under Annexes VII to X 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;

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 a standard information requirement in Annex VII, Section 8.3. to the REACH Regulation. Column 1 of Section 8.3. requires the registrants to submit information allowing a conclusion whether the substance is a skin sensitiser and 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, based on which you conclude that "*The available information is conclusive and sufficient for classification as skin sensitising cat.1.*" and have self-classified the Substance as skin sensitiser category 1:

i. *In chemico* Direct Peptide Reactivity Assay (DPRA) (key study, OECD TG 442C, GLP, J. [redacted], 2018).
ii. *In vitro* ARE-Nrf2 Luciferase Test Method (LuSens) (key study, OECD TG 442D, GLP, A. [redacted], 2018).

Although you did not explicitly claim such an adaptation, we understand that the information provided aims to adapt the standard information requirement according to Annex VII, Section 8.3.1, column 2, second paragraph.

According to Annex VII, Section 8.3.1. Column 2, second paragraph, studies addressing the other key events do not need to be conducted if information from test methods addressing one or two of the key events in column 1 already allows classification and risk assessment (where required) according to point 8.3. That is A) whether the substance causes skin sensitisation, and B) whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A), in case, the substance is considered to be a skin sensitiser.

ECHA has assessed to what extent the sources of information submitted enables a conclusion on these properties A) and B).

Concerning A), ECHA agrees with your conclusion that the Substance is a skin sensitiser based on two positive *in vitro/in chemico* study results for key events: molecular interaction with skin proteins and inflammatory response in keratinocytes.

However, concerning B), no conclusion can be reached. You have not provided any considerations of how potent a sensitiser the Substance is and whether it has the potential to cause significant sensitisation in humans (Cat 1A). You have only considered that the Substance is a skin sensitiser and have allocated a general category i.e. Cat 1 according to CLP Regulation for self-classification.

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

To fulfil the information requirement for the Substance, information on activation of dendritic cells (EU B.71/OECD TG 442E) must be provided. Furthermore an appropriate risk assessment is required as a result of the classification of the Substance as a skin sensitiser (Cat 1A or 1B).

In case no conclusion on the skin sensitisation potency can be made for the Substance based on the existing *in vitro/in chemico* data or newly generated *in vitro* data, *in vivo* skin sensitisation study must be performed and the murine local lymph node assay (OECD TG 429)

is considered as the appropriate study for the potency estimation.

In your comments on the draft decision you recognise that a consideration on the potency of the substance as skin sensitiser is not available in the dossier. You further state that you would like to report your considerations on the potency of the Substance as a skin sensitiser and amend your existing conclusion on classification of the substance as skin sens. 1A. in an update of the dossier.

ECHA acknowledges your intention to update the dossier with your considerations on the potency of the Substance as a skin sensitiser.

2. In vitro gene mutation study in bacteria

An *in vitro* gene mutation study in bacteria is a standard information requirement in Annex VII to REACH.

You have provided in your dossier:

i. An *in vitro* gene mutation study in bacteria performed similarly to OECD TG 471 (study year assumed to be 1984) with the following strains, TA 98, TA 100, TA 1535, TA 1537, TA 1538 and E. coli WP2.

We have assessed this information and identified the following issue:

To fulfil the information requirement, the study has to meet the requirements of OECD TG 471 (1997). The key parameters of this test guideline include:

a) Triplicate plating must be used at each dose level.
b) One positive control must be included in the study. The positive control substance must produce a statistically significant increase in the number of revertant colonies per plate compared with the concurrent negative control.
c) The number of revertant colonies per plate for the concurrent negative control must be inside the historical control range of the laboratory.
d) The mean number of revertant colonies per plate must be reported for the treated doses and the controls.

However, the reported data for the study you have provided did not include:

a) triplicate plating at each dose level.
b) a positive control that produced a statistically significant increase in the number of revertant colonies per plate compared with the concurrent negative control.
c) a negative control with a number of revertant colonies per plate inside the historical control range of the laboratory.
d) data on the number of revertant colonies per plate for the treated doses and the controls.

As a result, the information provided does not cover the key parameters required by OECD TG 471.

Therefore, the information requirement is not fulfilled.

In your comments on the draft decision you agreed to perform the requested study.

3. Short-term toxicity testing on aquatic invertebrates

A short-term toxicity study on aquatic invertebrates is a standard information requirement in Annex VII to REACH.

You have provided an OECD TG 202 study in your dossier.

We have assessed this information and identified the following issue:

A robust study summary must be provided for the sole study available or, if more than one is available, for the study/ies giving rise to the highest concern (Articles 3(28) and 10(a)(vii) and Annex I, Section [3.1.5] of REACH).
A robust study summary must cover sufficient information to make an independent assessment of the study. For a study conducted according to OECD 202, this includes (among other information:

- observations in the controls: (level of immobilisation to demonstrate validity of study);
- a description of the preparation of test solutions, including the use of a solvent and/or an emulsifier (if any was used);
- a full description of the analytical monitoring method (e.g. calibration, recovery and sensitivity determination) and of the preparation of the test samples for analysis (including the description of filtration and/or extraction steps, if any);
- the results of the analytical determination of exposure concentrations and (if necessary) the calculation of effect levels as measured concentrations;
- other measurements throughout the test (dissolved oxygen, pH, hardness, temperature);

The study summary you provided does not include any of the information listed above.

Therefore the documentation of this study is insufficient and does not allow an independent assessment of the adequacy of this study, its results and its use for hazard assessment.

Consequently to fulfil the information requirement, you must submit compliant information from a test performed on the substance in accordance with OECD TG 202.

In your comments on the draft decision you indicate that you intend to update the dossier to include the missing information which is available to you in the full study report.

4. Growth inhibition study aquatic plants

A short-term toxicity study on acquatic invertebrates is a standard information requirement in Annex VII to REACH.

You have provided an OECD 201 study in your dossier:

We have assessed this information and identified the following issue:

A robust study summary must be provided for the sole study available or, if more than one is available, for the study/ies giving rise to the highest concern (Articles 3(28) and 10(a)(vii) and Annex I, Section [3.1.5] of REACH).
A robust study summary must cover sufficient information to make an independent assessment of the study. For a study conducted according to OECD 201, this includes (among other information):

- a description of the preparation of test solutions, including the use of a solvent and/or an emulsifier (if any was used);
- a full description of the analytical monitoring method (e.g. calibration, recovery and sensitivity determination) and of the preparation of the test samples for analysis (including the description of filtration and/or extraction steps, if any);
- the results of the analytical determination of exposure concentrations and (if necessary) the calculation of effect levels as measured concentrations;

- adequate raw data relative to cell density determination to allow a verification that the validity criteria of the method were fulfilled.

The study summary you provided does not include any of the information listed above.

Therefore the documentation of this study is insufficient and does not allow an independent assessment of the adequacy of this study, its results and its use for hazard assessment.

Consequently to fulfil the information requirement, you must submit compliant information from a test performed on the substance in accordance with OECD TG 201.

In your comments on the draft decision you indicate that you intend to update the dossier to include the missing information which is available to you in the full study report.

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

1. In vitro gene mutation study in mammalian cells

Triggering of the requirement

An *in vitro* gene mutation study in mammalian cells is a standard information requirement in Annex VIII to REACH in case of a negative result in the *in vitro* gene mutation test in bacteria and the *in vitro* cytogenicity test.

Your dossier contains:

i. a negative result for *in vitro* cytogenicity study in mammalian cells
ii. an *in vitro* gene mutation study in bacteria.

However, the *in vitro* gene mutation study in bacteria (ii) is rejected for the reasons provided in section A 2.

Therefore, the result of the request for information in section A.2 will determine whether the present requirement for an *in vitro* mammalian cell gene mutation study in accordance with Annex VIII, Section 8.4.3 is triggered.

Assessment of the information provided

For Annex VIII, 8.4.3., you have not provided any study in your dossier. However, you have adaptated this standard information requirement according to Annex XI, Section 1.2. of REACH (weight of evidence) In support of your adaptation, you have provided the following sources of information:

a. An OECD QSAR Toolbox 4.2 prediction for the nitrile category
b. An OECD QSAR Toolbox 4.2 prediction for the azo category

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.4.4, a weight of evidence adaptation involves an assessment of the relative values/weights of 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 of the information for the given regulatory information requirement. Subsequently, relevance, reliability, 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.

To fulfil the information requirement, normally a study performed according to OECD TG 476 or according to 490[2] must be provided. OECD TG 476 or 490 requires the study to investigate the following key parameters:

1. *In vitro* gene mutations in mammalian cell lines induced by chemicals
2. For the OECD TG 476 detect forward mutations in reporter genes, either *Hprt* in rodent cells, *HPRT* in human cells
3. For the OECD TG 490 detect forward mutations in reporter genes, either *Tk* for rodent cells or *TK* for human cells

[2] ECHA Guidance R.7b, Section R.7.8.4.1

The sources of information (a) and (b) provided relevant information on gene mutations in mammalian cells.

However, the reliability of the sources of information (a) and (b) is significantly affected by the following deficiencies:

Annex XI, Section 1.3. states that results obtained from valid QSAR models may be used instead of testing when the following cumulative conditions are met, in particular: results are derived from a QSAR model whose scientific validity has been established.

According to ECHA's Practical guide "How to use and report (Q)SARs", section 3.4, a QSAR Model Reporting Format (QMRF) and a QSAR Prediction Reporting Format (QPRF) are required to establish the scientific validity of the model, to verify that the Substance falls within the applicability domain of the model, and to assess the adequacy of the prediction for the purposes of classification and labelling.

You have provided QSAR predictions for this endpoint, concluding that the Substance is predicted negative for *in vitro* gene mutation in mammalian cells.

We have assessed the sources of information (c) and (d) you provided and we identified the following issue(s):

In (a) and (b), the scientific validity of the model has not been established, because it does not fulfil the OECD principles for a QSAR model to be considered scientifically valid (see ECHA Guidance R.6, Section R.6.1.3, and ECHA's Practical guide "How to use and report (Q)SARs", section 3.1), in particular: The QSAR predictions are provided from two categories formed by application of the OECD QSAR Toolbox. The profiles "organic functional groups: Azo" and "organic functional groups: Nitrile" were used separately in the Toolbox to gather analogues. You explain the use of this approach because *"no category of substances was available having both (or all*) profiles of the substance"*. It is not clear from the provided documentation (e.g. from the category reports) how the analogues were selected.

However, a number of issues are readily apparent:

1) Scientific validity of the models

- You used the Toolbox to derive predictions within available endpoint schema. It is "Gene mutation I", which is an aggregated schema in the OECD QSAR Toolbox to combine results from different studies. You report mixed data from different endpoint types (e.g. Ames test data and data from chromosomal aberration tests). It is not clear which data were used to make the prediction. You furthermore define in the manually editable Toolbox reports that the predicted endpoint in all the cases is mouse lymphoma L5178Y cells; no duration is specified; no guideline is specified, only Unit/scale is given as "Gene mutation I".
- Mixing endpoints types does not have scientific and regulatory relevance for filling data gaps under REACH. Thus, we consider the results from mixed data are inadequate for the purpose of classification and labelling and/or risk assessment.
- You don't provide references for the data points used to derive the prediction.

Hence, you have not established the scientific validity of the models , because it does not fulfil the OECD principles for a QSAR model to be considered scientifically valid (see ECHA Guidance R.6, Section R.6.1.3, and ECHA's Practical guide "How to use and report (Q)SARs", section 3.1)

2) Applicability domain

- Aditionally, the structural similarity between the target and the analogues in both the "azo" and "nitrile" groups is either low or zero (as defined by the OECD QSAR Toolbox). For some analogues there was low similarity (highest at 53%) but none of these had relevant data on in vitro mammalian cells.
- There is large variation in physico-chemical properties between the Substance target and the analogues in the "azo" group used to make prediction and consequently some predictions are reported as out of domain. In addition, there is no information on the source of the octanol-water partition coefficients (log P) information (e.g. experimental or calculated) which is used in the prediction.
- The category report files shows many inconsistencies between the functional profiles of target and the analogues and possible bias in the selection of analogues. For example, mutagenicity alerts the target has an alert for Aliphatic azo and azoxy. It is not explained how the other selected analogues do not have this alert.

  In absence of clarity on the source of the log P information and given the lack of similarity between the Substance and the analogues, it is not possible to conclude that the Substance falls within the applicability domain.

Therefore, sources of information (a) and (b) are substantially unreliable.

As a conclusion on your weight of evidence adaptation, the sources of information as indicated above, may provide information on in vitro gene mutation in mammalian cells but essential parts of information of the dangerous property (key parameters listed above) is lacking.

Accordingly, 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 properties foreseen to be investigated in an OECD TG 476 or in an OECD TG 490 study. Therefore, your adaptation is rejected and the information requirements is not fulfilled.

In your comments on the draft decision you agreed to perform the requested study.

2. Short-term toxicity testing on fish

A short-term toxicity study on fish is a standard information requirement in Annex VII to REACH.

You have provided an OECD 203 study in your dossier:

We have assessed this information and identified the following issue:

A robust study summary must be provided for the sole study available or, if more than one is available, for the study/ies giving rise to the highest concern (Articles 3(28) and 10(a)(vii) and Annex I, Section 3.1.5 of REACH).
A robust study summary must contain sufficient information to make an independent assessment of the study. For a study conducted according to OECD 203, this includes (among others):

- test design (test concentrations, number of controls);
- observations in the controls:(mortality level to demonstrate validity of study);
- a description of the preparation of test solutions, including the use of a solvent and/or an emulsifier (if any was used);
- a full description of the analytical monitoring method (e.g. calibration, recovery and sensitivity determination) and of the preparation of the test samples for analysis (including the description of filtration and/or extraction steps, if any);

- the results of the analytical determination of exposure concentrations and (if necessary) the calculation of effect levels as measured concentrations;
- other measurements throughout the test (dissolved oxygen, pH, hardness, temperature);

The study summary you provided does not include any of the information listed above.

Therefore the documentation of this study is insufficient and does not allow an independent assessment of the adequacy of this study, its results and its use for hazard assessment.

Consequently to fulfil the information requirement, you must submit compliant information from a test performed on the substance in accordance with OECD TG 203.

In your comments on the draft decision you indicate that you intend to update the dossier to include the missing information which is available to you in the full study report.

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

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[4].

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

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

Appendix D: General recommendations when conducting and reporting new tests for REACH purposes

A. Testing strategy for aquatic toxicity testing

You are advised to consult ECHA Guidance R.7b, (Section R.7.8.5) which describes the Integrated Testing Strategy, to determine the sequence of aquatic toxicity tests and testing needed.

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 02 July 2019.

ECHA notified you of the draft decision and invited you to provide comments within 30 days of the notification.

In your comments on A. 2 and B.1 you agreed to the draft decision. ECHA took your comments into account and did not amend the requests.

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[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)[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.

OECD Guidance documents[7]

[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

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 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
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[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.