Helsinki, 30 July 2020

Addressees
Registrants of Vazo67_JSO as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
30/04/2019

Registered substance subject to this decision ("the Substance")
Substance name: 2,2'-azobis[2-methylbutyronitrile]
EC number: 236-740-8
CAS number: 13472-08-7

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 2022***.

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. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: EU B.13/14. /OECD TG 471) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102

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

1. In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2.; test method: OECD TG 473) or In vitro micronucleus study (Annex VIII, Section 8.4.2.; test method: OECD TG 487)
2. 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 TG 490)
3. Justification for an adaptation of a Short-term repeated dose toxicity (28 days) based on the results of the Sub-chronic toxicity study (90 days) requested below (Annex VIII, Section 8.6.1.)
4. 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
5. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: OECD TG 203)

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

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

3. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)
4. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210)

Reasons for the requests are explained in the following appendices:

- Appendix entitled "Reasons common to several requests";
- Appendices entitled "Reasons to request information required under Annexes VII to IX 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;
- 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 on Reasons common to several requests

1. **Assessment of your read-across approach under Annex XI, Section 1.5. concerning toxicological information requirements**

You seek to adapt the following standard information requirements on human health by applying a read-across approach in accordance with Annex XI, Section 1.5:

- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)
- In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)
- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)
- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

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.

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance[2] and related documents[3, 4].

You have provided a read-across justification document in IUCLID Section 13.2

You read-across between the structurally similar substances, 2,2'-dimethyl-2,2'-azodipropiononitrile, EC No. 201-132-3 (CAS No. 78-67-1) **"AIBN"** as source substance and the Substance **"AMBN"** as target substance.

You have provided the following reasoning for the prediction of toxicological properties: *"The underlying hypothesis for the read-across between the test substance and 2,2'-azobis(isobutyronitrile) is that the two substances are similar in physicochemical properties, have common effects seen at acute exposures, and are similar in metabolic pathway."*.

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

ECHA notes the following shortcomings with regards to predictions of toxicity.

1. Relevance of the supporting information

[2] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals. 2008 (May) ECHA, Helsinki. 134. pp. Available online: https://echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf/77f49f81-b76d-40ab-8513-4f3a533b6ac9

[3] 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)

[4] 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

According to the ECHA Guidance "*it is important to provide supporting information to strengthen the rationale for the read-across approach. Thus, in addition to the property/endpoint being read-across, it is also useful to show that additional properties, relevant to the endpoint, are also (qualitatively or quantitatively) similar between the source and target chemicals*".

In order to support your claim that your Substance and source substance(s) have similar properties for the endpoints under consideration in the read-across approach, you refer to their acute toxicity, skin irritation, eye irritation and, skin sensitisation properties.

Whilst this data set suggests that the substances may have similar properties for acute toxicity, skin and eye irritation, and skin sensitisation, these studies do not inform on the mutagenicity, repeated dose, developmental and reproductive toxicity properties of the target and source substances. Accordingly, these information are not considered as relevant to support prediction of all the endpoints under consideration.

2. Missing supporting information

As explained above, supporting information to verify the crucial aspects of the read-across is required.

Your read-across hypothesis is based on the assumption that the structurally similar substances cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) is necessary to confirm that both substance cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s).

The supporting information you have provided per information requirement is summarised below.

- *Mutagenicity*

  For mutagenicity you refer to various (Q)SAR predictions which indicate that the substance is not mutagenic.

  Also, in your comments to the proposals for amendment (PfAs), submitted by one of the Member States Competent Authorities (MSCA's), you refer to additional QSAR models that predict that "*The query structure does not match any structural alerts or examples for (bacterial in vitro) mutagenicity in Derek".* Additionally, you state that "*the query structure does not contain any unclassified or misclassified features and is consequently predicted to be inactive in the bacterial in vitro (Ames) mutagenicity test.*"

  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 not included endpoint study records for the QSAR predictions with a QMRF and/or a QPRF in your technical dossier under *in vitro* gene mutation in bacteria, *in*

vitro chromosomal aberration or *in vitro* gene mutation in mammalian cells. Also, for the *in vitro* gene mutation in bacteria, you have not provided the QSAR predictions with a QMRF and/or a QPRF in your comments to the PfAs.

Therefore, ECHA cannot establish whether the model is scientifically valid, whether the Substance falls within the applicability domain of the model, and whether the results are adequate for classification and labelling and/or risk assessment.

Regardless of the above critical deficiency, ECHA notes the following issues with your predictions.

a. Prediction for *in vitro* gene mutation in mammalian cells

You explain that your QSARs are typically derived from Ames (*in vitro* test in bacteria) data. Based on these QSAR data you note the following:

For *in vitro* gene mutation in mammalian cells you expect that the outcomes would be similar to the those from the Ames data.

The endpoint for which you predict is *in vitro* gene mutation in mammalian cells. *In vitro* mammalian cell investigations are required when an *in vitro* gene mutation study in bacteria and an *in vitro* cytogenicity study in mammalian cells are negative. This is because the sensitivity and specifity of the tests in the various cells can vary with different classes of substances.

Your QSAR predictions are built based on *in vitro* data from bacterical cells only. You have not sufficiently explained why you consider QSAR predicitions for gene mutation in bacterial cells (Ames data) as suitable predictors of gene mutation in mammalian cells. Consequently, ECHA concludes that these predictions do not provide any information on *in vitro* gene mutation in mammalian cells.

b. Prediction for *in vitro* chromosomal aberration

As explained above your QSARs are derived from Ames (*in vitro* test in bacteria) data. For *in vitro* chromosomal aberration you state that *"no prediction was feasible for either AIBN or AMBN"*.

Consequently, ECHA concludes that these predictions do not provide any information on *in vitro* chromosomal aberration.

- *Repeated dose toxicity and Developmental/Reproduction effects*

The data set reported in the technical dossier does not include relevant, reliable and adequate information on repeated dose toxicity and developmental toxicity for both the Substance and the source substance to enable comparison of the properties in support of your read-across hypothesis. The only relevant and reliable information available covering these endpoints is for the source substance only.

In your comments to the draft decision and to the PfAs you indicate your intention to strengthen the read-across justification document including the Annex VIII data (requested under Appendix B.1 to B.4). ECHA acknowledges your intention to strengthen and update the read-across document, including the Annex VIII data as requested in this decision.

As explained above, currently you have not established that relevant properties of the Substance can be predicted from data on the analogue substance. Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected.

2. Assessment of the weight of evidence adaptations, under the requirements of Annex XI, Section 1.2, provided for the ecotoxicological information requirements

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

- Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)
- Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)
- Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

Your WoE for each of the above involves QSAR predictions and read across information (studies on the analogue **AIBN**).

Annex XI, Section 1.2 states that there may be sufficient WoE 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 WoE 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.

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

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

In spite of this critical deficiency, ECHA has nevertheless assessed the validity of your adaptation and identified the following issues. These issues identified below apply systematically to all the information requirements in which you applied a WoE adaptation.

1. Reliability of the QSAR information as part of your WoE adaptation

The sources of information you provided refers to Qualitative or quantitative structure-activity relationship (QSAR) in accordance with Annex XI, Section 1.3:

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 validty has been established;
- the substance falls within the applicability domain of the QSAR model;

- adequate and reliable documentation of the applied method is provided; and
- the results are adequate for classification and labelling and/or risk assessment.

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 estimated toxicity values for the information requirements listed above using ECOSAR version 1.11. You have also provided a QMRF and QPRF.

ECHA has assessed the estimations and your documentation and notes the following issue.

The ECOSAR predictions of aquatic toxicity for the Substance are not scientifically valid.
The OECD principles for QSAR validity (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) list various principles for QSAR validity. These principles include (among others) that:

1. The model should be associated with appropriate measures of goodness-of–fit, robustness and predictivity. This principle expresses the need to provide two types of information: a) the internal performance of a model (as represented by goodness-of-fit and robustness), determined by using a training set; and b) the predictivity of a model, determined by using an appropriate test set.
2. The model should be associated with a defined domain of applicability. The need to define an applicability domain expresses the fact that QSARs are reductionist models which are inevitably associated with limitations in terms of the types of chemical structures, physico-chemical properties and mechanisms of action for which the models can generate reliable predictions.

The chemical class model *"Nitriles, polyaliphatic"* of ECOSAR for acute toxicity to fish was built using a training set containing two substances only (1,4-Dicyanobutane, with three test concentrations) and 1,6-Dicyanohexane (one test concentration). For acute toxicty to Daphnia the model is built on a single data point (1,4-Dicyanobutane).

Additionally, the predictions are outside of the applicability domain of the fish toxicity models because both substances in the training set are structurally different to the Substance as they do not contain an azo group. As regards the Daphnia toxicity model, an applicability domain cannot be defined for a model built on a single data point.

ECHA considers that the OECD principles for QSAR validityare not met due to the limited data in the training sets of these models, consequently they also are not considered adequate for classification and labelling and/or risk assessment.

Since the predictions for chronic toxicity to fish and daphnia are derived using acute-to-chronic ratios, the long-term predictions are equally unreliable.

Therefore the sources of information based on a QSAR adaptation according to Annex XI, Section 1.3 are substantially unreliable.

3. Reliability of the read across approach as part of your WoE adaptation

In your read across justification you explain that you read-across between the structurally similar substances, 2,2'-diazene-1,2-diylbis(2-methylpropanenitrile) EC No. 201-132-3,

abbreviated as **AIBN**, as source substance and the Substance (abbreviated as **AMBN**) as target substance.

You have provided the following reasoning for the prediction of aquatic toxicity: *"AMBN and AIBN could be categorised as "unspecific reacting" chemicals by virtue of their nitrile functionality".* You also state that *"Empirical data in invertebrates and algae is available for AMBN. Empirical data in all 3 species is available for AIBN. A comparison of these data coupled with predictions generated from ECOSAR should help to substantiate the validity in any read across if appropriate".* Finally you state that *"given the difference in LogKow, AMBN could be expected to be more a potent toxicant relative to AIBN. Accordingly, reading-across from AIBN to satisfy data gaps from AMBN could give rise to an underestimation of likely potency".*

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

ECHA notes the following shortcomings with regards to predictions of aquatic toxicity.

- *Relevance of the supporting information*

  According to the ECHA Guidance[5] "*it is important to provide supporting information to strengthen the rationale for the read-across approach. Thus, in addition to the property/endpoint being read-across, it is also useful to show that additional properties, relevant to the endpoint, are also (qualitatively or quantitatively) similar between the source and target chemicals*".

  In order to support your claim that your Substance and source substance have similar properties for the endpoints under consideration in the read-across approach, you refer to comparative QSAR data (ECOSAR v1.1) on the source and target substances.

  For the reasons explained in Section **Error! Reference source not found.** of the present Appendix ECHA concludes that your QSAR adaptations are not scientifically valid and are rejected. Consequently, ECHA considers that they are not relevant as supporting information in the prediciton of aquatic toxicty.

- *Read-across hypothesis contradicted by existing data*

  As explained above, supporting information to verify the crucial aspects of the read-across is required. The observation of differences in the (eco)toxicological properties among substances subject to read-across is a crucial aspect of any read-across and should be carefully examined. Any such difference which contradicts the similarity claimed in the read-across hypothesis needs to be documented and its impact on the prediction of (eco)toxicological properties explained.

  As indicated above, your read-across hypothesis is based on the assumption that the target and source substances cause the same type of effects. The available data summarised in your read across justification suggest that there are differences in the ecotoxicological properties of the substances with the Substance (**AMBN**) being more

[5] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.2.1.f

potent than the source (**AIBN**) in the short term Daphnia studies (EC50=51.9mg/L vs >367mg/L). The opposite is true for algae where you indicate AIBN to be more potent. You also acknowledge that *"given the difference in LogKow, AMBN could be expected to be more a potent toxicant relative to AIBN. Accordingly, reading-across from AIBN to satisfy data gaps from AMBN could give rise to an underestimation of likely potency".*

These differences in the ecotoxicological properties contradict your read-across hypothesis and you have not explained what impact these differences have on your prediction. You acknowledge that application of read-across to **AMBN** may underestimate the potency of the Substance. Therefore you have not demonstrated and justified that the properties of the source substance and the Substance are likely to be similar despite the observation of these differences.

Therefore the sources of information based on a read across adaptation according to Annex XI, Section 1.5 are substantially unreliable.

Additional issues related to WoE are addressed under the corresponding endpoints.

Appendix A: Reasons to request information required under Annex VII of REACH

1. 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 adapted 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:

1) *In vitro* gene mutation study in bacteria ([redacted] 1991) with the Substance, according to OECD TG 471 and GLP (reliability 2).
2) *In vitro* gene mutation study in bacteria (Takenaka, 1993) with the Substance, no test guideline followed and non GLP compliant (reliability 4).
3) *In vitro* gene mutation study in bacteria (1999) with the analogue substance 2,2'-diazene-1,2-diylbis(2-methylpropanenitrile) (AIBN) (EC no. 201-132-3), according to OECD TG 471 and GLP (reliability 2).

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.

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

However, 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 nevertheless assessed the validity of your adaptation and identified the following issues.

To fulfil the information requirement, normally a study performed according to OECD TG 471 (1997) must be provided. OECD TG 471 requires the study to investigate gene mutations in bacteria using 5 different bacterial strains: four strains of *S. typhimurium* (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101).

Information source 1) provides relevant information on gene mutations in bacteria however the reliability of this information source is significantly affected as the study does not

investigate the required fifth strain, *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101).

Therefore, information source 1) does not provide information that would contribute to the conclusion on the information investigated by OECD TG 471.

Information sources 2) and 3) may provide relevant information on gene mutations in the appropriate five strains of bacteria.

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

Information source 2):

Although you do not explicitly claim an adaptation, ECHA understands that source of information 2) was submitted in order to meet the information requirement by means of adaptation according to 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.

The adaptation rule in Annex XI, Section 1.1.2. imposes a number of cumulative conditions for an adaptation to be valid, in particular: adequate and reliable documentation of the study is provided.

However, you have not provided adequate and reliable documentation in a form of a robust study summary, as required by Article 10(a)(vii) and Article 3(28). You have also assigned a reliability score of 4 (not assignable) to this source of information 2) due to limited information provided on the study.

Information source 3):

Information from source substances can be used as part of weight of evidence adaptation if the read-across is accepted.

However, for the reasons explained under Appendix on Reasons common to several requests, there are deficiencies identified with the read-across adaptation. These deficiencies affect significantly the reliability of the information source 3) relating to analogue substances and relied upon in your weight of evidence adaptation. Therefore the information source 3) cannot contribute to the weight of evidence adaptation.

Based on the above, information sources 2) and 3) cannot be considered as reliable sources of information that could contribute to the conclusion on this information investigated by the required study.

Taken together, even if these information sources provide information on gene mutations in bacteria, their reliability is affected so significantly that they cannot be taken into consideration in a weight of evidence approach.

Therefore, no conclusion can be drawn on gene mutations in the specific bacterial strains (*E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102) as required by the information requirement.

Therefore your WoE adaptation is rejected and information requirement is not fulfilled.

Comments to the PfAs

In your comments to the PfAs you state that "*Performing an in vitro cytogenicity study and if, this study is negative, also an in vitro gene mutation study in mammalian cells. This makes the results of an additional Ames test of no additional scientific value.*"

The *in vitro* gene mutation study in bacteria is a standard information requirement at Annex VII. As explained in the ECHA Guidance R.7a[6], the study is required as part of the testing strategy for mutagenicity. Therefore, the higher-tier *in vitro* mutagenicity studies in mammalian cells, required at Annex VIII (section 8.4.2. and 8.4.3.), cannot be used to waive the bacterial test required at Annex VII.

Outcome

To fulfil the information requirement for the Substance, the *in vitro* gene mutation study in bacteria (OECD TG 471) should be performed using one of the following strains: *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102.

[6] ECHA Guidance R.7a, Section R.7.7.6.3

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

1. In vitro cytogenicity study in mammalian cells or In vitro micronucleus study

An *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study is a standard information requirement in Annex VIII to REACH.

You have adapted the standard information requirement according to Annex XI, Section 1.5. of REACH. You have provided a key study in your dossier:

i. an *in vitro* cytogenicity / chromosome aberration (1999) in mammalian cells according to OECD Guideline 473 and GLP with an analogue 2,2'-diazene-1,2-diylbis(2-methylpropanenitrile) (CAS 78-67-1, EC 201-132-3) "**AIBN**".

your dossier also contains the following *in vivo* abstract:

ii. an *in vivo* mammalian somatic cell study: cytogenicity / erythrocyte micronucleus (Takenaka, 1993, abstract, with reliability 4) with the Substance.

We have assessed this information and identified the following issue(s):

1. Concerning study i)

For the reasons explained in section 1 of the Appendix on Reasons common to several requests your read across adaptation is rejected.

2. Concerning the abstract of study ii)

Column 2 of Section 8.4.2 of Annex VIII exempts registrants to submit the required study "*if adequate data from an* in vivo *cytogenicity test are available*". To be considered adequate, an *in vivo* cytogenicity study in mammalian cells has to meet the requirements of OECD TG 474, and the key parameters of this test guideline include:

A. The study must include a minimum of three doses/groups of treated animals, as well as a negative control group and a positive control group.
B. Each group must have a minimum of 5 analysable animals (the test can be performed in either sex).
C. The highest dose studied must be the maximum tolerated dose (MTD), i.e. the highest dose that is tolerated without evidence of toxicity (e.g. body weight depression or hematopoietic system cytotoxicity, but not death or evidence of pain, suffering or distress necessitating humane euthanasia). The highest dose can also be a dose that produces toxicity in the bone marrow (e.g. a reduction in the proportion of immature erythrocytes among total erythrocytes in the bone marrow or peripheral blood).
D. The proportion of immature among total (immature + mature) erythrocytes must be determined for each animal (by counting a total of at least 500 erythrocytes for bone marrow and 2000 erythrocytes for peripheral blood).
E. At least 4000 immature erythrocytes per animal must be scored for the incidence of micronucleated immature erythrocytes.
F. The proportion of immature erythrocytes among total erythrocytes and the mean number of micronucleated immature erythrocytes must be reported for each group of animals.

However, the study abstract you provided does not include the information listed above.

Therefore, the provided *in vivo* test is not adequate.

Information on the study design

To fulfil the information requirement for the Substance, both *in vitro* cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method OECD TG 473) and *in vitro* micronucleus study (Annex VIII, Section 8.4.2., test method OECD TG 487) are considered suitable.

In your comments on the draft decision you agree to perform the requested test.

2. In vitro gene mutation study in mammalian cells

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.

Triggering of the requirement

Your dossier contains adaptations for an *in vitro* gene mutation study in bacteria, and for an *in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study.

The information for the *in vitro* gene mutation study in bacteria and for the *in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study provided in the dossier are rejected for the reasons provided in sections A.1. and B.1. of this decision.

Therefore, the result of the requests for information in sections A.1. and B.1. 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

You have adapted the standard information requirement for *in vitro* mammalian cell gene mutation according to Annex XI, Section 1.5. of REACH. You have provided the following key study study in your dossier:

a) Mouse lymphoma (in vitro gene mutation in mammalian cells) study (2006), similar to OECD TG 476 with the analogue 2,2'-diazene-1,2-diylbis(2-methylpropanenitrile)(CAS 78-67-1, EC 201-132-3).

For the reasons explained in section 1 of the "Appendix on Reasons common to several requests" your read across adaptation is rejected.

In addition to these reasons, we have also identified the following issue with the provided information on the source substance.

The source information must in all cases have adequate and reliable coverage of the key parameters addressed in the corresponding test method. In this context the *in vitro* gene mutation study on mammalian cells the information has to meet the requirements of OECD TG 476 or OECD TG 490. The key parameter(s) of these test guidelines include:

i. The maximum concentration tested must induce 80-90% of cytotoxicity compared to the negative control, or the precipitation of the tested substance.
ii. If no precipitate or limited cytotoxicity is observed, the highest test concentration

must correspond to 10 mM, 2 mg/mL or 2 µl/mL, whichever is the lowest.

The reported data for the study you have provided indicate that there was limited cytotoxity (55+5% of cytotoxicity compared to the negative control) and there was no precipitation of the tested substance. However the highest test concentration did not correspond to 10 mM, 2 mg/mL or 2 µl/mL

The source information provided does not cover key parameter(s) required by the relevant OECD TG.

Therefore, the information requirement is not fulfilled.

Information on the study design
To fulfil the information requirement for the Substance, both the *in vitro* mammalian cell gene mutation tests using the hprt and xprt genes (OECD TG 476) and the thymidine kinase gene (OECD TG 490) are considered suitable.

In your comments on the draft decision you agree to perform the requested test in case of negative results for the information requirement of Annex VIII, Section 8.4.2.

3. Justification for an adaptation of a Short-term repeated dose toxicity (28 days) based on the results of the Sub-chronic toxicity study (90 days)

A Short-term repeated dose toxicity study (28 days) is a standard information requirement in Annex VIII to REACH.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5.

As explained in the "Appendix on Reasons common to several requests" your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

Column 2 of Annex VIII, Section 8.6.1. provides that an experimental study for this endpoint is not needed if a reliable sub-chronic (90 days) or chronic toxicity study is available.

The present decision requests the registrants concerned to generate and submit a reliable sub-chronic toxicity study (90 days) (see Appendix B, Section 1). According to Column 2 of Annex VIII, Section 8.6.1., and to prevent unnecessary animal testing, a short term toxicity study (28 days) does not therefore need to be conducted.

However, you still must comply with the information requirement in Annex VIII, Section 8.6.1., and therefore you are requested to submit a justification for the adaptation provided in Column 2 of that provision.

In your comments on the draft decision you agree to provide a justification for the adaptation of the Short-term repeated dose toxicity study as you intend to perform the screening for reproductive/developmental toxicity study (requested under B.4) according to OECD TG 422.

4. Screening for reproductive/developmental toxicity

A Screening for reproductive/developmental toxicity study (OECD TG 421 or 422) is a

standard information requirement under Annex VIII to REACH, if there is no evidence from analogue substances, QSAR or *in vitro* methods that the Substance may be a developmental toxicant.

There is no information available in your dossier indicating that your Substance may be a developmental toxicant.

You have adapted the standard information requirement according to Annex XI, Section 1.5. of REACH. In support of your adaptation of this information requirement, you have provided the following information for this endpoint:

a. A screening for reproductive / developmental toxicity key study ([redacted], 1999), according to OECD Guideline 422 and GLP with the analogue 2,2'-diazene-1,2-diylbis(2-methylpropanenitrile) (CAS 78-67-1, EC 201-132-3) in rat.

For the reasons explained in section 1 of the "Appendix on Reasons common to several requests" regarding read-across, 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[7] administration of the Substance.

In your comments on the draft decision you agree to perform the study according to OECD TG 422.

4. Short-term toxicity testing on fish

Short-term toxicity testing on fish is a standard information requirement in Annex VIII to the REACH Regulation.)

While an adaptation was not specifically indicated by you, ECHA has evaluated the provided information 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:

(i) an experimental study (Acute Toxicity of Perkadox AIBN to Brachydanio rerio) according to guideline OECD 203 conducted on the analogue substance **AIBN** (2,2'-diazene-1,2-diylbis(2-methylpropanenitrile), EC 201-132-3),
(ii) a read-across justification document entitled "Analogue reporting format Jul 2013",
(iii) a QSAR prediction (ECOSAR, version 1.11);

explained in Section 2 of the "Appendix on Reasons common to several requests", the WoE must fulfill 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 according to OECD TG 203[8] must be provided. . OECD TG 203 requires the study to provide information on:

[7] ECHA Guidance R.7a, Section R.7.6.2.3.2.
[8] ECHA Guidance R.7b, Section R.7.8.4.1

1. Mortalities of fish following exposure to the substance recorded at 24, 48, 72 and 96 hours and the concentrations of the Substance which kill 50 per cent of the fish (LC50).:

Sources of information (i), (ii) comprise a read across justificaton for an OECD guideline 203 study which provide an LC50 value for fish and so are considered as relevant information. However, the studies are considered substantially unreliable for the reasons explained in section 2 of the "Appendix on Reasons common to several requests".

Source of information (iii) provides LC50 for fish and is considered relevant. However, it is considered substantially unreliable for the reasons explained in section 2 of the "Appendix on Reasons common to several requests".

Due to the substantial deficiencies affecting the reliability of all the sources of information, 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 by the required study. Therefore, your adaptation is rejected and the information requirement is not fulfilled.

In your comments on the draft decision you agree to perform the requested test.

Appendix C: Reasons to request information required under Annex IX of REACH

1. Sub-chronic toxicity study (90-day)

A Sub-chronic toxicity study (90 day) is a standard information requirement in Annex IX to REACH.

You have provided an adaptation according to Annex XI, Section 1.5. in your dossier.

You have provided a key study performed with the analogue 2,2'-diazene-1,2-diylbis(2-methylpropanenitrile) (CAS 78-67-1, EC 201-132-3) for this endpoint in your dossier:

i. A repeated dose toxicity 90-day study in rat according to OECD TG 408 and GLP ([redacted], 2014).

However, for the reasons explained in section 1 of the "Appendix on Reasons common to several requests" your adaptation is rejected.

In your comments to the draft decision you ask for a tiered approach; you indicate that a final decision on the requirement of the Annex IX studies (requested under Section C.1 & C.2 of this decision) should be based on the results of the Annex VIII data (requested under Section B.1 to B.4 of this decision) and a strengthened and updated read across document.

ECHA acknowledges your intention to strengthen and update the read-across document, including the Annex VIII data as requested in this decision. However, as already explained in the read-across section above (General Appendix) currently the read-across approach cannot be accepted.

As regards your request for a tiered approach, ECHA notes that as long as the information requested by this decision is provided by the deadline indicated above then it is at your discretion to plan the sequence of the performance of the studies requested in this decision.

Therefore, the information requirement is not fulfilled.

Information on the design of the study to be performed (route/ species/ strain)

Referring to the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity, because because the Substance is reported to occur as a white crystalline solid without spraying applications.

Therefore the sub-chronic toxicity study must be performed according to the OECD TG 408, in rats and with oral administration of the Substance

2. Pre-natal developmental toxicity study in one species

A Pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is a standard information requirement under Annex IX to REACH.

You have provided an adaptation according to Annex XI, Section 1.5. in your dossier.

You have provided a key study in rat performed with the analogue 2,2'-diazene-1,2-diylbis(2-methylpropanenitrile) (CAS 78-67-1, EC 201-132-3) for this endpoint in your dossier:

However, for the reasons explained in section 1 of the "Appendix on Reasons common to several requests" your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

Regarding your comments on the draft decision please refer to the above section (C.1.).

3. Long-term toxicity testing on fish

Long-term toxicity testing on fish is a standard information requirement in Annex IX to REACH.

You have adapted this information requirement by using weight of evidence according to Annex XI, Section 1.2. In support of your adaptation, you have provided the following sources of information:

1. an experimental study (14-Day extended toxicity study of 2,2'-azobis (2-methylpropanitrile) in Oryzias latipes) according to guideline OECD 204 conducted on the analogue substance **AIBN**, EC 201-132-3),
2. a read-across justification document entitled "Analogue reporting format Jul 2013",
3. a QSAR prediction (ECOSAR, version 1.11);

As explained in Section 2 of the "Appendix on Reasons common to several requests", the WoE must fulfill 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 according to OECD TG 210[9] must be provided. This study provides information on lethal and sub-lethal effects of the Substance on the early life stages of the fish species tested. The key parameters investigated by this test are:

- Stage of embryonic development,
- Hatching and survival of embryos and larvae,
- Survival of juvenile fish,
- Abnormal appearance,
- Abnormal behaviour (e.g. hyperventilation, uncoordinated swimming, atypical quiescence and atypical feeding behaviour),
- Weight at the end of the test,
- Length at the end of the test.

Additionally, the conditions of exposure set out in OECD TG 210 indicate that:

(i) the test should start as soon as possible after the eggs have been fertilised, and
(ii) the duration is species-specific but should be long enough to allow the control fish to reach a juvenile life-stage (28-60 days post-hatch[10]).

Source of information (i) coupled with (ii) can provide information on mortality of adult or juvenile fish weight, length and abnormal appearance/behaviour. Accordingly, this source can

[9] ECHA Guidance R.7b, Section R.7.8.4.1
[10] OECD TG 210, Annex 2

provide information on lethal and sub-lethal effects of the material tested on the early life stages of fish and is therefore considered relevant.

However, some critical key parameters of the OECD TG 210 study such as 1. Stage of embryonic development, and 2. Hatching and survival of embryos and larvae, are not investigated in the OECD TG 204 study. Furthermore, this test has a duration of 14 days which is significantly shorter than the duration of the OECD TG 210. Effects observed can be considerably more pronounced when monitored over a longer duration.

In addition as regards source of information (i), the provided OECD TG 204 study is conducted on the analogue subsatnce **AIBN**. This read across is considered unreliable for the reasons explained in the "Appendix on Reasons common to several requests".

Consequently source of information (i) is substantially unreliable.
Source of information (iii) provides information on lethal and sub-lethal effects of the material tested on the early life stages of the fish and is therefore considered relevant. However, it is substantially unreliable for the reasons explained in section 2 of the "Appendix on Reasons common to several requests".

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

In your comments on the draft decision you suggest a tiered approach and propose to first examine adaptation possibilities once the results of the other aquatic toxicty studies are available before conducting this study. ECHA notes that the deadline in the decision already affords you the opportunity to do this.

Study design
The preferred test method to cover this information requirement under REACH is the OECD TG 210.

4. Long-term toxicity testing on aquatic invertebrates

Long-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex IX to REACH.

You have adapted this information requirement by using weight of evidence according to Annex XI, Section 1.2. In support of your adaptation, you have provided the following sources of information:

- a Daphnia magna reproduction inhibition study according to guideline OECD 202 (extended to 21 days) conducted on the analogue substance **AIBN**, EC 201-132-3,
- a read-across justification document entitled "Analogue reporting format Jul 2013",
- a QSAR prediction (ECOSAR, version 1.11);

As explained in Section 2 of the "Appendix on Reasons common to several requests", the WoE must fulfill 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 according to OECD TG 211[11] must be provided. This study provides information on the effect of the Substance on the reproductive output of Daphnia magna Straus over a period of 21 days.

Source of information (i) is a long term test that follows an older guideline than OECD TG 211. Accordingly it provides information on the effect of the tested material on the reproductive output of Daphnia magna Straus over a period of 21 days and is could be considered as relevant.

However, the study is conducted on the analogue subsatnce **AIBN**. This read across is condidered unreliable for the reasons explained in the "Appendix on Reasons common to several requests".

Source of information (iii) provides information on effect of the Substance on the reproductive output of Daphnia magna Straus over a period of 21 days and is therefore considered relevant. However, it is not reliable for the reasons explained in of the "Appendix on Reasons common to several requests".

Due to the substantial deficiencies affecting the reliability of all the sources of information, 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 by the required study. Therefore, your adaptation is rejected and the information requirement is not fulfilled.

In your comments on the draft decision you agree to perform the requested test.

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

Appendix D: 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[12].

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[13].

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

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

Appendix E: 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 F: Procedure

The information requirement for an Extended one-generation reproductive toxicity study (EOGRTS; Annexes IX or X, Section 8.7.3.) is not addressed in this decision. This may be addressed in a separate decision once the information from the Sub-chronic toxicity study (90-day) requested in the present decision is provided; due to the fact that the results from the 90-day study is needed for the design of the EOGRTS. Similarly the information requirement for a Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.) is not addressed in this decision; as the EOGRTS will cover the same parameters.

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.

ECHA took into account your comments did not amend the request(s).

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

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s) and referred the modified draft decision to the Member State Committee.

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

In addition, you provided comments on the draft decision. These comments were not taken into account by the Member State Committee as they were considered to be outside of the scope of Article 51(5).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-70 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix G: List of references - ECHA Guidance[14] 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)[15]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[15]

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.

[14] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[15] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

OECD Guidance documents[16]

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.

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

Appendix H: 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.