Helsinki, 1 September 2016

Addressee: [redacted]

Decision number: CCH-D-2114339882-41-01/F
Substance name: 1,2-benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt
EC number: 204-886-1
CAS number: 128-44-9
Registration number: [redacted]
Submission number: [redacted]
Submission date: 06.02.2015

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on

1. ***In vitro*** **gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: Bacterial reverse mutation test, EU B.13/14 /OECD TG 471), with the registered substance;**

2. ***In vitro*** **cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2, test method: EU B.10/OECD TG 473) or *in vitro* micronucleus study (Annex VIII, Section 8.4.2, test method: OECD TG 487), with the registered substance;**

3. ***In vitro*** **gene mutation study in mammalian cells (Annex VIII, Section 8.4.3; OECD TG 476 or OECD TG 490) if the outcome of the studies performed under item 1 and 2 above are negative, with the registered substance;**

4. **Ready biodegradability (Annex VII, Section 9.2.1.1; test method: DOC die-away test, OECD TG 301A), or Ready biodegradability (Annex VII, Section 9.2.1.1; test method: CO2 evolution test, OECD TG 301B), or Ready biodegradability (Annex VII, Section 9.2.1.1; test method: MITI test (I), OECD TG 301C), or Ready biodegradability (Annex VII, Section 9.2.1.1; test method: Closed bottle test, OECD TG 301D), or Ready biodegradability (Annex VII, Section 9.2.1.1; test method: Modified OECD screening test, OECD TG 301E), or Ready biodegradability (Annex VII, Section 9.2.1.1; test method: Manometric respirometry test, OECD TG 301F), or Ready biodegradability (Annex VII, Section 9.2.1.1; test method: Ready biodegradability – CO2 in sealed vessels (headspace test), OECD TG 310) with the registered substance;**

5. **Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1; test method: *Daphnia sp.* Acute immobilisation test, EU C.2/OECD TG 202), with the registered substance;**

6. **Growth inhibition study aquatic plants (Annex VII, Section 9.1.2; test method: Alga, growth inhibition test, EU C.3/OECD TG 201) with the registered substance.**

You shall update the chemical safety report, where relevant.

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **8 September 2017**. The timeline has been set to allow for sequential execution of the *in vitro* studies.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

Appeal

[For the final decision: This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/web/guest/regulations/appeals.]

Authorised[1] by Claudio Carlon, Head of Unit, Evaluation E2

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons

A. Preliminary considerations

Article 13(1) of the REACH Regulation stipulates that information on intrinsic properties of substances may be generated by means other than tests, provided that the conditions set out in Annex XI are met.

In that respect, ECHA notes that you have adapted many of the information requirements addressed in the present decision with weight of evidence approaches. Section 1.2 of the Annex XI of the REACH Regulation sets out the prerequisites of weight of evidence approaches followingly:

> *"There may be sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property, while the information from each single source alone is regarded insufficient to support this notion".*

Therefore, an evidence based approach involves an assessment of the relative values/weights of different pieces of the available information that have been retrieved and gathered in previous steps. To this end, a value needs to be assigned to each piece of information. These weights/values can be assigned either in an objective way by using a formalised procedure or by using expert judgement. The weight given to the available evidence depends on factors such as the quality of the data, consistency of results, nature and severity of effects and relevance of the information for the given regulatory endpoint.

In the present case, the weight of evidence approaches you propose are themselves based on sources of information such as QSAR, grouping and read-across or existing studies. These sources of information are themselves adaptations, which are described in respective sections of Annex XI and subject to specific conditions. The fulfillment of all or parts of these conditions determines the quality and reliability of these sources of information for assuming or concluding that a substance has or has not a particular dangerous property.

However, ECHA notes systematic deficiencies regarding the conformity of these sources of information with the conditions set out in Annex XI of the REACH Regulation. These deficiencies are such that they call into question the quality and reliabity of these sources of information as valid pieces of a weight of evidence argumentation.

The following development addresses the invalidity of these sources of information for the purpose of justifying a weight of evidence approach.

1. Use of Qualitative or Quantitative structure-activity relationship ((Q)SAR) models

ECHA notes that you have provided sources of information based on Qualitative or Quantitative structure-activity relationship ((Q)SAR) models as part of weight of evidence approaches to fulfil several information requirements. (Q)SARs, are theoretical models that can be used to predict in a qualitative or quantitative manner the physico-chemical, biological (e.g. toxicological and ecotoxicological) and environmental fate properties of compounds from the knowledge of their chemical structure.

The quality and reliability of the (Q)SAR models can be assessed in the light of the criteria established in Section 1.3. of Annex XI to the REACH Regulation:

- results are derived from a (Q)SAR model whose scientific validity has been established,
- the substance falls within the applicability domain of the (Q)SAR model,
- results are adequate for the purpose of classification and labelling and/or risk assessment, and
- adequate and reliable documentation of the applied method is provided.

Adequate and reliable documentation should provide information on the scientific validity of the approach. The justification for using the (Q)SAR information should be based on the use of the QSAR Reporting Formats described in ECHA Guidance on information requirements and chemical safety assessment (May 2008), Chapter R.6 (Section R.6.1.6.):

- the description of a particular (Q)SAR model (i.e. description of the algorithm, its development and validation based on the OECD principles) will be stored in the (Q)SAR Model Reporting Format (QMRF).
- the (Q)SAR Prediction Reporting Format (QPRF) will explain how an estimate has been derived by applying a specific model or method to a specific substance. This should include information on the model prediction(s), including the endpoint, a precise identification of the substance modelled and the relationship between the modelled substance and the defined applicability domain.

These required reporting formats are essential to provide a comprehensive description of the reliability and use of the (Q)SAR during the chemical safety assessment, including the classification of a given substance for a specific endpoint. They are also necessary for justifying any further testing considered necessary to obtain adequate and complete information, or further adaptation, if appropriate.

However, ECHA notes that you have not provided any documentation of the applied methods in order to support the predictions. More concretely, because you have not provided any documentation to support your (Q)SAR model predictions, there is no basis on which the presence or absence of a certain dangerous property of the registered substance can be predicted. The absence of a reliable and justified basis disqualifies such QSAR models as sources of information for the respective weight of evidence approach intended to assume or conclude on the presence or absence of a certain dangerous property of the registered substance.

Furthermore, the non-fulfilment of the primary condition described above invalidates this approach for endpoints where QSAR models were invoked as adaptations as such and not as a mere source of information of a weight of evidence argumentation.

2. Use of OECD QSAR Toolbox - grouping of substances

ECHA notes that, for some information requirements, you have provided information on analogue substances identified from the OECD QSAR toolbox. More specifically, you have used these analogues as sources of information as part of a weight of evidence argumentation.

Even though you have reported this information as "QSAR" in the field study result type in IUCLID, on the basis of the indications included in the corresponding prediction report, ECHA understands that these arguments do not refer to QSAR models but rather to read-across approaches. Therefore, the quality and reliability of such sources of information shall be assessed against the conditions applying to read-across approaches.

3. Category approach

For several endpoints, ECHA notes that you also invoked a category approach as a source of information of your weight of evidence argumentation.

Substances, which physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity, may be considered as a group, or 'category' of substances. These similarities may be due to a chemical similarity within the group (i.e. common functional group).

If a structural similarity is established, it may be possible to make predictions within the group for the target substance(s) on the basis of a demonstrable regular pattern. Alternatively, whenever there is more than one source substance in the category and no regular pattern is demonstrated for the property under consideration, the prediction may be based on a read-across from a category member with relevant information in a conservative manner (worst case).

The supporting evidence is considered as an essential part of the category justification. Due to the diversity of cases, the property under consideration and the range of possible explanations, it is not possible to provide rules for the type of supporting evidence which would be required to support a particular read-across hypothesis.

In the present case, you have included a category justification document in IUCLID section 13 of your dossier. This justification document presents the methodology applied to select the category members, based on the presence of structural features and on the absence of alerts for specific mechanisms of toxicity. This led to the formation of a category composed of the registered substance and a number of analogue substances. As a result of this category approach, you have used experimental data obtained from several category members as sources of information in the context of weight of evidence approaches to fulfil multiple information requirements applying to the registered substance.

In the summary of the category approach, you justify the proposed category on the basis that all the category members share some structural elements and that "*Based on the above values for the aquatic toxicity related values it is observed that the values for both target as well as analogues are comparable*". Furthermore, you consider that "*based on the human health data it is observed that all the chemicals are not toxic in nature and safe for human use. Therefore the chemical category is likely justified with similar category members*".

ECHA has assessed these arguments and consider for the following reasons that they cannot legitimately support a weight of evidence approach.

1. Argument relating to the similarity of the substances in the category based on aquatic toxicity:

   - *You do not provide a category justification and you do not explain why or how the difference in structure affects the outcome of the prediction,*

- *common precursors or breakdown products have not been identified,*
- *from the data provided on the read-across substances there is either clear evidence for significant difference (up to two orders of magnitude) in (eco)toxicological properties between the supposed category members or no data, and*
- *a trend in (eco)properties across the category cannot be established.*

2. Argument relating to similarity of the substances in the category based on human health data:
   - *For Health hazard endpoints including toxicokinetics, the data matrix consists of only data from the target substance, except for dermal acute toxicity where the difference is roughly a factor of two (2.2 and 4.7 g/kg bw). ECHA notes that these values are about 5-10 times lower than acute oral toxicity of the target substance (8.4 - 17.5 g/kg bw) where information from the source substance is missing. The data provided for human health endpoints for the same substance and endpoint cover a large range and therefore are considered as hardly reliable.*
3. Deficiency in the documentation leaving the approach not valid:
   - there is no assessment provided to verify the adequacy for regulatory purposes, i.e. whether the results are adequate for classification and labelling and/or risk assessment;
   - robust study summaries of the test using the source substances have not been provided, thus in how far the key parameters of the corresponding test methods referred to in Article 13(3) are covered cannot be assessed;
   - as robust study summaries of the test using the source substances have not been provided, it cannot be assessed whether the exposure duration is adequate; and
   - from the documentation provided and the said above it can be concluded that the approach taken is not adequate.

For the reasons above, ECHA considers that you have not established a basis according to which the properties of the registered substance can be predicted from other members of this category. In the absence of a reliable and justified basis for reading across information from members of the category, these sources of information cannot be used as part of weight of evidence approaches intended to determine the properties of the registered substance.

4. Use of existing data

In the technical dossier you have provided information which was not generated according to good laboratory practice (GLP). You did not report these studies with sufficient detail to make it possible for ECHA to assess to what extent the provided information covers all key parameters addressed by the corresponding standard test method. ECHA considers that you have failed to demonstrate to which extend the existing information covers the key parameters addressed by the recognised international test guideline as specified in Annexes VII-IX of the REACH Regulation.

ECHA considers this a failure to provide adequate and reliable documentation of the study provided as required by Annex XI, section 1.1.2. As a result, the respective information cannot be used either as stand alone information or as a valid suorce of information in a weight of evidence approach.

B. Endpoint specific considerations:

1. *In vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

An "In vitro gene mutation study in bacteria" is a standard information requirement as laid down in Annex VII, Section 8.4.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

According to Article 13(3) of the REACH Regulation, tests required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods recognised by the Commission or ECHA.

In the technical dossier you adapted the information requirements using two existing Ames tests in a weight of evidence approach.

However, as already explained above in Appendix 1, section A "Preliminary Considerations", your adaptation of the information requirement cannot be accepted.

More specifically, ECHA notes that for neither of the tests there is information available on cytotoxicity or the validity criteria "negative and positive controls". ECHA considers therefore that the information used as evidence is poorly documented to such an extend that the reliability of the information cannot be assessed. ECHA concludes that adequate and reliable information for the existing information is missing and none of the studies can be considered in a weight of evidence approach. Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Bacterial reverse mutation test (test method: EU B.13/14. / OECD TG 471).

2. *In vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study (Annex VIII, Section 8.4.2.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

An "In vitro cytogenicity study in mammalian cells or an in vitro micronucleus study" is a standard information requirement as laid down in Annex VIII, Section 8.4.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier you have provided not provided a cytogenicity study but adapted the information using an existing *in vitro* Comet assay. ECHA notes that there is currently no OECD guideline available for such an *in vitro* comet assay.

This study does not provide the information required by Annex VIII, Section 8.4.2., because the presented comet assay *in vitro* may not address all key parameters alike the study referred to in Article 13(3) of REACH. Furthermore, ECHA notes that the study is very poorly reported and an independent assessment on the validity of the study cannot be made. More specifically, it is not possible to evaluate the study because it lacks essential details. Particularly, there is no information on the metabolic activation system, test concentrations, test substance preparation, medium used, cytotoxicity, negative/positive controls, historic control data, nor the criteria for a negative or positive outcome of the test. ECHA therefore considers the reliability of the study as "not assignable" (Kliemish score 4).

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: In vitro cytogenicity study in mammalian cells (test method: EU B.10./OECD TG 473) or in vitro mammalian cell micronucleus study (test method: OECD TG 487).

3. *In vitro* gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

An "*In vitro* gene mutation study in mammalian cells" is an information requirement as laid down in Annex VIII, Section 8.4.3. of the REACH Regulation, "if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2." is obtained.

ECHA notes that the registration dossier contains negative results for both information requirements in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2. However, as explained in sections 1 and 2 above, these results cannot be considered reliable. Therefore, depending on the outcome of the studies requested under sections 1 and 2 above, adequate information on this endpoint may need to be present in the technical dossier for the registered substance to meet this information requirement.

There is a potential information gap and it may be necessary to provide information for this endpoint.

ECHA considers that the in vitro mammalian cell gene mutation tests using the Hprt and xprt genes (OECD TG 476) and the in vitro mammalian cell gene mutation tests using the thymidine kinase gene (OECD TG 490) are appropriate to address the standard information requirement of Annex VIII, Section 8.4.3. Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: *In vitro* mammalian cell gene mutation test (test method: OECD TG 476 or OECD TG 490) provided that the studies requested under section 1 and 2 above have a negative result.

4. Ready biodegradability (Annex VII, Section 9.2.1.1.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"Ready biodegradabililty" is a standard information requirement as laid down in Annex VII, section 9.2.1.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You did not provide experimental data for ready biodegradation but adapted the information requirements using two QSAR models as key and supporting study.

However, as already explained above in Appendix 1, section A "Preliminary Consiedrations", your adaptation of the information requirement cannot be accepted. More specifically, in the key study, you refer to the "BIOWIN Linear and Nonlinear method" without providing further details on the model used. ECHA notes that the BIOWIN software consists of 7 different models (BIOWIN1-7). The REACH guidance R7b (p. 186, v2.0, November 2014) refers only to BIOWIN3 and to BIOWIN5 for predicting ready biodegradability as being applicable for REACH purposes.

You have not specified which of the models you used for the prediction, thus ECHA cannot assess the reliability of the information provided and your key study cannot be used in a weight of evidence approach.

In the supporting study, you refer to a level III fugacity model. ECHA notes that a fugacity model predicts the distribution of the substance between the different environmental compartments, i.e. water and air, and can calculate the corresponding half-life of the substance in a given environmental compartment. However, migration of the substance from one compartment to another is a different process than biodegradation and the calculated half-lives cannot be considered biodegradation half-lives. This information can therefore not be used in a weight of evidence approach either.

As result, there is no valid information available for ready biodegradability for your substance and there is a data-gap. Therefore, you are requested to conduct an experimental study following one of the protocols provided by OECD TG 301 and OECD TG 310.

ECHA notes that in case the outcome of the required ready biodegradability test is negative, *i.e.* the substance is not ready biodegradable, "Simulation testing on ultimate degradation in water" may be required as standard information requirement laid down in Annex IX, section 9.2.1.2. of the REACH Regulation. In case you identify such a need, you are requested to submit a testing proposal according to Article 12(d) of REACH.

5. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"Short-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex VII, Section 9.1.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You did not provide experimental data for short term toxicity to aquatic invertebrates but adapted the information requirements in a WoE approach using the output from the OECD QSAR Toolbox as key study and two QSAR predictions as supporting studies.

However, as already explained above in Appendix 1, section A Preliminary Considerations, your adaptation of the information requirement cannot be accepted. More specifically, in the key study you simply took the average of values covering an overly large range without any justification. For the supporting studies you used the same model, but it is unclear, what the difference between the two studies may be and which parameters were chosen for the prediction. None of the studies meets the provisions of Annex XI and they cannot be used in a weight of evidence approach.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Daphnia sp. Acute immobilisation test, EU C.2./OECD TG 202).

Please note that Column 2 of Annex IX, Section 9.1. specifies that long-term aquatic toxicity testing shall be proposed by you if the chemical safety assessment according to Annex I indicates the need to investigate further effects on aquatic organisms. According to ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R7b (Section R.7.8.5., including Figure R.7.8-4), if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. In such case, according to the integrated testing strategy, the Daphnia study is to be conducted first. If based on the results of the long-term Daphnia study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, the long-term fish study needs to be conducted. In case you identify such a need, you are requested to submit a testing proposal according to Article 12(d) of REACH.

6. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"Growth inhibition study aquatic plants (algae preferred)" is a standard information requirement as laid down in Annex VII, Section 9.1.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You did not provide experimental data for growth inhibition on aquatic plants but adapted the information requirements in a weight of evidence approach by providing two endpoint study records (ESR) containing each one output of the application of the OECD QSAR Toolbox and one ESR containing a read across study on "*N-Chlorobenzenesulfonamide, Sodium salt*".

However, as already explained above in Appendix 1, section A Preliminary Considerations, your adaptation of the information requirement cannot be accepted. More specifically, in the two ESRs where you used the OECD-Toolbox you took the average of values covering an overly large range without any justification. Where you used the one-to-one read-across from "*N-Chlorobenzenesulfonamide, Sodium salt*" as well as where you used the OECD-toolbox, you did not explain the structural relationships between the source substances and the target substance or why you think that the prediction would be reliable despite the obvious structural differences.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Alga, growth inhibition test, EU C.3/OECD TG 201.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 13 October 2015.

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

ECHA did not receive any comments by the end of the commenting period.

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

ECHA received proposals for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendments.

ECHA referred the draft decision to the Member State Committee.

Your comments on the proposed amendments 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 during its MSC-48 meeting and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

2. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

3. In relation to the information required by the present decision, the sample of substance used for the new test(s) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance composition manufactured or imported by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of substance tested in the new test(s) is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new test(s) must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the test(s) to be assessed.