ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 4 May 2018

Addressee: [redacted]

Decision number: CCH-D-2114408199-46-01/F
Substance name: Exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl acrylate
EC number: 227-561-6
CAS number: 5888-33-5
Registration number: [redacted]
Submission number: [redacted]
Submission date: 21/02/2013
Registered tonnage band: 100-1000

**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. **Surface tension (Annex VII, Section 7.6.; test method: EU A.5./OECD TG 115) of the registered substance;**

2. ***Robust study summary for "In vitro* micronucleus study (Harlan, 2013b)" (Annex VIII, Section 8.4.2., test method: OECD TG 473);**

3. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26./OECD TG 408) in rats with the registered substance;**

4. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a first species (rat or rabbit), oral route with the registered substance;**

5. **Extended one-generation reproductive toxicity study (Annex IX, Section 8.7.3.; test method: EU B.56./OECD TG 443) in rats, oral route with the registered substance specified as follows:**
   - **Ten weeks premating exposure duration for the parental (P0) generation;**
   - **Dose level setting shall aim to induce some toxicity at the highest dose level;**
   - **Cohort 1A (Reproductive toxicity);**
   - **Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation;**

6. **Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD TG 309) at a temperature of 20 °C with the registered substance. The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study;**

7. **Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method with the registered substance;**

8. **Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD TG 305, [aqueous exposure/dietary exposure]) with the registered substance. The bioaccumulation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study;**

9. **PBT and vPvB assessment of relevant constituents and degradation products (Article 14 (3)(d) in conjunction with Annex I, Section 4 and Annex XIII).**

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 to the REACH Regulation. 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 adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by ***11 November 2021***except for the information requested under point *[3]* for a sub-chronic toxicity study (90-day) which shall be submitted in an updated registration dossier by **13 May 2019**. You may only commence the extended one-generation reproductive toxicity study as requested under point *[5]* after ***12 August 2019***, unless an indication to the contrary is communicated to you by ECHA before that date. You shall also update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

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

## Appeal

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, has to 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/regulations/appeals.

Authorised[1] by Kevin Pollard, Head of Unit, Evaluation E1

[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**

PHYSICOCHEMICAL PROPERTIES

**1. Surface tension (Annex VII, Section 7.6.)**

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation.

"Surface tension" is a standard information requirement as laid down in Annex VII, Section 7.6 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 have sought to adapt this information requirement according to Annex VII, Section 7.6., column 2. You provided the following justification for the adaptation: "*Based on structure, surface activity is not expected*".

However, ECHA considers that your adaptation does not meet the specific rules for adaptation of Annex VII, Section 7.6., column 2, because based on the chemical structure surface activity is expected considering that structurally similar substances have been identified as potent surfactants. More specifically, the registered substance and isobornyl acetate (EC No. 204-727-6) are both alkyl esters of isoborneol. For isobornyl acetate a surface tension of 30.95 mN/m has been reported, which indicates that surface activity should also be expected for the registered substance.

In your comments on the draft decision according to Article 50(1) of the REACH Regulation, you indicate that the registered substance does not meet the criteria of being considered a substance with surface active properties since a "*pronounced hydrophilic group typical for detergents is missing*".

ECHA notes however that, although the registered substance is not an ionic surfactant, it seems to be behaving as a non-ionic surfactant composed of a hydrophobic group and non-ionic oxygen-containing hydrophilic group, i.e. the ester moiety. As explained above, this is further supported by the information available for structurally similar substances which indicate that surface activity should also be expected for the registered substance.Therefore, the surface active properties of the substance need to be clarified.

Hence, your adaptation of the information requirement is rejected. 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: Surface tension (test method EU A.5) or surface tension of aqueous solutions (test method: OECD TG 115).

(ECO)TOXICOLOGICAL AND FATE INFORMATION

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information

specified in Annexes VII to IX to the REACH Regulation. The information generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

Your registration dossier contains for the endpoints sub-chronic toxicity (90-day) study (Annex IX, 8.6.2.), pre-natal developmental toxicity study (Annex IX, 8.7.2.), extended one-generation reproductive toxicity study (Annex IX, 8.7.3) and study on bioaccumulation in aquatic species (Annex IX, Section 9.3.2.) adaptation arguments in form of a grouping and read-across approach under Annex XI, Section 1.5. of the REACH Regulation. ECHA has considered first the scientific and regulatory validity of your read-across approach in general before assessing the individual endpoints (sections 3, 4, 5 and 8).

**Grouping of substances and read-across approach**

You have sought to adapt the information requirements for a sub-chronic toxicity (90-day) study (Annex IX, Section 8.6.2.), pre-natal developmental toxicity study (Annex IX, Section 8.7.2.), extended one-generation reproductive toxicity study (Annex IX, 8.7.3) and a study on bioaccumulation in aquatic species (Annex IX, Section 9.3.2.) by applying a read-across approach in accordance with Annex XI, Section 1.5.

According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled: Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and environmental fate 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 (read-across approach). ECHA considers that the generation of information by such alternative means should offer equivalence to prescribed tests or test methods.

Based on the above, a read-across hypothesis needs to be provided. This hypothesis establishes why a prediction for a toxicological or environmental property is reliable and should be based on recognition of the structural similarities and differences between the source and registered substances. This hypothesis explains why the differences in the chemical structures should not influence the toxicological/environmental fate properties or should do so in a regular pattern. The read-across approach must be justified scientifically and documented thoroughly, also taking into account the differences in the chemical structures. There may be several lines of supporting evidence used to justify the read-across hypothesis, with the aim of strengthening the case.

Due to the different nature of each endpoint and consequent difference in scientific considerations (e.g. key parameters, biological targets), a read-across must be specific to the endpoint or property under consideration. Key physicochemical properties may determine the fate of a compound, its partitioning into a specific phase or compartment and largely influence the availability of compounds to organisms, e.g. in bioaccumulation and toxicity tests. Similarly, biotic and abiotic degradation may alter the fate and bioavailability of compounds as well as be themselves hazardous, bioaccumulative and/or persistent.

Thus, physicochemical and degradation properties influence the human health and environmental properties of a substance and should be considered in read-across assessments. However, the information on physicochemical and degradation properties is

only a part of the read-across hypothesis, and it is necessary to provide additional justification which is specific to the endpoint or property under consideration.

The ECHA Read-across assessment framework foresees that there are two options which may form the basis of the read-across hypothesis- (1) (Bio)transformation to common compound(s)- the read-across hypothesis is that different substances give rise to (the same) common compounds to which the organism is exposed and (2) Different compounds have the same type of effect(s)- the read-across hypothesis is that the organism is exposed to different compounds which have similar (eco)toxicological and fate properties as a result of structural similarity (and not as a result of exposure to common compounds).

Finally, Annex XI, Section 1.5. lists several additional requirements, which deal with the quality of the studies which are to be read-across.

You consider to achieve compliance with the REACH information requirements for the registered substance isobornyl acrylate using data of structurally similar substances 2-ethylhexyl acrylate (EC No 203-080-7), methyl acrylate (EC No 202-500-6), and butyl acrylate (EC No 205-480-7) (hereafter the 'source substances').

However, you have not provided a read-across documentation in the registration dossier, as required by REACH Annex XI, Section 1.5, last indent, and as further explained in ECHA's Read-across assessment framework.

ECHA therefore concludes that the requirements of Annex XI, Section 1.5. for predicting human health effects and environmental fate property from data for the reference substance(s) has not been met. ECHA moreover notes that there are specific considerations for the individual endpoints, which also result in a failure to meet the requirement of Annex XI, Section 1.5. These are set out under the endpoint concerned.

On a final note, ECHA observes the following regarding the information already submitted with the registration dossier. There is some information related to the toxicokinetics of the registered substance that supports your selection of the source substances:

ECHA understands that you regard the structural similarity between the source and registered substances as a sufficient basis for predicting the properties of the registered substance. Structural similarity is a prerequisite for applying the grouping and read-across approach. However, structural similarity does not necessarily lead to predictable or similar human health properties. You have not established and documented why a prediction for a human health or environmental fate property is reliable.

Structural similarity per se is not sufficient to enable the prediction of human health or environmental fate properties of a substance.

Furthermore, data for the relevant toxicological endpoints have only been submitted for the acrylic part of the registered substances. Even if your registered substance is demonstrated to be rapidly transformed into an acrylate and an isobornyl moiety, to justify and enable a read-across prediction also data on the isobornyl moiety would be required.

In your comments onthe draft decision according to Article 50(1) of the REACH Regulation, you indicate that you intend to revise and further support your read-across approach by performing a new toxicokinetic study *in vivo* to investigate the hydrolysis rate of the registered substance to gain further information on the systemic availability of the parent compound and its metabolites. A comparable study will be performed with isobornyl acetate as a potential isoborneol donor substance. The systemic effects of the metabolites will then be evaluated. You also intend to re-evaluate the existing biodegradation data and update the dossier with improved read-across and weight of evidence assessment according to ECHA's guidance on read-across, and also for the bioaccumulation endpoint.

ECHA will evaluate the revised read-across approach, if the registration dossier will be updated, for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

As described above, further elements are needed to establish a reliable prediction for toxicological and environmental fate properties, based on recognition of the structural similarities and differences between the source and registered substances. This could be achieved (if it is possible) by a well-founded hypothesis of (bio)transformation to (a) common compound(s), or that the registered and source substances have the same type of effect(s), together with sufficient supporting factual information to allow a reliable prediction of human health properties.

**2. Robust study summary for Robust study summary for the "*In vitro* micronucleus study ([redacted], 2013b)" (Annex VIII, Section 8.4.2. in conjunction with Annex I, Section 1.1.4.);**

An "*In vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study" is a standard information requirement as laid down in Annex IX, 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.

Robust summaries will be required of all key data used in the hazard assessment. Article 3(28) defines a robust study summary as a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report. Guidance on the preparation of the robust study summaries is provided in the Practical Guide on "How to report robust study summaries".

You have provided a study record for an *In vitro* micronucleus study ([redacted] 2013b) to meet the standard information requirement of Annex IX, Section 8.4.2.

However, ECHA considers that this study record does not meet the requirements for a robust study summary, because the documentation of this study is insufficient and does not allow an independent assessment of the adequacy of this study, its results and its use for hazard assessment. In particular, the reporting is inconsistent, i.e. with regard to the test guideline used, and the cells types that were used for the testing. Furthermore, the data provided with metabolic activation is difficult to interpret as the negative controls for study IIA is close to the highest historical negative control limit and the negative control for study IIB is lower than the historical negative control limit. This should be further explained in order to demonstrate the compliance for this endpoint.

Hence, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement.

In your comments on the draft decision according to Article 50(1) of the REACH Regulation, you indicate that you will update your dossier with the requested information.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information: Robust study summary for the "*In vitro* micronucleus study ([redacted], 2013b)".

### 3. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

A "sub-chronic toxicity study (90 day)" is a standard information requirement as laid down in Annex IX, Section 8.6.2. 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 a study record for a "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (test method: OECD TG 422). However, this study does not provide the information required by Annex IX, Section 8.6.2., because exposure duration is less than 90 days.

You have also sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing the study records for analogue substances as listed below:

- End-point study record 2:- Weight of evidence study: repeated dose toxicity study, rat, oral (equivalent or similar to OECD TG 408; GLP not specified) with source substance butyl acrylate (EC no 205-480-7), Gorzinski et al., 1982 (publication), rel 2.
- End-point study record 3:- Key study: repeated dose toxicity study, rat, inhalation (according to OECD TG 413; GLP) with source substance 2-ethylhexyl acrylate (EC No 203-080-7) [redacted], 1989 (study report), rel 2. (reported in IUCLID section 7.5.2.)

These two studies are referred to as weight of evidence studies. However, as they were performed with analogous substances ECHA has evaluated them under Annex XI, Section 1.5 (Grouping of substances and read-across approach). As explained above in Appendix 1, section "Grouping of substances and read-across approach" of this decision, your adaptation of the information requirement according to Annex XI, Section 1.5. is rejected.

Because each of the studies is considered inadequate as source studies of the read-across, ECHA considers that the studies would also not contribute to an overall weight of evidence to cover this information request. ECHA further observes that a weight of evidence adaptation would require adequate and reliable documentation, as stipulated by REACH Annex XI, 1.2, last sentence.

Therefore, your adaptation of the information requirement is rejected.

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.

ECHA has evaluated the most appropriate route of administration for the study. Based on the information provided in the technical dossier and/or in the chemical safety report, ECHA considers that the oral route - which is the preferred one as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 5.0, December 2016) Chapter R.7a, Section R.7.5.4.3 - is the most appropriate route of administration. In the Chemical Safety Report, you conclude that due to the physical/chemical properties of the substance, you do not consider inhalation exposure a relevant route of exposure. Hence, the test shall be performed by the oral route using the test method EU B.26./OECD TG 408. According to the test method EU B.26./OECD TG 408, the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

In your comments on the draft decision according to Article 50(1) of the REACH Regulation, you indicate that you intend to revise and further support your read-across approach by new experimental data. ECHAwill evaluate the revised read-across approach, if the registration dossier will be updated, for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

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: Repeated dose 90-day oral toxicity study (test method: EU B.26./OECD TG 408) in rats.

*Notes for your consideration*

ECHA notes that a revised version of OECD TG 408 may be adopted later on this year by the OECD. This revised version contains enhancements of certain endocrine disrupting relevant parameters. After the adoption of the revised version of the OECD TG 408 you should test in accordance with that version of the guideline as published on the OECD website for adopted test guidelines (https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788).

Even if you start testing before the guideline is published, it is appropriate to consider including these endocrine-sensitive parameters in your testing protocol in accordance with the proposed revised version of the draft guideline (see http://www.oecd.org/env/ehs/testing/section4-health-effects.htm).

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**4. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species**

A "pre-natal developmental toxicity study" (test method EU B.31./OECD TG 414) for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. 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 a study record for a "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (test method: OECD TG 422). However, this study does not provide the information required by Annex IX, Section 8.7.2., because it does not cover key parameters of a pre-natal developmental toxicity study like examinations of foetuses for skeletal and visceral alterations. Therefore, your adaptation of the information requirement is rejected.

You have also sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing the study records for analogue substances as listed below:

- End-point study record 2:- Weight of evidence study: teratogenicity study, mouse, oral (similar to OECD TG 414; GLP not specified) with source substance butyl acrylate (EC no 205-480-7), NTP, 1987 (study report), rel 2.

- End-point study record 3:- Weight of evidence study: teratogenicity study, rat, inhalation (similar to OECD TG 414; GLP not specified) with source substance ethylhexyl acrylate (EC No 203-080-7), Sallenfait, 1999 (study report), rel 2.

- End-point study record 4:- Weight of evidence study: teratogenicity study, rat, inhalation (similar to OECD TG 414; GLP not specified) with source substance butyl acrylate (EC no 205-480-7), Sallenfait, 1999 (study report), rel 2.

These three studies are referred to as weight of evidence studies. However, as they were performed with analogous substances, ECHA has evaluated them under Annex XI, Section 1.5 (Grouping of substances and read-across approach). As explained above in Appendix 1, section "Grouping of substances and read-across approach" of this decision, your adaptation of the information requirement according to Annex XI, Section 1.5. is rejected.

Because the read-across is not acceptable, there is no data to be considered under Annex XI, Section 1.2, weight of evidence adaptation.

Therefore, your adaptation of the information requirement is rejected.

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.

According to the test method EU B.31./OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default assumption, ECHA considers testing should be performed with rats or rabbits as a first species.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

In your comments onthe draft decision according to Article 50(1) of the REACH Regulation, you indicate that you intend to revise and further support your read-across approach by new experimental data. ECHA will evaluate the revised read-across approach, if the registration dossier will be updated, for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

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 Pre-natal developmental toxicity study (test method: EU B.31./OECD TG 414) in a first species (rat or rabbit) by the oral route.

*Notes for your consideration*

ECHA notes that a revised version of OECD TG 408 may be adopted later on this year by the OECD. This revised version contains enhancements of certain endocrine disrupting relevant parameters. After the adoption of the revised version of the OECD TG 408 you should test in accordance with that version of the guideline as published on the OECD website for adopted test guidelines (https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788).
Even if you start testing before the guideline is published, it is appropriate to consider including these endocrine-sensitive parameters in your testing protocol in accordance with the proposed revised version of the draft guideline (see http://www.oecd.org/env/ehs/testing/section4-health-effects.htm).

## 5. Extended one-generation reproductive toxicity study (Annex IX, Section 8.7.3.)

The basic test design of an extended one-generation reproductive toxicity study (test method EU B.56./OECD TG 443 with Cohorts 1A and 1B, without extension of Cohort 1B to include a F2 generation, and without Cohorts 2A, 2B and 3) is a standard information requirement as laid down in column 1 of 8.7.3., Annex IX of the REACH Regulation, if the available repeated dose toxicity studies (e.g. 28-day or 90-day studies, OECD TGs 421 or 422 screening studies) indicate adverse effects on reproductive organs or tissues or reveal other concerns in relation with reproductive toxicity.

Concerns in relation with reproductive toxicity are observed from the OECD TG 422 screening study performed with the registered substance ([redacted], 2012). More specifically, you have reported that "*statistically significant reduced litter size and litter weight were found in the high dose group compared to controls, starting from birth up to Day 4 post partum. In addition, the percentage of cumulative pup loss on Day 4 post partum, starting from the total litter size of birth, was increased in the high dose group*".

Pursuant to Annex IX, Section 8.7.3. an extended one-generation reproductive toxicity study is thus an information requirement for registrations of the registered substance.

If the conditions described in column 2 of Annex IX are met, the study design needs to be expanded to include the extension of Cohort 1B, Cohorts 2A/2B, and/or Cohort 3. Further detailed guidance on study design and triggers is provided in in ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.7a, Section R.7.6 (version 6.0, July 2017).

Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

*a) The information provided*

You have not provided any study record of an extended one-generation reproductive toxicity study in the dossier that would meet the information requirement of Annex IX, Section 8.7.3.

Instead, you have provided the following information in IUCLID section 7.8.1:

- End-point study record 1:- key study: "*screening for reproductive / developmental toxicity*", rat, oral (similar to OECD TG 422; GLP) with registered substance, [redacted] 2012 (study report), rel 1.
- End-point study record 2:- key study: "*two-generation reproductive toxicity*", rat, oral (OECD TG 416; GLP) with analogue substance (methyl acrylate, EC no: 202-500-6), the [redacted] 2009 (study report), rel 1.

You have also provided the following statement in the chemical safety report page 38: "*based on the OECD TG 422 result and on studies with analogous acrylate esters in experimental animals, there is no evidence for toxicity of Isobornyl acrylate to the reproductive system*".

ECHA understands that while you have not explicitly claimed an adaptation, you have provided information that could be interpreted as an attempt to adapt the information requirement that could be interpreted as an adaptation according to Annex XI, Section 1.1.2 (existing data); and Annex XI, Section 1.5 (read across).

ECHA has first evaluated the information you provided on use of existing data and then on read-across.

***Existing data***

ECHA has evaluated the existing information on the OECD TG 422 study with the registered substance on whether it meets the requirements for the use of existing data according to the provision of REACH Annex XI, Section 1.1.2. However, this study does not provide the information required by Annex IX, Section 8.7.3., because it does not cover key elements, such as exposure duration, life stages and statistical power of an extended one-generation reproductive toxicity study. More specifically, the main missing elements are the 10 weeks premating exposure duration, at least 20 pregnant females per group, and an extensive postnatal evaluation of F1 generation. Therefore, your adaptation of the information requirement is rejected.

***Read-across***

ECHA has evaluated whether the two-generation study with source substance meets the requirements for read-across according to the provision of REACH Annex XI, Section 1.5. With this regard, ECHA has considered whether this information is sufficient to predict the properties of the registered substance with respect to reproductive toxicity. However, as explained above in section "*Grouping of substances and read-across approach*" of this decision, your adaptation of the information requirement according to Annex XI, Section 1.5., is rejected.

Furthermore, you have concluded that "*there is no evidence for toxicity of Isobornyl acrylate to the reproductive system*" by considering the results of "*studies with analogous acrylate esters in experimental animals*". However, you have only provided two-generation reproductive toxicity study with the source substance (methyl acrylate, EC no: 202-500-6) where the read-across adaptation according to Annex XI, Section 1.5., is rejected. Hence, the other "studies" you have described are not provided in the registration dossier.

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. Thus, an extended one-generation reproductive toxicity study according to Annex IX, Section 8.7.3., is required. The following refers to the specifications of this required study.

*b) The specifications for the required study*

*Information from studies to be conducted before the extended one-generation reproductive toxicity study*

The sub-chronic toxicity study shall be conducted before the extended one-generation reproductive toxicity study and the results from that study shall be used, among other relevant information, to decide on the study design of the extended one-generation reproductive toxicity study following ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.7a, Section R.7.6 (version 6.0, July 2017).The sub-chronic toxicity study may provide information on effects that is relevant for triggers (e.g. weight changes and histopathological observations of organs as indication(s) of one or more modes of action related to endocrine disruption which may meet the toxicity-trigger for extension of Cohort 1B or as evidence of specific mechanism/modes of action and/or neurotoxicity and/or immunotoxicity which may meet the particular concern criteria for developmental neurotoxicity and/or developmental immunotoxicity cohorts).

*Premating exposure duration and dose-level setting*

To ensure that the study design adequately addresses the fertility endpoint, the duration of the premating exposure period and the selection of the highest dose level are key aspects to be considered. According to the ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.7a, Section R.7.6 (version 6.0, July 2017), the starting point for deciding on the length of the premating exposure period should be ten weeks to cover the full spermatogenesis and folliculogenesis before the mating, allowing meaningful assessment of the effects on fertility.

Ten weeks premating exposure duration is required because there is no substance specific information in the dossier supporting shorter premating exposure duration as advised in the ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.7a, Section R.7.6 (version 6.0, July 2017).

The highest dose level shall aim to induce some toxicity to allow comparison of effect levels and effects of reproductive toxicity with those of systemic toxicity. The dose level selection should be based upon the fertility effects with the other cohorts being tested at the same dose levels.

If there is no existing relevant data to be used for dose level setting, it is recommended that results from a range-finding study (or range finding studies) are reported with the main study. This will support the justifications of the dose level selections and interpretation of the results.

*Species and route selection*

According to the test method EU B.56/ OECD TG 443, the rat is the preferred species. On the basis of this default assumption, ECHA considers that testing should be performed in rats.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

*c)* Outcome

In your comments onthe draft decision according to Article 50(1) of the REACH Regulation, you indicate that you intend to revise and further support your read-across approach by new experimental data. ECHA will evaluate the revised read-across approach, if the registration dossier will be updated, for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

Based on the available information, 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: Extended one-generation reproductive toxicity study (test method EU B.56./OECD TG 443), in rats, oral route, according to the following study-design specifications:

- Ten weeks premating exposure duration for the parental (P0) generation;
- Dose level setting shall aim to induce some toxicity at the highest dose level;
- Cohort 1A (Reproductive toxicity);
- Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation;

Currently, the extension of Cohort 1B and the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) and Cohort 3 (developmental immunotoxicity) are not requested. However, the sub-chronic toxicity study (90-day) requested in this decision and/or any other relevant information may trigger changes in the study design.

Therefore, the sub-chronic toxicity study (90-day) is to be conducted first and the study results submitted to ECHA in a dossier update by the 12-month deadline indicated in this decision. If, on the basis of this update and/or other relevant information, a need for changes to the study design is identified, ECHA will inform you within three months after expiry of the 12-month deadline to provide the sub-chronic toxicity study (90-day)), as indicated in this decision, of its intention to initiate a new decision making procedure under Articles 41, 50 and 51 of the REACH Regulation to address the design of the extended one-generation reproductive toxicity study. If you do not receive a communication from ECHA by the expiry of three months following the 12-month deadline for providing the results of the sub-chronic toxicity study (90-day), the request of the present decision for the extended one-generation reproductive toxicity study remains effective and you may commence the conduct of the study and the results will need to be submitted by the deadline given in this decision.

*Notes for your consideration*

When submitting the study results of the sub-chronic toxicity study (90-day) you are invited to also include in the registration update your considerations whether changes in the study design are needed (see also *ECHA Guidance on information requirements and chemical safety assessment Chapter R.7a, Section R.7.6 (version 6.0, July 2017)*).

Furthermore, after having commenced the extended one-generation reproduction toxicity study in accordance with the ECHA decision, you may also expand this study to address a concern identified during the conduct of it and also due to other scientific reasons in order to avoid a conduct of a new study. The justification for the changes in the study design must be documented. The study design must be justified in the dossier and, thus, the existence/non-existence of the conditions/ triggers must be documented.

## 6. Simulation testing on ultimate degradation in water (Annex IX, Section 9.2.1.2.)

"Simulation testing on ultimate degradation in water" is a standard information requirement as laid down in Annex IX, section 9.2.1.2. 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.

While you have not explicitly claimed an adaptation, you have provided information that could be interpreted as an attempt to adapt the information requirement based on Annex IX, Section 9.2.1.2., column 2. You provided the following justification for the adaptation: *"As the substance was demonstrated to be not persistent in an OECD TG 310 study, a study on biodegradation in water and sediment was not considered as necessary."*

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.2.1.2, column 2, according to which simulation testing on ultimate degradation in surface water does not need to be conducted, if the substance is highly insoluble in water or is readily biodegradable. ECHA notes that based on the information in the technical dossier, the registered substance is not readily biodegradable in OECD TG 310 (degradation rate 57% in 28 days and "*10-day window*" not achieved) and has a water solubility of 19.8 mg/L.

Furthermore, ECHA notes that you have not provided adequate justification in your chemical safety assessment (CSA) or in the technical dossier for why there is no need to investigate further the degradation of the registered substance and its degradation products. ECHA observes that the information available in your submission does not allow deriving reliable degradation half-lives for the registered substance. As explained further below, ECHA considers that you need this information and the identification of the degradation products for the PBT/vPvB assessment.

ECHA observes that according to Section 1.2. of the IUCLID technical dossier, the purity of the registered substance is "equal to or higher than 85%". However, information on environmental fate and toxicity of the impurities is not available in the technical dossier or chemical safety assessment. For example, ready biodegradability studies described in the technical dossier were conducted with a test material of "more than 99% purity". Consequently, the degradation behaviour of the impurities was not taken into account in the assessment of persistency of the registered substance.

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 requirements. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) Aerobic mineralisation in surface water – simulation biodegradation (test method EU C.25. / OECD TG 309) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.2.

One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of the REACH Regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*". The Guidance on information requirements and chemical safety assessment R.7b (version 4.0, June 2017) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-8 (version 3.0 February 2016) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD TG 309. However, as for the registered substance the main concern is on the PBT/vPvB properties of the degradation products, the test may be performed at the temperature of 20°C.

In the OECD TG 309 Guideline two test options, the "pelagic test" and the "suspended sediment test", are described. ECHA considers that the pelagic test option should be followed as that is the recommended option for P assessment. The amount of suspended solids in the pelagic test should be representative of the level of suspended solids in EU surface waters. The concentration of suspended solids in the surface water sample used should therefore be approximately 15 mg dw/L.

Testing natural surface water containing between 10 and 20 mg SPM dw/L is considered acceptable. Furthermore, when reporting the non-extractable residues (NER) in your test results you should explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

In your comments on the draft decision according to Article 50(1) of the REACH Regulation you indicate that you intend to re-evaluate the existing biodegradation data and update the dossier with improved read-across and weight of evidence assessment according to ECHA's guidance on read-across. Related to your comments on technical difficulties to test volatile substances, ECHA notes that the possibilities to test such slightly volatile substances as the registered substance without losses in the test system are indicated in the OECD test guideline 309, page 2, para 7. You also indicate your intention to update the dossier with consistent substance/composition information. ECHA will evaluate the revised read-across approach, and any other submitted information, if the registration dossier will be updated, for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

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: Aerobic mineralisation in surface water – simulation biodegradation test (test method: EU C.25./OECD TG 309).

The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study. ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.11* (version 3.0, June 2017), explains that "*the term "constituent" refers to the main constituents, impurities and additives of substances of well-defined composition and constituents of UVCB substances*".

*Notes for your consideration*

Before conducting the requested test you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapter R7b, Sections R.7.9.4 and R.7.9.6 (version 4.0, June 2017) and Chapter R.11, Section R.11.4.1.1 and Figure R.11-3 (version 3.0, June 2017) on PBT assessment for the integrated testing strategy for persistency assessment. In accordance with Annex I, Section 4, of the REACH Regulation you shall revise the PBT assessment when results of the test detailed above are available.

## 7. Identification of degradation products (Annex IX, Section 9.2.3.)

The identification of the degradation products is a standard information requirement according to column 1, Section 9.2.3. of Annex IX 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.

The biodegradation section in the technical dossier does not contain any information in relation to the identification of degradation products, nor an adaptation in accordance with column 2 of Annex IX, Sections 9.2 or 9.2.3. or with the general rules of Annex XI for this standard information requirement.

According to Annex IX, Section 9.2.3., column 2 of the REACH Regulation, identification of degradation products is not needed if the substance is readily biodegradable.
ECHA notes that based on the information in the technical dossier, the registered substance is not readily biodegradable as discussed in Section 6 above.

Furthermore, ECHA notes that you have not provided any justification in your chemical safety assessment (CSA) or in the technical dossier for why there is no need to provide information on the degradation products. ECHA considers that this information is needed in relation to the PBT/vPvB assessment and risk assessment.

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

Regarding appropriate and suitable analytical methods, ECHA notes that the methods will have to be substance-specific. When analytically possible, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound should be investigated. In addition, degradation half-life, log Kow and potential toxicity of the metabolites should be determined. You may obtain this information from the simulation study also requested in this decision, or by some other measure. You will need to provide a scientifically valid justification for the chosen method.

In your comments on the draft decision according to Article 50(1) of the REACH Regulation you indicate that you intend to re-evaluate the existing biodegradation data and update the dossier with improved read-across and weight of evidence assessment according to ECHA's guidance on read-across. You also indicate your intention to update the dossier with consistent substance/composition information. ECHA will evaluate the revised read-across approach, and any other submitted information, if the registration dossier will be updated, for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

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:

Identification of the degradation products (Annex IX, Section 9.2.3.) by using an appropriate and suitable test method, as explained above in this section.

The identification of the degradation products of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be performed. This can be done simultaneously during the same study. ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.11* (version 3.0, June 2017), explains that "*the term "constituent" refers to the main constituents, impurities and additives of substances of well-defined composition and constituents of UVCB substances*".

*Notes for your consideration*

Before conducting the requested test, you are advised to consult the ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R.7b., Sections R.7.9.2.3 and R.7.9.4.

These guidance documents explain that the data on degradation products is only required if information on the degradation products following primary degradation is required in order to complete the chemical safety assessment. Section R.7.9.4. further states that when substance is not fully degraded or mineralised, degradation products may be determined by chemical analysis.

## 8. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.)

"Bioaccumulation in aquatic species, preferably fish" is a standard information requirement as laid down in Annex IX, Section 9.3.2.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 have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a study record for a Bioconcentration: flow-through Fish test (OECD TG 305) with the analogue substance 2-ethylhexyl methacrylate (EC no 211-708-6). However, as explained above in Appendix 1, section "Grouping of substances and read-across approach" of this decision, your adaptation of the information requirement according to Annex XI, Section 1.5. is rejected.

Therefore, your adaptation of the information requirement fails.

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.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7c* (version 3.0, June 2017) bioaccumulation in fish: aqueous and dietary exposure (test method EU C.13. / OECD TG 305) is the preferred test to cover the standard information requirement of Annex IX, Section 9.3.2. ECHA Guidance defines further that results obtained from a test with aqueous exposure can be used directly for comparison with the B and vB criteria of Annex XIII of REACH Regulation and can be used for hazard classification and risk assessment. Comparing the results of a dietary study with the REACH Annex XIII B and vB criteria is more complex and has higher uncertainty. Therefore, the aqueous route of exposure is the preferred route and shall be used whenever technically feasible.

If you decide to conduct the study using the dietary exposure route, you shall provide scientifically valid justification for your decision. You shall also attempt to estimate the corresponding BCF value from the dietary test data by using the approaches given in Annex 8 of the OECD 305 TG. In any case, you shall report all data derived from the dietary test as listed in the OECD 305 TG.

With regard to PBT screening assessment, you indicate that the registered substance is not readily biodegradable (57% in 28 days) and no further valid data on degradation of the registered substance is available. ECHA notes that this information indicates that the registered substance may have persistent or very persistent (P or vP) properties. Furthermore the value used in the dossier for the log Kow is 4.52, which meets screening criteria for the aquatic organisms (log Kow>4.5), described in ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), Chapter R.11.4. and Figure R.11-4.

In addition, as explained in Section 1 above, the registered substance is potentially surface active, and in this case predictions of BCF based on log Kow are not reliable. ECHA also notes, that according OECD TG 305, "*For surfactants it should be considered whether the aqueous bioaccumulation test is feasible, given the substance properties*".

In your comments on the draft decision according to Article 50(1) of the REACH Regulation you indicate that you intend to improve the robust study summary of a bioaccumulation study in fish with the analogous substance Ethylhexyl methacrylate and also the read-across assessment according to ECHA's guidance on read-across during the re-evaluation of the data. ECHA acknowledges, that in case the substance would not be persistent nor very persistent, bioaccumulation testing in aquatic species is not necessary. You also indicate your intention to update the dossier with consistent substance/composition information. ECHA will evaluate the revised read-across approach, and any other submitted information, if the registration dossier will be updated, for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation..

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: Bioaccumulation in fish: aqueous or dietary bioaccumulation fish test (test method: OECD TG 305).

The bioaccumulation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study. ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.11* (version 3.0, June 2017), explains that "*the term "constituent" refers to the main constituents, impurities and additives of substances of well-defined composition and constituents of UVCB substances*".

*Notes for your consideration*

Before conducting the requested test you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapter R7c, Sections R.7.10.4 and R.7.10.6 (version 3.0, June 2017) and Chapter R.11, Section R.11.4.1.2 and Figure R.11-4 (version 3.0, June 2017) on PBT assessment. In particular, you are advised to first conclude whether the registered substance may fulfil the REACH Annex XIII criteria of being persistent or very persistent, and then to consult the PBT assessment for Weight-of-Evidence determination and integrated testing strategy for bioaccumulation assessment.

In accordance with Annex I, Section 4, of the REACH Regulation you shall revise the PBT assessment when information on bioaccumulation is available.

## 9. PBT and vPvB assessment of relevant constituents and degradation products (Article 14 (3)(d) in conjunction with Annex I, Section 4 and Annex XIII)

According to Article 14 (3) of the REACH Regulation a chemical safety assessment of a substance shall include persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment. Annex I, Section 4 of the REACH Regulation notes that the objective of the PBT and vPvB assessment shall be to determine whether the substance fulfils the criteria given in Annex XIII and if so, to characterise the potential emissions of the substance with the aim of minimisation.

Pursuant to Annex XIII of the REACH Regulation the identification of the PBT and vPvB substances shall also take account of the PBT/vPvB-properties of relevant constituents of the substance and relevant transformation and/or degradation products.

ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.11* (version 3.0, June 2017), explains that "*the term "constituent" refers to the main constituents, impurities and additives of substances of well-defined composition and constituents of UVCB substances*". Furthermore, in this Guidance document it is noted that the registrant should carry out a PBT/vPvB assessment for all constituents, impurities and additives present in concentrations above 0.1% (w/w). Similar arguments apply to relevant transformation/degradation products. The PBT/vPvB assessment should normally be carried out for each relevant transformation or degradation product.

ECHA observes that according to Section 1.2. of the IUCLID technical dossier, the purity of the registered substance is equal to or higher than 85%. However, information on environmental fate and toxicity of impurities is not available in the technical dossier or chemical safety assessment. For example, ready biodegradability studies described in the technical dossier were conducted with a registered substance of more than 99% purity. Consequently, the degradation behaviour of the impurities was not taken into account in the assessment of persistency of the registered substance.

In addition, you have not provided any information on the PBT/vPvB properties of the degradation products of the registered substance in your chemical safety assessment (CSA) or in the technical dossier.

In your comments on the draft decision according to Article 50(1) of the REACH Regulation you indicate that you intend to re-evaluate the existing biodegradation data and update the dossier with improved read-across and weight of evidence assessment according to ECHA's guidance on read-across. You also indicate your intention to update the dossier with consistent substance/composition information. ECHA will evaluate the revised read-across approach, and any other submitted information, if the registration dossier will be updated, for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation you are requested to provide PBT and vPvB assessment of relevant constituents and degradation products. The results of this assessment shall be recorded in section 2.3 of the IUCLID technical dossier and in Section 8 of the chemical safety report.

## 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 29 June 2017.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

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

ECHA took into account your comments but did not amend the requests.
ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

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

As no amendments were proposed, ECHA took the decision according to Article 51(3) 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 requests in this decision, or to otherwise fulfil the information requirements 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 the substance used for the new tests 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 compositions 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 the substance tested in the new tests 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 tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.