EUROPEAN CHEMICALS AGENCY

Decision Number: CCH-D-0000001990-72-06/F Helsinki, 2 November 2012

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For 2-dimethylaminoethyl methacrylate, CAS No 2867-47-2 (EC No 220-688-8), registration number [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation the ECHA has performed a compliance check of the registration dossier for 2-dimethylaminoethyl methacrylate, CAS No 2867-47-2 (EC No 220-688-8) submitted by [redacted], submission number [redacted], for above 1000 tonnes per year.

The compliance check was initiated on 14 April 2011.

On 24 January 2012 ECHA notified the Registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

On 21 February 2012 the Registrant provided to ECHA comments on the draft decision.

ECHA reviewed the further information received and amended the draft decision in section III accordingly.

On 14 June 2012 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States submitted proposals for amendment to the draft decision.

On 18 July 2012 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

ECHA reviewed the proposals for amendment received and decided to amend the draft decision accordingly.

On 30 July 2012 ECHA referred the draft decision to the Member State Committee.

On 16 August 2012, the Registrant provided comments on the proposed amendments. The Member State Committee took the comments of the Registrant into account.

After discussion in the Member State Committee meeting on 19-21 September 2012, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 21 September 2012. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

This compliance check decision does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

II. Information required

1) Pursuant to Articles 41(1)(a), 41(3), and 10(a)(vi) and (vii) and Annexes IX and X of the REACH Regulation the Registrant shall submit the information using the test method as indicated on:

    a. 90-day repeated dose toxicity study (Annex IX, 8.6.2. REACH Regulation) in the rat, by the oral route (method B.43 of Regulation (EC) No 440/2008 or OECD 424), and in accordance with paragraph 16 of OECD 424, the study protocol shall be combined with method B.26 of Regulation (EC) No 440/2008 or OECD 408.
    b. Prenatal developmental toxicity study (Annex X, 8.7.2. REACH Regulation) in the rat, by the oral route (method B.31 of Regulation (EC) no 440/2008 or OECD 414).

2) Pursuant to Articles 41(1)(a), 41(3), 10(a)(iv) and Annex VI, Section 4 of the REACH Regulation in conjunction with Articles 4(3) and 61(3) of Regulation (EC) No 1272/2008 (CLP Regulation) the Registrant shall apply the harmonised classification and labelling of the substance in accordance with Annex VI Tables 3.1 and 3.2 of the CLP Regulation.

3) Pursuant to Articles 41(1)(c), 41(3), 10(b), and 14 and Annex I of the REACH Regulation the Registrant shall submit the following information in the form of an updated Chemical Safety Report (CSR):

    a. Refinement of exposure scenario development, exposure assessment and risk characterisation (Annex I, 5.1.1, 5.2.2, 5.2.4) by providing consistent information on identified uses, operational conditions and risk management measures for environment:
    b. Documentation on risks to workers adequately controlled for all exposure scenarios
    c. DNEL derivation, exposure assessment and risk characterisation for worker short-term inhalation exposure
    d. Missing elements for consumer exposure assessment
    e. PBT assessment

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by **2 November 2014**.

Data from a second pre-natal developmental toxicity study on another species is a standard information requirement according to Annex X, 8.7.2. of the REACH Regulation. The Registrant should firstly take into account the outcome of the pre-natal developmental toxicity on a first species and all other relevant available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI. If the Registrant considers that testing is necessary to fulfill this information requirement, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other registrants.

III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant for registration of the above mentioned substance within the applicable tonnage band of above 1000 tonnes per year does not comply with the requirements of Articles 10, 12 and 13 and Annexes I, IX and X of the REACH Regulation. Consequently, the Registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

1) Missing information related to endpoints

Pursuant to Articles 10(a)(vi) and 12(1)(c) of the REACH Regulation, a registration for a substance produced in quantities of above 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

1.a) 90-day repeated dose toxicity

The technical dossier did not provide information on the following endpoint:

90-day repeated dose toxicity study (Annex IX, 8.6.2. REACH Regulation)

The technical dossier contained the results of a Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test (OECD 422) with 43-day (for males) and 52-day (for females) exposure period, of a 21-day inhalation study, and of a 7-day dermal study. Due to the short exposure time, none of these studies qualifies as a valid sub-chronic toxicity study.

It follows that the Registrant has an information deficiency for the endpoint for Annex IX, 8.6.2. and should therefore fulfil the information requirement.

In the original draft decision, ECHA requested a 90-day repeated dose toxicity study in the rat via inhalation, considering that human exposure via this route is likely. In response to ECHA's draft decision, the Registrant agreed with the need for the 90-day repeated dose toxicity study, but indicated the preference for oral administration on the basis that the irritating properties of the substance do limit the dose range and critical systemic levels will not be achieved. ECHA considers that both routes of administration are appropriate. However, in light of the Registrant's comment and the proposals for amendment by the Member State Competent Authorities, ECHA has changed the route of administration of the 90 day repeated dose toxicity study from inhalation to oral.

In the OECD 422 study by the oral route, neurological symptoms were reported and hence there is a concern about neurotoxicity of the substance. Accordingly, the study protocol of the 90 day repeated dose toxicity study shall be performed according to method B.43 (or OECD 424) to evaluate neurotoxic effects, in combination with a standard 90-day repeated dose toxicity study (method B.26 or OECD 408).

Therefore, the Registrant is required to carry out the following test using the indicated test method and the registered substance: Neurotoxicity study in rodents (Annex IX, 8.6.2. REACH Regulation) in the rat, by the oral route for 90 days (method B.43 of Regulation (EC) No 440/2008 or OECD 424), and in accordance with paragraph 16 of OECD 424, the study protocol shall be combined with a repeated dose 90-day oral toxicity study (method B.26 of

Regulation (EC) No 440/2008 or OECD 408)

The Registrant is requested to update the technical dossier and the CSR with the relevant information.

While requesting the Registrant to perform the 90 day repeated dose toxicity study via the oral route of administration, ECHA considers that there will be a residual uncertainty arising from the route-to-route extrapolation of the results of this study and, consequently, in the derivation of a DNEL for inhalation toxicity. Therefore, following the update of the dossier based on the present decision, ECHA will decide whether the Registrant has satisfactorily addressed the residual concern for the substance. ECHA reserves the rights to request further information necessary to address this concern, if the Registrant has not done so.

1.b) Prenatal developmental toxicity

The technical dossier did not provide information on the following endpoint:

Prenatal developmental toxicity study (Annex X, 8.7.2. REACH Regulation)

The technical dossier contained: 1) the results of a Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test (OECD 422) and additionally 2) the results of a prenatal developmental toxicity study (OECD 414) on methyl methacrylate.

The information provided does not meet the requirements for this endpoint for the following reasons:

1) Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test. The Registrant conducted an OECD 422 study. However, this study, which is only meant to fulfil the requirements of Annex VIII, 8.7.1., cannot be regarded as the equivalent of a prenatal developmental toxicity and therefore cannot fulfil the requirements of Annex IX, 8.7.2. of the REACH Regulation. Inter alia, the OECD 422 study does not have a sufficient statistical power, and does not ensure analysis of all of the fetuses, while this is achieved in a pre-natal developmental toxicity study.
2) Prenatal developmental toxicity study on methyl methacrylate. The Registrant included in the technical dossier the results of an OECD 414 study on a substance different from the registered one, methyl methacrylate. The Registrant apparently intended to adapt the standard information requirement by applying a read-across approach in accordance with Annex XI, section 1.5.

However, the Registrant has not provided any justification for the adaptation of the standard information requirements according to Annex XI, 1.5. Indeed, it is a prerequisite according to Annex XI, 1.5, that adequate and reliable documentation of the applied method shall be provided.

ECHA further notes that in any event a valid read-across cannot be made between the two substances as the toxicological properties of the two substances differ, with *e.g.* the registered substance being corrosive and the read-across substance not being corrosive. The read-across would therefore fail the basic requirement of Annex XI, 1.5, that the properties of the registered substance may be predicted from the properties of the read-across substance.

In response to ECHA's draft decision, the Registrant put forward a read-across to a study, according to OECD 416 (two-generation reproductive toxicity study), on methyl methacrylate. The Registrant further explained that the read-across to the structural

analogue methyl methacrylate is meaningful as there is an analogy in the metabolic pathway where the first step is ester cleavage by unspecific esterases leading to methacrylic acid and the according alcohol. ECHA considers that the additional information provided by the Registrant during the commenting period to support the read-across does not constitute adequate and reliable documentation of a read-across according to Annex XI, 1.5. More specifically, a two-generation reproductive toxicity study does not cover evaluation of pre-natal toxic effects like skeletal and visceral malformations, and so the proposed read-across fails to meet the requirement of Annex XI, 1.5 for adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3). The proposed read-across fails to meet key requirements of Annex XI, 1.5, and accordingly cannot be accepted.

Given that the OECD 422 study is insufficient to satisfy the information requirements of Annex IX, 8.7.2., and that there is no valid adaptation according to Annex XI, 1.5, it follows that the Registrant has an information deficiency for the endpoint of Annex IX, 8.7.2.and is therefore obliged to fulfil the information requirement. The Registrant is accordingly requested to submit the information for this endpoint using the test method: Prenatal developmental toxicity study in the rat, by the oral route (method B.31 of Regulation (EC) no 440/2008 or OECD 414).

When considering the need for a testing proposal for a prenatal developmental toxicity study in a second species, the Registrant should take into account the outcome of the pre-natal developmental toxicity study on the first species and all available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if Weight of Evidence assessment of all relevant available data provides scientific justification that the study in a second species is not needed.

The Registrant is requested to update the technical dossier and the CSR with the relevant information.

2) Harmonized classification and labelling

Article 10(a)(iv) of the REACH Regulation requires that the technical dossier shall include the classification and labelling of the substance as specified in section 4 of Annex VI to the REACH Regulation. Pursuant to Article 4(3) of the CLP Regulation a substance needs to be classified in accordance with the entry of a harmonised classification and labelling listed in Annex VI to the CLP Regulation. Article 61(3) of the CLP Regulation stipulates that from 1 December 2010 until 1 June 2015, substances shall be classified in accordance with both Directive 67/548/EEC and the CLP Regulation. Table 3.2 of Annex VI of the CLP Regulation contains Annex I of Directive 67/548/EEC.

The information for classification and labelling provided in the fields of section 2 of the technical dossier is not consistent with Annex VI of the CLP Regulation. Specifically, the Registrant has classified the substance as H314-318. The registered substance should instead be classified with the Hazard statement Codes H302-312-315-317-319. The registrant is accordingly requested to apply the existing harmonised classification and labelling of the substance, in accordance with Annex VI Tables 3.1 and 3.2 of the CLP Regulation and to update the relevant parts of the CSR in the registration dossier, including exposure assessment and risk characterization. For other hazard classes and categories the Registrant is requested to apply self-classification.

ECHA also notes that according to CLP Article 37 (6) manufacturers, importers and

downstream users who have new information which may lead to a change of the harmonised classification and labelling elements of a substance in Part 3 of Annex VI shall submit a proposal in accordance with the second subparagraph of paragraph 2 to the competent authority in one of the Member States in which the substance is placed on the market.

3) Missing information related to the Chemical Safety Report

Annex I sets out the general provisions for assessing substances and preparing chemical safety reports (CSR).

3.a) Refinement of exposure scenario development, exposure assessment and risk characterisation (Annex I, 0.1, 0.7, 5.1.1, 5.2.2, 5.2.4) by providing consistent information on identified uses, operational conditions and risk management measures for environment

Pursuant to Articles 14(1, 3 and 4) and Annex I of the REACH Regulation, a Chemical Safety Report shall be provided, including exposure assessment and risk characterisation addressing all identified uses of the substance. Annex I sets out the general provisions for assessing substances and preparing CSRs.

In the CSR, the Registrant has built the Generic Exposure Scenario (GES) for workers' exposure and has directly applied this approach to the environmental exposure, carrying out the environmental emission estimation, risk assessment and risk characterisation for each GES, rather than for each identified use (IU). The way the GES approach has been applied in the CSR to derive the exposure assessment for the registered substance leads to inconsistencies in the information provided by the Registrant. As a consequence, information provided by the Registrant in the CSR does not comply with the requirements of Annex I, for the reasons listed below:

First, there are inconsistencies between IUs, GESs and Environmental Release Categories (ERCs) identified in the CSR by the Registrant. For example, in IUCLID section 3.5 and in the CSR table *"Mapping emissions to the environment"*, identified use IU4 (professional end use in formulation) is linked to ERCs 8a-8f which are relevant to professional use. However, the Registrant also included IU4 for instance in GES 1, and GES 4-6 which are related mainly to Industrial use. In addition, release and exposure estimates for the environment are inconsistent with the exposure scenarios and the use descriptions. For example, for GES 7, [redacted] used per year and site are assumed as a worst case situation. However, if GES 7 is meant to cover only outdoor processes, as indicated in the title of the GES given by the Registrant, site related scenarios are not relevant for such kind of outdoor conditions. Accordingly, the operational conditions described do not match the description of GES. Given these inconsistencies in the documentation and throughout the exposure assessment, ECHA considers that it is not possible to evaluate whether the risks arising from the manufactured substance are adequately controlled during manufacture and use of the substance. As a consequence, the Registrant failed to comply with the provisions of Annex I 0.1 of the REACH Regulation which requires the Registrant to document that the risks arising from the substance are adequately controlled.

Second, the description of operational conditions (OC) and risk management measures (RMMs) for each GES presented in the CSR is focused on worker protection. As a consequence, the RMMs related to environment are similar in most scenarios and they are not described in sufficient detail (*e.g.* size and efficiency of the STP are not specified). While the environmental RMMs seem appropriate for industrial use, those RMMs are inappropriate for professional and consumer use of the registered substance (e.g. the municipal STP is not warranted as RMM for professional and consumer uses of the substance). Given that not all

OC/RMMs are adequately described for each exposure scenario, that not all OC/RMMs are appropriate for the use of the registered substance and that they are not taken into account in the exposure estimation, the provisions in Annex I 5.1.1 and 5.2.4 of the REACH Regulation are not met.

Third, in the GES approach used by the Registrant, each IU is covered by multiple ESs and multiple ERCs. Therefore, the release estimates for each IU are not clearly identified. They could be calculated either as the worst case estimate of all GESs, or the sum of the exposure estimations of each GES. The two approaches do not lead to similar conclusions in terms of RCRs, and the Registrant does not indicate which approach he has followed. Given that there is not an unequivocal link between IUs and emission estimates, the provisions of Annex I, 5.2.2 of the REACH Regulation are not met.

Fourth, the conditions of use described in the exposure scenarios (ESs) do not provide appropriate information for the downstream user to assess if the ES is suitable to cover his use. For example, according to GES 7 (consumer relevant GES, outdoor conditions), the downstream user should limit the annual used amount to [redacted], should ensure that this amount is evenly distributed over 300 days and that process category (PROC) related containment as well as proper process controls are used. The RMMs recommended for this scenario may be far too stringent for a downstream user with a low tonnage use of the substance. Since ambiguous recommendations are given to the downstream user on how to control exposures of humans and the environment, the provisions in Annex I 0.7 are not met.

In conclusion, ECHA considers that the exposure assessment and risk characterization provided for the environmental compartment is not compliant with the provisions of Annex I.

Therefore, the Registrant is requested to provide more detailed and consistent information on identified uses, operational conditions and risk management measures in exposure scenario development, in exposure assessment and in the risk characterisation parts of the CSR. The Registrant is also requested to indicate the OC/RMMs taken into account in each exposure scenario, to provide unequivocal emission estimates for each IU, and to give unambiguous recommendations for downstream users of the substance.

3.b) Documentation on risks to workers adequately controlled for all exposure scenarios

Article 14(6) as well as Annex I, 0.1, 5.2.4 and 6.2-6.4 of the REACH Regulation require registrants to identify and apply appropriate measures to adequately control the risks identified in the CSR. The exposure shall be estimated and risks shall be characterised in the CSR under the assumption that relevant risk management measures have been implemented.

Pursuant to Annex VI, section 5 of the REACH Regulation the information provided in the registration dossier must be consistent with that in the Safety Data Sheet. The requirements of Safety Data Sheets are specified in Annex II (amended in Commission Regulation 453/2010). According to section 8.2.2.2 (a) of Annex II, the type of eye/face protection equipment required shall be specified based on the hazard of the substance or mixture and potential for contact. According to section 8.2.2.2 (b) of Annex II, the type of gloves to be worn shall be clearly specified based on the hazard of the substance or mixture and potential for contact and with regard to the amount and duration of dermal exposure, including:

- The type of material and its thickness,
- The typical or minimum breakthrough times of the glove material.

In the risk characterisation part of the CSR the combined risk characterisation ratios (RCR) are not shown to be below 1 for workers in GESs 8, 9, 11 and 12. The Registrant explains that this is related to activities described by PROC 19 (hand mixing) and describes the risk management measures (gloves) required to get the RCR below 1. However, these measures are already named as RMMs and taken into account in exposure estimation, thus using them again as additional risk management in the risk characterisation calculations is not appropriate. In addition, for the dermal protection, the protection efficacy of gloves (90 %) is given only in excel sheets for exposure estimation, not in the description of RMMs, and no recommendation for breakthrough time for gloves is given in the CSR.

Accordingly, the RMMs described in the ESs are not sufficient to show the safe use of the substance. The present ESs, in concert with the RMMs, yield RCRs that cannot be shown to be below 1, and show potential concern for the safe use of the substance. Consequently, the risk to humans cannot be considered to be adequately controlled (Annex I, 6.4).

The Registrant is therefore requested to update worker exposure assessments and risk characterisations using relevant risk management measures, which have to be identified and implemented in order to achieve RCRs of less than 1. In addition, the Registrant is requested to provide the recommended breakthrough times for protective gloves, with regard to the amount and duration of dermal exposure in the CSR.

3.c) DNEL derivation, exposure assessment and risk characterisation for worker short-term inhalation exposure

Annex I, section 5.2.4 of the REACH Regulation, requires the Registrant to perform an estimation of the exposure levels for all human populations (workers in this case) for which exposure to the substance is known or reasonably foreseeable. Such estimations shall take account of spatial and temporal variations in the exposure pattern, and in particular, duration and frequency of exposure according to the operational conditions, and the activities of workers related to the processes and the duration and frequency of their exposure to the substance. This is specified in the REACH Guidance on Information Requirements and Chemical Safety Assessment (R.14.4.6), which states:

> "Exposure to some substances may lead to acute health effects. If a substance is classified for acute effects and 'peak exposure' is likely to occur, an acute DNEL should be derived (Chapter R.8). Exposure situations without 'peak exposure' (i.e. an acute exposure level clearly higher than the related full shift exposure level) are very rare. Therefore, in most cases a classification for acute effects should lead to an acute DNEL. In order to provide a relevant estimate of exposure the assessor should request acute exposure data. If such data are available they should be evaluated in the same way as described earlier. Where the data are of sufficient quality and reliability they can be used to provide a reasonable worst case and typical value for acute exposure. In the risk assessment the comparison should be made with a relevant DNEL, e.g. an acute DNEL."

The Registrant has not derived short-term inhalation DNELs. According to Annex I, section 1.4.1., "(a) DNEL(s) shall be established for the substance, reflecting the likely route(s), duration and frequency of exposure", and short-term inhalation exposure is reasonably foreseeable. The Registrant has not derived exposure estimates or risk characterisation ratios for short-term inhalation exposure. Since the substance has a harmonized classification for short-term effects (short-term toxicity/eye irritation/skin irritation), and it is self-classified for skin corrosion/eye damage, then according to Annex I, section 5.2.4. and the Guidance (R.14.4.6), these are required. There is therefore a lack of required information.

The Registrant is accordingly requested to derive the acute inhalation DNEL, perform the appropriate exposure assessment and risk characterisation, and to update the CSR for this endpoint.

3.d) Missing elements for consumer exposure assessment

1) Exposure estimations for all identified uses

The substance is classified as dangerous in Annex VI of Regulation (EC) No 1272/2008. Consequently, pursuant to Article 14(4) of the REACH Regulation, exposure scenarios, exposure assessment and risk characterisation shall address all identified uses of the Registrant.

The CSR section 9.1.2 includes Table VII: Mapping consumer uses, with more than 20 uses described for consumers. However, exposure estimation has been developed only for one use: PC 1 adhesives and sealants, representing products with reactive monomer in mixture and assessed for GES 7 and 10.

The Registrant is requested to update his CSR by identifying and describing the relevant consumer uses, by carrying out and clearly documenting in the CSR consumer exposure assessment and risk characterisation for all identified consumer uses.

2) Applying default emission values in exposure assessment or scientifically supported justification

Pursuant to Annex I, 5.2.5 of the REACH Regulation, appropriate models can be used for the estimation of exposure levels.

Exposure estimation in the CSR is done by ECETOC TRA Consumer Tool. In the CSR the Registrant considers that the default fraction (100 %) of dimethylaminoethyl methacrylate released to air in the TRA tool is unrealistic, and uses [redacted] instead ([redacted]) without scientific justification. This application of environmental release fraction from [redacted] use is not scientifically justified, because the use and emission pattern for [redacted] is very different from the consumer use.

The Registrant is requested to apply the default values of the ECETOC tool for substance release, or to give scientific justification for the non-default use of values for substance release into the air (Annex I, 5.2.5).

In conclusion, under the point (i) of this decision the Registrant is requested to update his consumer exposure assessment in the CSR by identifying and describing the relevant consumer uses and by carrying out consumer exposure assessment and risk characterisation for all identified consumer uses. In addition, the Registrant is requested to present scientific justification for the model adaptations for consumer exposure, and update the CSR accordingly.

3.e) PBT assessment

Pursuant to Article 14(3)(d) of the REACH Regulation, a chemical safety assessment shall include a persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment.

In the CSR, the section of the CSR related to PBT and vPvB assessment is empty, and no comparison with the criteria indicated given in Annex XIII is reported. The Registrant is

therefore requested to perform a PBT/ vPvB assessment in line with Annex I, 4.1 and to update the CSR accordingly.

IV. Deadline for submitting the required information

In the draft decision, ECHA requested that the Registrant shall submit an update of the registration dossier containing the required information within 18 months from the date of the decision. Considering ECHA's current practice of providing sufficient time for the Registrant to conduct the studies sequentially, ECHA has spontaneously extended the deadline for providing the required information to 24 months from the date of the final decision.

V. Adequate identification of the composition of the tested material

ECHA notes that this dossier is the lead dossier of a joint submission. The evaluation process set out in Articles 40 and 41 of the REACH Regulation aims to ensure that the generation of information is tailored to real information needs in order to prevent unnecessary testing. In relation to the tests imposed, the sample of the substance to be used for these tests must be suitable for use by all the joint registrants. Hence the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. The outcome of the studies should be shared by the joint registrants concerned.

VI. General requirements for the generation of information and Good Laboratory Practice

ECHA always reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VII. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
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