EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004538-67-03/F Helsinki, 20 August 2014

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

For methacrylonitrile, CAS No 126-98-7 (EC No 204-817-5), 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 ECHA has performed a compliance check of the registration for methacrylonitrile, CAS No 126-98-7 (EC No 204-817-5), submitted by [redacted] (Registrant).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates submitted after 6 March 2014, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

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

The compliance check was initiated on 24 October 2013.

On 28 November 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 45 days of the receipt of the draft decision.

On 13 January 2014 ECHA received comments from the Registrant agreeing on the request to conduct an environmental exposure assessment and risk characteristation. The Registrant provided comments on the request to perform an explosiveness test and to revise DNELs for workers and the general population which are addressed in the Statement of Reasons (Section III).

The ECHA Secretariat considered the Registrant's comments. On basis of this information, ECHA has not amended Section II of the draft decision while the Statement of Reasons (Section III) was changed to reflect Registrant's comments.

On 6 March 2014 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 for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 41(1), 41(3), 10(a)(vi), 12(1)(e), 13 and Annex VII of the REACH Regulation the Registrant shall submit the following information using the indicated test method and the registered substance subject to the present decision:

1. Explosive properties (Annex VII, 7.11.; test method: as specified in Section III).

B. Information related to chemical safety assessment and chemical safety report

Pursuant to Articles 41(1), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:

1. Revised DNELs for workers and for the general population using the assessment factors recommended by ECHA and re-assessment of related risks or a full justification for not using the recommended assessment factors in DNEL derivation (Annex I, 1.4.1.);

2. Environmental exposure assessment and risk characterisation (Annex I, sections 5 and 6).

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **27 February 2015**.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 10(a)(vi), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

1. Explosive properties (Annex VII, 7.11.)

"Explosive properties" is a standard information requirement as laid down in Annex VII, Section 7.11. 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.

ECHA notes that the Registrant reported contradicting information in the IUCLID dossier with respect to the endpoint study record for explosiveness.

The Registrant has included a data waiving statement for this standard information requirement indicating that the study does not need to be conducted due to the absence of chemical groups associated with explosive properties, according to column 2 specific rules for adaptation of Annex VII, Section 7.11. of the REACH Regulation. Nevertheless, ECHA observes that the Registrant reported as well the results of three supporting studies which, according to the information provided by the Registrant, meet Klimisch criterion 4 only and are therefore not assignable. The Klimisch criterion is a system to assess the reliability of data as laid out in the Guidance on information requirements and chemical safety assessment Chapter R.4: Evaluation of available information, Section R.4.2. (Version of December 2011). Additionally ECHA observes that the Registrant reported the results of these supporting studies in terms of upper and lower explosion limits (explosion limits lie between 1.7-2.1 vol. % in air (lower value) and 13.2-15.5 vol. % in air (upper value)) concluding that the substance is explosive. ECHA notes as well that under the International Program on Chemical Safety (IPCS- INCHEM), the registered substance is reported as presenting explosive properties when in vapour/air mixtures.

ECHA concludes that the information provided to fulfil the information requirement for explosive properties is contradictory and that the Registrant has neither provided any reliable data to fulfil the standard information requirement of Section 7.11. of Annex VII of the REACH Regulation nor submitted a justified adaptation argument for the requirement.

As explained above, the information available 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.

The Registrant, in his comments submitted according to Article 51(1) of the REACH Regulation, indicated his willingness to update the dossier removing the literature references and also stated that, in his opinion, meeting the explosive properties endpoint requirement should be done according to test method EU A.14 which would indicate that the prediction is negative and allow to omit an experimental study.

ECHA underlines that the explosive potential of a substance should be determined following the testing strategy described in Part I of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria for the following reason. Pursuant to Annex I, section 2 of the REACH Regulation, the Registrant shall determine the classification of a substance in accordance with Regulation (EC) No 1272/2008. As a minimum the potential effects to human health shall be assessed for the following physico-chemical properties: explosiveness, flammability, oxidising potential. According to Annex I section 2 of the Regulation (EC) No 1272/2008, the test methods which shall be used to assess the explosive potential of a substance are described in Part I of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria.

For these reasons, ECHA considers that test methods which shall be followed to assess the explosive potential of a substance are the ones described in Part I of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria and therefore did not amend the current request.

Nevetheless, ECHA notes that the test method EU A.14 provides the possibility to predict the explosive properties endpoint being negative with the result that no experimental study may need to be performed. In parallel, also Appendix 6 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, as described in Annex I, section 2.1.4.3. of the Regulation (EC) No 1272/2008 provides for this option that the Registrant had indicated to apply.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Explosive properties according to the testing strategy described in Part I of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria.

B. Information related to the chemical safety assessment and chemical safety report

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation the registration shall contain a chemical safety report which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

1. Revised DNELs for workers and for the general population using the assessment factors recommended by ECHA and re-assessment of related risks or a full justification for not using the recommended assessment factors in DNEL derivation (Annex I, 1.4.1.)

Annex I, 1.4.1 of the REACH Regulation requires that the following factors shall, among others, be taken into account when deriving DNELs:

a) the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
b) the nature and severity of the effect;
c) the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies;
d) and that the DNELs reflect the likely route(s), duration and frequency of exposure.

The ECHA *Guidance on information requirements and chemical safety assessment* Volume 8, Chapter R.8 provides further details and specifically provides default factors which should be applied to derive DNELs in the absence of substance specific information.

The assessment factors (AF) applied by the Registrant and the default assessment factors recommended in the ECHA Guidance[1] are given in detail in Annex I attached to this decision.

ECHA observes that the Registrant has not followed recommendations of ECHA guidance R.8 and has not provided a full justification for the derivation of DNELs in line with Annex I, 1.4.1. Instead, the Registrant has applied less protective assessment factors than those recommended by the ECHA guidance for the intraspecies extrapolation and has not applied assessment factors to cover uncertainties due to remaining interspecies differences (i.e. not related to allometric scaling). ECHA notes that as regards the selection of the intraspecies AFs, the Registrant states that "in accordance with ECETOC Guidance on assessment factors to derive a DNEL: Technical Report 110, ISSN- 0773-8072-110 (October 2010), [....]; intraspecies variation (general population):5 because the higher (10) value recommended by ECHA is not justified". ECHA notes that it is the Registrant's obligation to demonstrate the safe use of his substance and therefore to fully justify the AFs that he chooses with substance-specific arguments, if he deviates from the AFs foreseen in the ECHA Guidance. The mere fact that the AFs are in line with ECETOC Guidance is not a justification for deviation and the Registrant has therefore not justified that proposed AFs are adequate for the safe use of his substance. In addition ECHA notes that as regards the selection of the AFs for remaining interspecies differences, the Registrant states that "the mechanism of toxicity via metabolism to hydrogen cyanide is understood (ECETOC JACC Report 53, ISSN-0773 -6339 -53, September 2007) and excessive safety factors add no value to evaluation of a threshold effect." ECHA notes that the Registrant has not provided any justification why

[1] Link to ECHA guidance document R.8 is: http://echa.europa.eu/documents/10162/17224/information_requirements_r8_en.pdf

conclusions of a report on toxicity via metabolism to hydrogen cyanide would apply to the interspecies AF selection of the registered substance.

As explained above, the information provided on DNEL for the registered substance in the chemical safety report (CSR) does not meet the general provisions for preparing a CSR as described in Annex I, 1.4.1. because the assessment factors used are not in accordance with ECHA *Guidance on information requirements and chemical safety assessment* Volume 8, Chapter R.8. and are not fully justified. Consequently it is necessary to revise the DNELs or to provide a full scientific justification.

The Registrant is given two options: The Registrant shall revise the DNELs for workers and for the general population by applying the assessment factors recommended by ECHA that are appropriate in this case. Subsequently, the Registrant shall re-assess related risks.

In the alternative, the Registrant shall, in accordance with Annex I, 1.4.1, provide a full justification for the DNELs derived for workers and for the general population provided in the chemical safety report by specifying how the following has been taken into account:

a) the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
b) the nature and severity of the effect;
c) the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies;
d) and that the DNELs reflect the likely route(s), duration and frequency of exposure.

The Registrant, in his comments submitted according to Article 51(1) of the REACH Regulation, proposed to further justify the use of ECETOC assessment factors in the derivation of the DNELs and referred to arguments presented in the ECETOC TR 110 document and scientific articles referred in that document.

ECHA points out that, according to ECHA Guidance R.8, deviations from default assessment factors should be justified with substance-specific arguments, more specifically the introductory part of paragraph R.8.4.3, page 22 reports: "*However, when the available data do not allow the derivation of substance-specific or analogue-specific assessment factors, default assessment factors should be applied.*" Moreover, ECHA underlines that the guidance document R.8 was developed and approved in cooperation with the Member States, industry and non-governmental organisations in order to define further the derivation of DNELs according to the provisions of Annex I section 1.4.1.

Additionally ECHA notes that the Registrant lists 3 conditions under which an allometric scaling would not need to be performed. ECHA points out however that the present decision and its Annex I do not challenge the Registrant's choices concerning allometric scaling. Instead ECHA underlines the need of substance-specific arguments to justify the Registrant's choice not to apply an AF of 2.5 for remaining interspecies AF when deriving each of the DNELs. ECHA notes that according to Table R.8-6 of the ECHA guidance such a default AF would not be needed for local effects on skin, eye and gastrointestinal (GI) tract via simple destruction of membranes, which is not the case for the registered substance. Indeed, the Registrant did not provide any substance specific arguments for deviating from this default AF

Finally, ECHA notes that the Registrant justifies the use of intraspecies AF of 3 (workers) and 5 (general population) by general references to ECETOC guidance and with two scientific articles referred in that guidance. The ECETOC guidance or the two articles contain no substance-specific arguments concerning the registered substance. The Registrant also states that "*Methacrylonitrile is well investigated and results between tests are relatively*

consistent. The mechanism of toxicity is known." ECHA notes that the Registrant has not substantiated how the effect levels in the studies available would allow to conclude that a lower intraspecies AF than the default would apply. ECHA notes further that the Registrant provides the specific argument that "*cyanide toxicity is almost a threshold event*" while ECHA guidance R.8 does not contain any provisions to use lower intraspecies AFs for threshold or "almost threshold effects". Instead, it is stated (paragraph R.8.4.3.1, pages 27 and 28) that for threshold effects the default AF is 10 for the general population and 5 for workers. ECHA concludes that the registrant did not provide an adequate justification why interspecies and intraspecies AFs deviating from default AFs of ECHA guidance would fulfil the condition of Annex I 1.4.1 a) mentioned above and concerning uncertainty arising from intra- and interspecies variation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit in the CSR either of the following information: Revised DNELs for workers and for the general population using the assessment factors recommended by ECHA and re-assessment of related risks *or* a full justification for not using the recommended assessment factors in DNEL derivation.

The CSR shall be amended accordingly.

2. Environmental exposure assessment and risk characterisation (Annex I, sections 5 and 6)

According to Article 14(4) of the REACH Regulation, if the substance fulfils the criteria for any of the hazard classes of Annex I to Regulation (EC) No 1272/2008 listed in Article 14(4) or is assessed to be a PBT or vPvB, the chemical safety assessment (CSA) shall include an exposure assessment and risk characterisation.

ECHA notes that according to the Regulation 1272/2008 the registered substance has harmonised classification as Flam. Liquid 2, Acute Tox. 3 (oral, inhalation and dermal); Skin Sens. 1. In addition, the Registrant has self-classified the substance as Acute Tox. 2 (inhalation) and STOT Single Exp. 1. Therefore, pursuant to Article 14(4) of the REACH Regulation, the exposure assessment shall be carried out according to section of 5 of Annex I and shall include exposure scenarios and exposure estimations for the registered substance.

In the CSR provided by the Registrant the exposure assessment and risk characterisation for the environment are missing. The Registrant seeks to justify this with the argument that "the substance is not classified as hazardous to the environment and has not been identified as PBT or vPvB. Therefore, in accordance with draft ECHA Guidance on information requirements and chemical safety assessment Chapter B.8: Scope of Exposure Assessment, it is considered unnecessary to perform a quantitative exposure assessment and risk characterisation".

However, ECHA observes that once the requirement for an exposure assessment and risk characterisation is triggered pursuant to Article 14(4), the exposure assessment and risk characterisation shall be carried out pursuant to Sections 5 and 6 of Annex I (Section 0.6.3. of Annex I of the REACH Regulation). Pursuant to Section 5.0 of Annex I, the exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the hazards identified in the hazard assessment. Annex I, Section 6 of the REACH Regulation requires the Registrant to characterise the risk for each exposure scenario. Sections 5 and 6 of Annex I do not limit the scope of the exposure assessment and risk characterisation to

the hazard(s) that triggered the requirement, but require an assessment encompassing any hazard identified in the hazard assessment.

Guidance on information requirements and chemical safety assessment Part B: Hazard assessment, section B.8 Scope of Exposure Assessment (ECHA, version 2.1, December 2011) further explains that if "*the substance meets the criteria for at least one of the hazard classes or categories (physical, health or environmental), or is assessed as having any of the properties set out in Article 14(4) of REACH,: in this case, exposure assessment is mandatory and should be considered for all standard exposure estimations as listed in Table B-8-1.*".

Therefore, provided that there is an identified hazard for the environment, the exposure assessment and risk characterisation shall also cover the environment.

The Guidance clarifies that in addition to classifiable hazards a registrant shall consider "*whether adverse effects have been observed in studies conducted at the highest practicable & biologically-relevant concentration on environmental toxicity e.g. according to OECD and EU Guidelines (e.g. 100 mg/l in OECD guideline as a limit test for acute aquatic toxicity), taking into account the properties of the substance determining the environmental fate.[...] If there are ecotoxicity data showing effects in aquatic organisms, but the substance is not classified as dangerous for the aquatic environment, an aquatic PNEC can nevertheless be derived thus indicating a hazard to the aquatic environment. In these circumstances there are also unclassified hazards to the sediment and soil compartments because toxicity to aquatic organisms is used as an indicator of concern for sediment and soil organisms and a screening risk characterisation is undertaken using the equilibration partitioning method (EPM) to derive PNECs for sediment and soil. Hence quantitative exposure assessment, i.e. derivation of PECs, is mandatory for the water, sediment and soil environmental compartments.*".

ECHA notes that according to the information provided in the registration dossier and CSR, a hazard to aquatic environment was identified (although not classifiable), because the lowest short-term effect concentrations identified during experimental studies are below 100 mg/l (72 h effect concentration (EC50) for algae based on growth rate is 25.3 mg/L and based on biomass is 15.1 mg/L) and as the long-term effect concentrations identified are below 10 mg/l (this concentration is indicated as a limit concentration for long-term toxicity testing in OECD Guidelines for *Daphnia* and fish; 21 d no observed effect concentration for *Daphnia* is 2.2 mg/L). Therefore, there are also unclassified hazards to the sediment and soil compartments. Thus, ECHA concludes that quantitative exposure assessment, i.e. derivation of PECs, is mandatory for the water, sediment and soil environmental compartments. Consequently, the risk characterisation for these environmental compartments should be performed for each exposure scenario.

Therefore, the Registrant's argument seeking to explain the absence of the exposure assessment and risk characterisation for the environment is unjustified.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, the Registrant is requested to generate and provide in the CSR quantitative exposure assessment and risk characterisation for for the water, sediment and soil compartments. The CSR shall be amended accordingly.

Furthermore, ECHA notes that in the IUCLID dossier PNECstp of 10 mg/l is provided, therefore quantitative risk characterisation may also be performed and would require quantification of exposure in sewage treatment systems for each exposure scenario.

IV. Adequate identification of the composition of the tested material

In carrying out the study required by the present decision it is important to ensure that the particular sample of substance tested 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. If the registration of the substance covers different grades, the sample used for the new study must be suitable to assess these.

Furthermore, there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the study to be assessed.

In relation to the information required by the present decision, the sample of substance used for the new study 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. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new study 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new study must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the study to be assessed.

V. 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/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
Leena Ylä-Mononen
Director of Evaluation

Annex I.

Assessment factors (AF) applied by the Registrant:

For workers - systemic long term – inhalation route:
- interspecies: [redacted] (remaining differences between species non related to allometry)
- intraspecies: 3
- exposure duration: [redacted]
  (overall AF: 6.0)

For workers - systemic long term – dermal route:
- interspecies - allometric correction: [redacted] (rat to human)
- interspecies - remaining differences: [redacted]
- intraspecies: 3
- exposure duration: [redacted]
- absorption difference dermal-oral: [redacted]
  (overall AF: 24)

For the general population - systemic long term – inhalation route:
- interspecies: [redacted] (remaining differences between species non related to allometry)
- intraspecies: 5
- exposure duration: [redacted]
  (overall AF: 10)

For the general population - systemic long term – dermal route:
- interspecies - allometric correction: [redacted] (rat to human)
- interspecies - remaining differences: [redacted]
- intraspecies: 5
- exposure duration: [redacted]
- absorption difference dermal-oral: [redacted]
  (overall AF: 40)

For the general population - systemic long term – oral route:
- interspecies - allometric correction: [redacted] (rat to human)
- interspecies - remaining differences: [redacted]
- intraspecies: 5
- exposure duration: [redacted]
  (overall AF: 40)

The default assessment factors recommended in the ECHA Guidance[2]:

For workers - systemic long term – inhalation route:
- interspecies: 2.5 (remaining differences between species non related to allometry)
- intraspecies: 5 (workers)
- exposure duration: 2 (sub-chronic to chronic)
  (overall AF: 25)

For workers - systemic long term – dermal route:
- interspecies - allometric correction: 4 (rat to human)
- interspecies - remaining differences: 2.5 (non-related to allometry)
- intraspecies: 5 (workers)
- exposure duration: 2 (sub-chronic to chronic)
- absorption difference dermal-oral: 1

[2] Link to ECHA guidance document R.8 is: http://echa.europa.eu/documents/10162/17224/information_requirements_r8_en.pdf

(overall AF: 100)

For the general population - systemic long term – inhalation route:
- interspecies: 2.5 (remaining differences between species non related to allometry)
- intraspecies: 10 (general population)
- exposure duration: 2 (sub-chronic to chronic)
(overall AF: 50)

For the general population - systemic long term – dermal route:
- interspecies - allometric correction: 4 (rat to human)
- interspecies - remaining differences: 2.5 (non-related to allometry)
- intraspecies: 10 (general population)
- exposure duration: 2 (sub-chronic to chronic)
- absorption difference dermal-oral: 1
(overall AF: 200)

For the general population - systemic long term – oral route:
- interspecies - allometric correction: 4 (rat to human)
- interspecies - remaining differences: 2.5 (non-related to allometry)
- intraspecies: 10 (general population)
- exposure duration: 2 (sub-chronic to chronic)
(overall AF: 200)