ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000001879-58-03/F Helsinki, 7 February 2012

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

For N-(n-octyl)-2-pyrrolidinone, CAS No 2687-94-7 (EC No 403-700-8), 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 (the REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration dossier for N-(n-octyl)-2-pyrrolidinone, CAS No 2687-94-7 (EC No 403-700-8) submitted by [redacted] (Registrant), latest submission number [redacted], for 1-10 tonnes per year.

The compliance check was initiated on 28 September 2010.

On 31 August 2011 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.

By 30 September 2011 the Registrant did not provide to ECHA any comments on the draft decision.

On 4 November 2011 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.

Subsequently, Competent Authorities of the Member States did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) 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.

ECHA
EUROPEAN CHEMICALS AGENCY

II. Information required

1) Pursuant to Articles 41(1)(a), 41(3) and 10(a)(ii) as well as Annex VI, Section 2 of the REACH Regulation the Registrant shall submit for the registered substance:

- the spectral data (Annex VI, 2.3.5.).

2) Pursuant to Articles 41(1)(a), 41(3), 10(a)(vi), 12(1)(a) and 13 as well as Annex VII of the REACH Regulation, the Registrant shall submit the following information using the test method as indicated below

- In vitro gene mutation study in bacteria (Annex VII, 8.4.1) using one bacterial strain which may detect mutagens, such as cross-linking agents or oxidising mutagens, i.e. one *E. coli* WP2 uvrA strain or *S. typhimurium* TA102, following recommendations of EU Method B.13/14 laid down in Commission Regulation (EC) No 440/2008 or OECD Test Guideline 471.

3) Pursuant to Articles 41(1)(a), 41(3) and Annex VI, Section 4 of the REACH Regulation the Registrant shall harmonize the data provided concerning the classification of the substance, in accordance with Annex VI of Regulation 1272/2008 (the CLP Regulation).

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 **07/02/2013**.

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 in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Articles 10, 12 and 13 and Annexes VI and VII 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 substance identity

Pursuant to Article 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation, the technical dossier of the registration shall include information on the identity of the substance. Annex VI, Section 2 lists information requirements that shall be sufficient to identify the registered substance.

The spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum) are not included in the submitted analytical data in IUCLID Section 1.4 "Spectral data and analytical information". Without such information the substance identity cannot be verified and consequently the requirement of Annex VI, Section 2.3.5 is not met. Therefore, the Registrant is requested to submit an updated dossier including, as a minimum, ultra-violet/visible (UV/Vis), infra-red (IR) and proton nuclear magnetic resonance (NMR) spectra. Additionally, information such as a carbon-13 NMR spectrum and/or a mass spectrum may be required if the other techniques (UV/Vis, IR and proton NMR) are not sufficient to identify the registered substance in accordance with Annex VI, Section 2.3.5 of the REACH Regulation.

ECHA
EUROPEAN CHEMICALS AGENCY

2) Missing information related to Mutagenicity

Pursuant to Articles 10(a)(vi), 12(1)(a) and (b) of the REACH Regulation, a registration for a substance manufactured or imported in quantities of 1-10 tonnes per year shall contain as a minimum the information specified in Annex VII of the REACH Regulation.

ECHA notes that for the endpoint 8.4.1 of Annex VII, in vitro gene mutation study in bacteria, the Registrant provided data from an in vitro gene mutation study in bacteria performed in 1989 according to OECD Test Guideline (TG) 471 in force at that time and in accordance with the OECD good laboratory practice (GLP) principles. This data was provided to the Registrant by ECHA pursuant to Article 25(3) of the REACH Regulation as a response to the inquiry submitted by the Registrant pursuant to Article 26 of the REACH Regulation.

According to Article 13(3) of the REACH Regulation, tests required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods recognised by the Commission or ECHA. Other tests may be used if the conditions of Annex XI are met.

In the present case, the test submitted was carried out according to GLP and to OECD TG 471. However, since the test was conducted, significant changes have been made to OECD 471 and this means that the study does not meet the current guidelines, nor can it be considered as providing equivalent data according to the criteria in Annex XI.

The version of the EU Test Method B. 13/14 OECD TG 471 in force since 1997 introduced the need for performing the test in at least 5 strains of bacteria whereas the OECD TG 471 in force in 1989 only required testing in a minimum of 4 bacterial strains. The required 5th bacterial strain, i.e. *E. coli* WP2 uvrA strains or *S. typhimurium* TA102, has the potential to detect certain types of mutagens, such as cross-linking agents or oxidising mutagens, which the 4 bacterial strains recommended in the former version of the OECD TG 471 may not detect. The data set submitted does not provide data for the required 5th bacterial strain.

Consequently, the Registrant is required to complete the data set on mutagenicity by performing an *in vitro* gene mutation study in bacteria (Annex VII, 8.4.1) using one bacterial strain which may detect mutagens, such as cross-linking agents or oxidising mutagens, i.e. one *E. coli WP2* strain or *S. typhimurium TA102*, following recommendations of EU Method B.13/14 laid down in Commission Regulation (EC) No 440/2008 or OECD Test Guideline 471.

3) Other missing information

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. As of 1 December 2010, this section requires the registration dossier to include the hazard classification of the substance resulting from the application of Title I and II of Regulation 1272/2008 for all hazard classes and categories in that Regulation. The information for classification and labelling provided in the fields of section 2 of the technical dossier is not consistent with Annex VI of Regulation 1272/2008 (CLP Regulation). Specifically, R52 (harmful) should be replaced by R51/53 (toxic). The Registrant is accordingly requested to harmonize the classification of its substance, in accordance with Annex VI of the CLP Regulation.

ECHA
EUROPEAN CHEMICALS AGENCY

IV. 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.

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

[redacted]
Jukka Malm
Director of Regulatory Affairs