EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004815-69-04/F Helsinki, 25 August 2014

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

For 1-vinyl-2-pyrrolidone, CAS No 88-12-0 (EC No 201-800-4), 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 1-vinyl-2-pyrrolidone, CAS No 88-12-0 (EC No 201-800-4), 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 5 March 2013.

On 14 May 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted]

On 11 June 2013 ECHA received comments from the Registrant agreeing to the request related to the substance identity, but disagreeing to the request for exposure assessment and risk characterisation. On 19 July 2013 and 21 November 2013 the Registrant updated his registration dossier (submission numbers [redacted] respectively).

The ECHA Secretariat considered the Registrant's comments and dossier updates. On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

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.

Subsequently, proposals for amendment to the draft decision were submitted.

On 10 April 2014 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and amended the draft decision.

On 22 April 2014 ECHA referred the draft decision to the Member State Committee.

By 12 May 2014, in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant on the proposals for amendment into account.

After discussion in the Member State Committee meeting on 10-13 June 2014, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 12 June 2014. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

Information related to chemical safety assessment and chemical safety report

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

1. Environmental exposure assessment and risk characterisation (Annex I, Sections 5.2.4. and 6.3.); and
2. Documentation for the recommended personal protective equipment, i.e. gloves to be worn need to be specified clearly when handling the substance or mixture (Article 14(6), Annex I, 5.1.1., in conjunction with Annex II, 0.1.2. and 8.2.2.2.(b)(i)), including:
   - The type of material and its thickness, and
   - The typical or minimum breakthrough times of the glove material.

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 **4 March 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.

Information related to the chemical safety assessment and chemical safety report

1. Environmental exposure assessment and risk characterisation (Annex I, Sections 5.2.4. and 6.3.)

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.

According to Article 14(1) and (4) and Annex I, section 0.6., the Registrant is required to perform a chemical safety assessment (CSA) for the registered substance. The CSA shall cover 1) Human health hazard assessment, 2) Human health hazard assessment of physicochemical properties, 3) Environmental hazard assessment and 4) PBT and vPvB assessment. If as a result from these steps, the substance meets the criteria for any hazard classes or categories[1] set out in Annex I to Regulation (EC) No 1272/2008 (CLP Regulation), or is assessed to be a PBT or vPvB, the CSA shall also include the additional steps: Exposure assessment, including generation of exposure scenario(s) and exposure estimation, and Risk characterisation. The additional steps of the CSA shall be carried out in accordance with Sections 5 (for Exposure assessment) and 6 (for Risk characterisation) of Annex I of the REACH Regulation.

Further, according to Annex I, section 5.0., the objective of the Exposure assessment is to make quantitative or qualitative estimate of the dose/concentration of the substance to which humans and the environment are or may be exposed. The assessment shall consider all stages of the life-cycle of the substance and shall cover any exposures that may relate to the hazards identified in Sections 1 to 4 of chapter 0.6 of Annex I.

The Registrant has waived the exposure assessment and risk characterisation for the environment on the basis that the substance is not classified for an environmental hazard. However, the substance has a harmonized classification for human health as oral acute toxicity 4, dermal and inhalation acute toxicity 3, eye damage 1, carcinogenicity 2, STOT single exposure 3, STOT repeated exposure 2. Therefore, as the substance meets the criteria for classification, the CSA shall include exposure assessment and risk characterisation as additional steps.

With regard to the scope of the required exposure assessment, as stated above and in accordance with Annex I, section 5.0., it has to cover all hazards that have been identified according to sections 1 to 4 of Annex I of REACH Regulation.

In the registration dossier the Registrant has identified a hazard for the environment: effects (immobility) are seen in the short term Daphnia test at concentrations as low as 8 mg/L (EC50 Daphnia=45 mg/L with Daphnia being the most sensitive species). Therefore, the Registrant is required to carry out the exposure assessment and subsequent risk characterisation also for the environment in order to address a hazard identified for the environment. As further outlined in the Guidance on information requirements and chemical assessment, (Part B: Hazard assessement 2011, version 2.1), such identified hazards (among others) necessitating exposure assessment are the "hazards for which there are classification criteria and there is information on these properties of the substance showing

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- hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F.
- hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10.
- hazard class 4.1:
- hazard class 5.1;

that it does have these properties, but the severity of the effects is lower than the criteria for classification and so the substance is not classified". Moreover, the above mentioned guidance specifies further (in Section 8.4.2.2) that "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. (...) Hence, quantitative exposure assessment, i.e. derivation of PECs, is mandatory for the water, sediment and soil environmental compartments."

In the comments to the draft decision, the Registrant argued that an exposure assessment for environment has to be performed only if environmental hazards leading to classification have been identified. Additionally, the registered substance would be ready biodegradable and consequently, in the event of effects occuring, they would be localised and of short duration, thus allowing as a basis to waive the PNEC derivation and the environmental risk assessment. With regard to these comments ECHA points out the following:

Generally, two of the main purposes of both the REACH and CLP Regulation are to ensure a high level of protection of human health and the environment (Article 1(1) of the REACH and CLP Regulation respectively). The additional steps in a chemical safety assessment of exposure assessment and risk characterisation serve this objective as they allow estimating and characterising any risk to mankind or the environment. The arguments of the Registrant that this shall be done only for hazards that have been classified in accordance with the CLP Regulation and not for other identified hazards ignore this overall context. These arguments remain on a formal level leaving aside the rationale of the legislation.

The REACH Regulation obliges manufacturer and importer to ensure the safe use of their substances in general while the CLP Regulation sets up an obligation to conclude on concrete risk management measures by classification for certain hazards and to communicate this via labelling in the supply chain. The REACH and CLP Regulations can be interpreted in a coherent and consistent way without reducing unnecessarily the scope of both pieces of legislation. Whereas in line with recital 12 of the CLP Regulation terms and definitions of REACH and CLP should be interpreted consistently, 'hazard' or 'identified hazard' is not defined in either of the Regulations. More explicitly, ECHA points out firstly that both REACH and CLP Regulations make a difference between the terms 'hazard' and 'hazardous' and 'hazard classes'. This becomes clear from:

- Article 3 of the CLP Regulation referring to fulfilling the criteria relating to 'physical hazards', 'health hazards' or 'environmental hazards';
- Article 14(4) and Annex I, Section 0.6.3. to the REACH Regulation referring to 'hazard classes';
- Annex I, section 5 to the REACH Regulation referring to the term 'hazard' (and not hazard class) when defining the scope of the exposure assessment.

Hence, both in the REACH and CLP Regulation the term 'hazard' is independent from the term 'hazardous' and consequently from the classification of the substance in 'hazard classes'. Thus, the term 'hazard' in Annex I, Section 5 does not refer solely to 'hazard classes'. The legislation contains both clearly distinct terms and the legislator would have used the more specific term 'hazard classes' instead of the term 'hazard' if that was his intention.

Pursuant to Annex I, Section 3.0.2. of the REACH Regulation five environmental spheres shall be assessed for hazards (aquatic including sediment, terrestrial, atmospheric compartments, including the potential effects via food-chain accumulation, microbiological activity of sewage treatment systems). Annex I, Sections 5 and 6 require an exposure assessment and risk characterisation for the "environmental spheres for which exposure to the substance is known or reasonably foreseeable". ECHA points out that following the Registrant's argumentation, the environmental exposure assessment and risk characterisation would only be possible for the aquatic environmental sphere (and excluding sediment) since the results for a number of standard data requirements for the other environmental spheres (e.g. information on soil/sediment toxicity, activated sludge respiration inhibition testing etc.) do not lead to the classification of substances as hazardous, as no hazard classes or classification criteria based on the results of these tests are codified in the CLP Regulation. As this would result in a situation where a large part of standard data requirements set out in the REACH Annexes would become irrelevant in the hazard and exposure assessment and risk characterisation of a substance, such an approach cannot be correct.

Instead it is self-evident that the legislator has a clear intention to use the standard information required in Annexes VII to X of the REACH Regulation for the hazard assessment. I.e. hazards might be determined from any of standard information required in Annexes VII to X and not only from information leading to classification of the substance as hazardous, and use it for the risk characterisation of the substance.

Second, from a scientific point of view, if a hazard is identified as a consequence of assessing all the available information, and levels of exposure to the substance above which humans or the environment should not be exposed are derived then, the consequence should be to assess whether those levels are exceeded during the lifecycle of the substance. However, for reasons of proportionality, the REACH Regulation limits the requirement of this assessment only to those substances that fulfil the criteria for classification in any of the hazard classes or categories set out in Article 14(4) to the REACH Regulation and Annex I to the CLP Regulation. In that regard the request by ECHA to understand exposure and risk of the substance subject to the present decision is not exceeding of what is appropriate and necessary to attain the objectives of the legislation. As outlined above, knowledge of properties and possible exposure to mankind or environment is crucial in chemicals regulation. The additional administrative to gain this knowledge has to be balanced against the safe use of the substance as one of the core REACH objectives. The identified hazard, even though not classified, in this case has been demonstrated by immobility of daphnia. On that basis ECHA's request for environmental exposure assessment and risk characterisation does not exceed what is necessary to address the concern.

Finally, the ready biodegradability of the substance shall be taken into account in the environmental exposure assessment, but it cannot be considered as a basis to waive PNEC derivation and the environmental risk assessment in presence of identified environmental hazards. According to Annex I, 3.3.1. the PNEC for each environmental sphere shall be established, based on the available data. According to Annex I, 3.3.2. if it is not possible to derive a PNEC this shall be clearly stated and justified. In the registration dossier, effects values are reported for the aquatic organisms and these should constitute the basis for the PNEC derivation.

In conclusion, the arguments by the Registrant cannot lead to omit the required data that is needed in order to comply with the REACH Regulation. Therefore, the Registrant is requested to perform an environmental exposure assessment covering all life-cycle stages of the registered substance originating from manufacture and identified uses, and subsequently perform risk characterisation for each exposure scenario to demonstrate the safe use of the substance, and update the dossier accordingly.

2. Details of the personal protective equipment employed and recommended for handling the substance

Article 14(6) as well as Annex I, 0.1., 5.1.1., 5.2.4. and 6.2. of the REACH Regulation require registrants to identify and apply appropriate measures to adequately control the risks identified in a 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 and Annex II, section 0.1.2. of the REACH Regulation the information provided in the registration dossier shall be consistent with that in the Safety Data Sheet (SDS). The requirements of Safety Data Sheets are specified in Annex II of the REACH Regulation (amended by Commission Regulation (EU) No 453/2010). According to Annex I, 0.3, 0.5 and 5.1.1 applied Risk Management Measures (RMM) have to be indicated in the CSR. Annex II, section 8.2.2.2 (b)(i), requires the Registrant to describe the relevant RMM in detail (e.g. 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) in order to minimise the exposure for workers handling the registered substance. In particular, the following requirements for hand protection in order to avoid dermal exposure need to be provided consistently in the SDS and CSR:

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

In the CSR, the use of personal protective equipment is adviced e.g. in chapter 9.1.1. However, further characteristics are lacking e.g. type of materials, thickness, design etc. Not all materials are well suited to protect against exposure to all substances, mixtures or materials. This has to be specified further to match the specific substances. A concern is raised if workers are not properly informed to use the right type of e.g. gloves to protect themselves against exposure to chemicals. The use of unsuited material may even result in higher level of exposure, than not using any protection at all, as the inside of contaminated gloves, may be covered with migrated substance – and the skin inside a glove is often humid – corresponding to exposure under occlusion.

Information on the specification of personal protective equipment shall be provided for all scenarios where the use of personal protective equipment is advised. In particular the type of material of the gloves for all exposure scenarios where the use of gloves is advised.

The Registrant is accordingly required to provide documentation for the recommended material type, its thickness and the typical or minimum breakthrough time for the glove type recommended, with regard to the amount and duration of dermal exposure.

Note for consideration by the Registrant:

Regarding how to report the gloves specifications, the information should be included both in section 11 of the technical IUCLID dossier (Guidance on Safe Use), which is the disseminated part of the dossier, and in the CSR where the appropriate measures to adequately control the risk are to be reported.

It is the responsibility of the Registrant to ensure consistency of the information within the CSR, and between the CSR, IUCLID section 11 and the safety data sheet.

Moreover, ECHA notes that, in response to the proposal for amendment by a Member State Competent Authority requesting to use a glove efficiency of maximum 95 %, the Registrant has provided additional information to justify the use of 98 % efficiency in their assessment instead. This information is currently not included in the dossier. Therefore, ECHA invites the Registrant to provide also this information in the dossier update.

IV. 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.

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