~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: CCH-D-0000001603-81-07/F Helsinki,
Date of the decision: 3 November 2011

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

For Vinyl Neodecanoate, CAS 51000-52-3 (EC Nr. 256-905-8), 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 **Vinyl neodecanoate, CAS 51000-52-3 (EC NR. 256-905-8),** submitted by [redacted] (Registrant), latest submission number [redacted], for [redacted].

The compliance check was initiated on 22 June 2010.

On 20 April 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.

On 6 May 2011 the Registrant provided to ECHA comments on the draft decision.

ECHA considered the comments received and decided not to amend the draft decision.

On 17 June 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 submitted proposals for amendment to the draft decision.

On 20 July 2011 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 within 30 days of the receipt of the notification.

European Chemicals Agency
Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland
Tel.: +358 9 6861 80 | Fax +358 9 6861 8210 | http://echa.europa.eu

ECHA reviewed the proposals for amendment received and modified the draft decision accordingly.

On 1 August 2011 ECHA referred the draft decision to the Member State Committee.

On 19 August 2011 the Registrant submitted comments on the proposals for amendment.

The Member State Committee took the comments of the Registrant on the proposals for amendment of the Member State Competent Authorities into account.

A unanimous agreement of the Member State Committee on the modified draft decision was reached on 2 September 2011 in a written procedure launched on 22 August 2011.

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)(ii) as well as Annex VI, Section 2 of the REACH Regulation the Registrant shall submit for the registered substance:

   a. Spectral data (Annex VI, 2.3.5.): ultra-violet (UV), nuclear magnetic resonance (NMR) or mass spectrum (MS).
   b. Chromatographic data in form of high-pressure liquid chromatogram or gas chromatogram that enables the composition of the registered substance to be quantified (Annex VI, 2.3.6.).
   c. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance. This information shall be sufficient to allow the method to be reproduced (Annex VI, 2.3.7.).

2) Pursuant to Articles 41(1)(a), 41(3), 10(a)(vii), 12(1)(c) and Annex VIII of the REACH Regulation the Registrant shall submit the information using the test method as indicated below

   a. In vitro cytogenicity study in mammalian cells (Annex VIII, 8.4.2.; EU Test Method B.10).

3) Pursuant to Articles 41(1)(c), 10(b), 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. Revised PBT Assessment - Bioaccumulation Assessment.
   b. Release estimation for the environment using the default (worst case) daily use of the substance for each identified use or supporting justification for deviating from the default values (Annex I, 5.1.1, and 5.2.4.).

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 5 November 2012, 12 months from date of decision.

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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 for the purpose of registration within the applicable tonnage band of [redacted] in accordance with Article 6 and 11(2) of the REACH Regulation, does not comply with the requirements of Articles 10, 12 and 13 and with Annexes VI and VIII thereof. 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 registered substance that shall be sufficient to identify it.

a. The information provided in the technical dossier is not sufficient to enable the substance to be identified as required according to Annex VI, 2 of the REACH Regulation. The data requirements include spectral and chromatographic data (sections 2.3.5 and 2.3.6 of Annex VI). However, the UV, NMR and/or MS spectra are not present in the technical dossier. No justification for the omission of this data is included either. Alternative method(s) and results were also not provided. Therefore the Registrant is requested to submit the spectral data (UV, NMR or MS).
b. The technical dossier contains a Gel Permeation Chromatogram (GPC) which does not allow verifying the concentration of the main constituent and the impurities of the substance. Therefore, the Registrant is required to submit chromatographic data that enables the composition to be quantified.
c. The technical dossier does not contain sufficient details on the analytical methods, as required pursuant to Annex VI, 2.3.7. The Registrant is therefore requested to provide the necessary information for substance identification in order to allow the method(s) to be reproduced.

2) Missing information related to Genetic toxicity in vitro

Pursuant to Articles 10(a)(vii) and 12(1)(c) of the REACH Regulation, a registration for a substance produced in quantities of 10-100 tonnes per year shall contain as a minimum the information specified in Annexes VII and VIII of the REACH Regulation.

The Registrant provided for the endpoint *8.4.2 In vitro cytogenicity study in mammalian cells*, a non-guideline in vitro mammalian chromosome aberration assay performed in 1981; the assay tested vinyl neodecanoate for its ability to induce chromosome aberrations in rat liver epithelial cell line RL4. In the absence of significant increase of chromosome damage, the Registrant has concluded that the substance does not induce chromosome damage.

Article 13(3) of the REACH Regulation provides that tests "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 Agency as being appropriate." The rat liver cell chromosome aberration assay does not meet this standard. Article 13(3) further provides that "information on intrinsic properties of substances may be generated in accordance with other test methods provided that the conditions set out in Annex XI are met."

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The rat liver cell chromosome aberration assay lacks coverage of the endpoint with and without metabolic activation.

ECHA considers that the condition of Annex XI, 1.1.2. (2) (which would allow to use data generated by other than recognised test methods) is not met because the measurement of chromosome aberration with and without metabolic activation is a key parameter foreseen to be investigated in the corresponding test methods referred to in Article 13(3). Consequently, the rat liver cell chromosome aberration assay does not meet the requirements of Annex XI, 1.1.2. (2).

As the test provided does not meet the information requirements of Annex VIII, 8.4.2. the Registrant is requested to perform a new study using the EU test method B.10.

3) Information related to the Chemical Safety Report

a) Pursuant to Article 14(3)(d) and Annex I, 4.1 of the REACH Regulation, a chemical safety assessment of a substance shall include a persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment.
For the Bioaccumulation assessment, to fulfil the objective of the PBT assessment, the Registrant has reported in the CSR the results of a Fish dietary bioaccumulation study.
ECHA notes that the principle results of the Fish dietary bioaccumulation study do not include, in sufficient details, the growth corrected biomagnification factor, the lipid normalized biomagnification factor and how both are calculated. Also, an indicative kinetic bioconcentration factor range with the appropriate derived equation from the relevant bioaccumulation factor should be reported.
Consequently, the Registrant is requested to revise the bioaccumulation assessment of the registered substance by including the above missing information, and to update the CSR and the technical dossier (section 5.3.1 of IUCLID), accordingly.

b) Pursuant to Annex I, 5.1.1. of the REACH Regulation, each exposure scenario shall contain a description of the operational conditions such as the duration and frequency of emission of the substance to the different environmental compartments. Pursuant to Annex I, 5.2.4 of the REACH Regulation, exposure estimations shall take account, among others, of the duration and frequency of emissions of the substance to the different environmental compartments.

The Registrant used for exposure calculations 365 days usage and has indicated that this is the worst case scenario. The Registrant did not provide any justification for the use of this value. According to ECHA Guidance R16 on Environmental Exposure Estimation, the default daily usage for a substance manufactured in quantities less than 1000 tonnes per annum is 20 release days. For further iteration, the Registrant can overwrite the daily and annual use, by using suitable and specific on-site, downstream user data, if available.

The Registrant is therefore requested to provide a justification for the number of production days used in the exposure calculations or, alternatively, use in the exposure calculations the default daily usage value of 20 days. The Registrant is also requested to update the CSR accordingly.

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IV. Avoidance of unnecessary testing by data and cost sharing

The Registrant is hereby designated already now to perform the above mentioned tests in accordance with Article 53(1) of the REACH Regulation in case the same substance is registered by further registrant(s) at a later stage and subject to evaluation. This is to avoid unnecessary testing and the duplication of tests as a general aim of the REACH Regulation (Article 25). The legal text foresees the sharing of information between registrants.

In case an evaluation decision for another registration for the same substance will request the same elements of information requested from the Registrant of this decision, ECHA will inform the subsequent registrant of this decision. The costs of the test shall be shared equally and the Registrant shall provide each of the other registrant(s) concerned with a copy of the full study report. This is stipulated by Article 53(2) and (3) of the REACH Regulation.

V. 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 reads:

> "*Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable.*"

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 1907/2008 adapted to the technical progress by Commission Regulation (EC) No 761/2009 and use the applicable test methods to generate the information on the endpoints indicated above.

National authorities monitoring good laboratory practice (GLP) maintain lists of test facilities indicating the relevant areas of expertise of each facility.

VI. 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.

Done at Helsinki,

[redacted]

Jukka Malm
Director of Regulatory Affairs

European Chemicals Agency
Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland
Tel.: +358 9 6861 80 | Fax +358 9 6861 8210 | http://echa.europa.eu