EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002047-80-03/F Helsinki, 17 April 2012

DECISION ON A TESTING PROPOSAL SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For Butyl glycollate, CAS No 7397-62-8 (EC No 230-991-7), 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 40(1) of the REACH Regulation the ECHA has examined the following testing proposal submitted as part of the registration dossier for Butyl glycollate, CAS No 7397-62-8 (EC No 230-991-7) submitted by [redacted] (Registrant), latest submission number [redacted], for 1000 or more tonnes per year.

In accordance with Articles 10(a)(ix) and 12(1)(e) of the REACH Regulation, the Registrant submitted the following testing proposal as part of the registration dossier to fulfil the information requirements set out in Annex IX:

> Annex IX, 8.6.2.: Sub-chronic toxicity study (90-day) in rats via the oral route according to OECD Guideline 408 (Repeated Dose 90-day Oral Toxicity in Rodents)

The examination of the testing proposals was initiated on 08/11/2010.

ECHA opened a third party consultation for the testing proposal including testing on vertebrate animals that was held from 15 April 2011 until 30 May 2011. ECHA did not receive comments from third parties.

On 15 November 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 15 December 2011 the Registrant did not provide any comments on the draft decision to ECHA.

On 20 January 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 did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

This decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the requirements of the REACH Regulation. The decision does not prevent ECHA to initiate a compliance check on the present dossier at a later stage.

II. Testing required

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant shall carry out the following test using the indicated test method:

- Sub-chronic toxicity study (90-day) (Annex IX, 8.6.2., Test Method B.26 of Regulation (EC) No 440/2008, OECD Guideline 408) in rat by the oral route.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **17 October 2013** an update of the registration dossier containing the information required by this decision.

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

The decision of ECHA is based on the examination of the testing proposals of the Registrant for the registered substance.

A sub-chronic toxicity study (90-day) is a standard information requirement as laid down in Annex IX, 8.6.2 of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to generate the data for this endpoint. The test shall be carried out using the test methods indicated in section II above.

ECHA considered the Annex IX, 8.6.2 column 1 requirement concerning the most appropriate route of administration. In this regard, ECHA notes that the oral route is the one preferred by ECHA Guidance (R.7.5.4.3) for testing systemic repeated dose toxicity effects. Furthermore ECHA observes, that although the registered substance is a liquid substance with a low vapour pressure, the exposure scenarios developed by the Registrant indicate inhalation exposure via formation of aerosols. Thus, inhalation might be an appropriate route of administration. However, in an acute toxicity study via the inhalation route provided by the Registrant, the substance caused signs of upper respiratory irritation in the nose, but only at high dose and at one day after exposure. In addition, persistence of the effects could not be estimated. Thus there are insufficient triggers or information to consider that the registered substance will have route-specific toxicity via the inhalation route. Moreover, testing the substance using the oral route will generate information in order to enable a good understanding of the general toxicity profile of the registered substance via the oral route. Having regard to the above considerations, ECHA concludes that the oral route proposed by the Registrant is the most appropriate route of administration in the sub-chronic toxicity study (90-day).

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is thus requested to carry out the following test: 90-day sub-chronic toxicity study in rat, oral route (EU Test Method B.26 (OECD Guideline 408)).

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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