EUROPEAN CHEMICALS AGENCY

Helsinki, 24.02.2014

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DECISION ON SUBSTANCE EVALUATION PURSUANT TO ARTICLE 52(1) OF REGULATION (EC) NO 1907/2006

For a mixture of cistetrahydro-2-isobutyl-4-methylpyran-4-ol; transtetrahydro-2-isobutyl-4-methylpyran-4-ol, CAS No 63500-71-0 (EC No 405-040-6)

Addressees: Registrants of a mixture of cistetrahydro-2-isobutyl-4-methylpyran-4-ol; transtetrahydro-2-isobutyl-4-methylpyran-4-ol (concerned registrants)

This decision is addressed to all Registrants of the above substance with active registrations on the date on which the draft for the decision was first sent, with the exception of the cases listed in the following paragraph. A list of all the relevant registration numbers subject to this decision is provided as an enclosure to this decision.

Registrants meeting the following criteria are *not* addressees of this decision: i) Registrants who exclusively use the above substance as an on-site isolated intermediate and under strictly controlled conditions and ii) Registrants who have ceased manufacture/import of the above substance in accordance with Article 50(3) of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation) before the decision is adopted by ECHA.

Based on an evaluation by the Ministry of Agriculture, Food and Environment as the Competent Authority of Spain (evaluating MSCA) for the environment aspects, the European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 52 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

This decision does not take into account any updates of the registrations of the concerned registrants after 1 August 2013, the date upon which the draft decision was circulated to the other Competent Authorities of the Member States and ECHA pursuant to Article 52(1) of the REACH Regulation.

This decision does not imply that the information provided by the concerned registrants in the registrations is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossiers of the concerned registrants at a later stage, nor does it prevent a new substance evaluation process once the present substance evaluation has been completed.

I. Procedure

Pursuant to Article 45(4) of the REACH Regulation the Competent Authority of Spain has initiated substance evaluation for a mixture of cistetrahydro-2-isobutyl-4-methylpyran-4-ol; transtetrahydro-2-isobutyl-4-methylpyran-4-ol, CAS No 63500-71-0 (EC No 405-040-6) submitted by the concerned registrants and prepared the present decision in accordance with Article 46(1) of the REACH Regulation.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds

for concern relating to to exposure, wide dispersive use and high risk characterisation ratio for the environment a mixture of cistetrahydro-2-isobutyl-4-methylpyran-4-ol; transtetrahydro-2-isobutyl-4-methylpyran-4-ol was included in the Community rolling action plan (CoRAP) for substance evaluation pursuant to Article 44(2) of the REACH Regulation to be evaluated in 2012. The CoRAP was published on the ECHA website on 29 February 2012. The Competent Authority of Spain was appointed to carry out the evaluation.

The evaluating MSCA considered that further information was required to clarify the abovementioned concerns. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 25 February 2013.

In two sendings, on 4th and 26th April 2013, ECHA sent the draft decision to the concerned registrants and invited them pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

By 27th May 2013 ECHA received comments from concerned registrants of which it informed the evaluating MSCA without delay. Registrants agreed the comments made within the draft decision and suggested providing an update of the dossier, within 6 months, including additional information which would remove the uncertainties regarding the environmental classification and exposure data to confirm a RCR ratio < 1 for the environmental compartment.

The evaluating MSCA considered the registrants' comments received and did not amend Section II of the draft decision.

In accordance with Article 52(1) of the REACH Regulation, on 1st August, 2013 the evaluating MSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days.

Subsequently, a Competent Authority of a Member State submitted proposal for amendment to the draft decision.

On 6 September 2013 ECHA notified the concerned registrants of the proposal for amendment to the draft decision and invited them pursuant to Articles 52(2) and 51(5) of the REACH Regulation to provide comments on this proposal for amendment within 30 days of the receipt of the notification.

The evaluating MSCA reviewed the MSCA's proposal for amendment and amended the draft decision accordingly.

On 16 September 2013 ECHA referred the amended draft decision to the Member State Committee.

On 2 October 2013 the Registrant provided comments on the proposed amendment. The Member State Committee took the comments of the Registrant into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 21 October 2013 in a written procedure launched on 10 October 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

Pursuant to Article 46(1) of the REACH Regulation the registrants shall submit the following

information on the registered substance using the indicated test method and instructions subject to the present decision:

1. Short-term growth inhibition study aquatic plants (algae preferred) (Annex VII, 9.1.2.; test method: Algae, Growth Inhibition Test, EU C.3/OECD 201).

2. Information to refine the exposure assessment regarding:

   - Operational Conditions (OC) (including specific environmental conditions);
   - Risk Management Measures (RMM);
   - Release rate measurements during the emission period of releases to environmental compartments.

The above has to be provided for the production, compounding and formulation life cycle stages, as well as for two STPs and aquatic, soil and sediment environmental compartments at different sites. If local risk characterisation ratios in the chemical safety assessment (Guidance on IR&CSA, Part E4.3) prove to be higher than 1, long term toxicity testing will be required according to ECHA Technical guidance (IR&CSA, R7.8.3):

- Long-term toxicity testing on invertebrates (section 9.1.5.)
- Long-term toxicity testing on fish (section 9.1.6).

Pursuant to Article 46(2) of the REACH Regulation, the concerned registrants shall submit to ECHA by 24 November 2014 an update of the registration dossiers containing the information required by this decision.

At any time, the concerned registrants 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 substance was included in the CoRAP processes due to exposure, wide dispersive use and high risk characterisation ratio for the environment. These aspects have been assessed by the MSCA concluding that a refinement of the environemental risk assessment is needed by providing specific on site information.

Based on the evaluation of all relevant information submitted on a mixture of cistetrahydro-2-isobutyl-4-methylpyran-4-ol; transtetrahydro-2-isobutyl-4-methylpyran-4-ol, ECHA concludes that further information is required in order to enable the evaluating MSCA to complete the evaluation of whether the substance constitutes a risk to human health or the environment.

1. Short-term growth inhibition study aquatic plants

The substance is not classified for the environment by the registrants, but the information presented in the registration dossier on algae can not allow concluding clearly on this point (EC50 >94 mg/L).

Nevertheless, a relevant study provided in 2006 to the Spanish CA during the previous notification procedure was considered. This study has been validated and confirms that the toxicity of florosal to algae is well above 100 mg/l. Information on the source of this study was provided to registrants in order to facilitate the sharing of information. Therefore, this relevant information should be included in the registration dossier in a dossier update to

confirm that florosal is not classified for the environment.

2. Information to refine the exposure assessment

The initial grounds of concern for the inclusion of the substance in the CoRAP process (exposure, wide dispersive use and high risk characterisation ratio for the environment) were assessed by the MSCA according to the information presented by the registrants for the registration process.

As the registrants did not identify for the substance any PBT, vPvB or hazardous properties for the environment, the exposure estimation and risk characterization was considered to be not necessary, and therefore no information is provided within the registration dossier in this sense.

Therfore, due to the lack of information on both, real emissions and information on the existence of management measures, default emissions exposure values have been used in the environmental risk assessment. This initial (Tier I) assessement confirmed an unacceptable risk for the environment, RCR >1, for the production, compounding and formulation life cycle stages for the aquatic, soil and sediment environmental compartments at those sites over 10 tonnes/year and also for the STPs.

The substance is considered to be poorly biodegradable and stable in the aquatic compartment and the environmental risk assessment results in RCR ratios >1 estimated for the aquatic compartment. According to Annex IX (quantities of 100 tonnes or more) long-term toxicity testing could be proposed if the chemical safety assessment indicates the need to investigate further the effects on aquatic organisms:

- Long-term toxicity testing on invertebrates (section 9.1.5.) and,
- Long-term toxicity testing on fish (section 9.1.6).

Thus a Tier II approach with on-site specific information is necessary to refine the unnaceptable RCR ratio for the environment and to avoid long-term tests, including vertebrate organisms. As indicated in Section II, information on Operational Conditions, Risk Management Measures and release rate measurements during emission period of releases episodes to environmental comparements is required in order to enable the evaluating MSCA to assess the exposure and refine the unacceptable risk characterization ratio estimated for the environment. If the provided on-site specific exposure information do not allow reducing the RCR below 1, a further Tier III approach relating to the above mentioned long-term toxicity tests is required.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the concerned registrants are required to provide specific on-site information, corresponding to the proposed Tier II refinement, on: Operational Conditions (OC) (including specific environmental conditions); Risk Management Measures (RMM); release rate measurements under frequent and regular monitoring of releases to environmental compartments. These are:

1. **Number of emission days per year or daily use at sites.** Sometimes production/formulation is characterised by intermittent processess. Indicate if the emission of florosal from the plant-site is continuously distributed during the year ("annual use at a site") or concentrated during some days ("release(s) time per year"). In this latter case, indicate how many days.

2. **Inform on the existence of Waste Water Treatment Plant (WWTP) in the production/formulation plants, if any**. Inform on the existence of any sewage treatment of the effluents at the production/formulation plants. If so, indicate the

percentage of elimination of florosal thought this treatment system.

3. **Indicate the average concentration of Florosal, during the emission period, in the final effluent from the site-plant to the receiving water.**

4. **Information on the effluent discharge rate(s) to freshwater from the WWWTP(s) or form the plant (in case of no existence of WWTP).** Indicate the rate of your effluent into the receiving water.

5. **Inform on the existence of Municipal Sewage Treatment Plant STP(s)**. By default it is assumed that the discharge from the site is treated in a municipal sewage treatment plant (STP). Confirm the existence of an STP.

6. **Information on the management of STP-sludge (i.e. incineration, agricultural soil application), if any.** By default it is assumed that the discharge from the site are treated in a municipal sewage treatment plant (STP). Inform on how the STP-sludge is managed or disposed.

7. **River flow rate(s) in which effluents are discharged.** Indicate the flow rate of the receiving water in which your effluents are discharged.

8. **Release(s) fraction to soil.** By default it is assumed that the discharge from the site is treated in a municipal sewage treatment plant (STP) and the STP-sludge is applied to agricultural soil. Therefore it is needed to confirm what fraction of releases is applied to agricultural soil, if any.

9. **Confirmation on the existence of releases to marine water compartment.** Indicate whether your effluents are discharged to the marine compartment or near.

All measures and information should be provided during the "release time of the year". The provided information will have to clearly indicate or refer to how the information has been measured or where it comes from.

The above has to be provided to clarify the concerns for the production, compounding and formulation life cycle stages, as well as for two STPs and aquatic, soil and sediment environmental compartments at different plant-sites.

IV. Adequate identification of the composition of the tested material

The substance identity information submitted in the registration dossiers has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the required test, the sample of substance used for the new study shall have a composition that is within the specifications of the substance composition that are given by all concerned registrants. It is the responsibility of all the concerned registrants to agree on the tested materials to be subjected to the test subject to this decision and to document the necessary information on composition of the test material. The substance identity information of the registered substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation. Finally, the study must be shared by the concerned registrants.

Avoidance of unnecessary testing by data- and cost- sharing

Avoidance of unnecessary testing and the duplication of tests is a general aim of the REACH

Regulation (Article 25). The legal text foresees the sharing of information between registrants. Since several registrants of the same substance are required to provide the same information, they are obliged to make every effort to reach an agreement for every endpoint as to who is to carry out the test on behalf of the other concerned registrants and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation.

If ECHA is not informed of such agreement within 90 days, it shall designate one of the concerned registrants to perform the tests on behalf of all of them. If a registrant performs a test on behalf of other registrants, they shall share the cost of that study equally and the registrant performing the test shall provide each of the others concerned with copies of the full study reports.

This information should be submitted to ECHA using the following form stating the decision number above at:
https://comments.echa.europa.eu/comments_cms/SEDraftDecisionComments.aspx

Further advice can be found at http://echa.europa.eu/datasharing_en.asp.

V. General requirements regarding 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.

VI. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Articles 52(2) and 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 the ECHA's internet page at http://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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Deputy Executive Director

Annex: List of registration numbers for a mixture of cistetrahydro-2-isobutyl-4-methylpyran-4-ol; transtetrahydro-2-isobutyl-4-methylpyran-4-ol – This annex is confidential and not included in the public version of this decision