EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114315210-72-01/F Helsinki, 13 July 2016

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

For tetrahydrothiophene, CAS No 110-01-0 (EC No 203-728-9), 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 tetrahydrothiophene, CAS No 110-01-0 (EC No 203-728-9), submitted by ARKEMA FRANCE (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 3 September 2015, 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 21 February 2014.

On 5 June 2014 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 QS901546-12.

On 11 July 2014 ECHA received comments from the Registrant on the draft decision.

On 4 September 2014 the Registrant updated his registration dossier (submission number [redacted]).

The compliance check requirement to submit information of a two-generation reproductive toxicity study (EU B.35, OECD TG 416) or an extended one-generation reproductive toxicity study (EU B.56, OECD TG 443) has been removed from this draft decision due to the legislative amendments to the REACH Regulation regarding Annex X, Section 8.7.3.
In light of this, ECHA Secretariat did not consider further the Registrant's comments and update concerning the information requirement of Annex X, Section 8.7.3.

However, ECHA Secretariat did consider further the Registrant's comments and update concerning the information requirements of Annex X, section 8.7.2., Annex VII, section 8.3, Annexes IX and X, section 9.4 and Annex I, section 3.3. On the basis of all this information and change of scope, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 3 September 2015 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, a proposal for amendment to the draft decision was submitted.

On 9 October 2015 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposal for amendment received and did not amend the draft decision.

On 19 October 2015 ECHA referred the draft decision to the Member State Committee.

By 9 November 2015, in accordance to Article 51(5), the Registrant provided comments on the proposal for amendment. The Member State Committee took the comments on the proposal for amendment of the Registrant into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 23 November 2015 in a written procedure launched on 12 November 2015.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 41(1), 41(3), 10(a)(vi) and/or (vii), 12(1)(e), 13 and Annexes VII, IX and X of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: EU B.31./OECD 414) in rabbits, oral route;

B. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit the information required by this decision in the form of an updated registration to ECHA by **20 July 2017.**

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.

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.)

Pre-natal developmental toxicity studies on two species are part of the standard information requirements for a substance registered for 1000 tonnes or more per year (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

The technical dossier contains information on a pre-natal developmental toxicity study in rats by the inhalation route using the registered substance as test material.

However, there is no information available for a pre-natal developmental toxicity study in a second species.

In the dossier submission number [redacted] (prior to the update) the Registrant sought to adapt this information requirement. The justification of the adaptation given by the Registrant is "*No effects on litter size, fetal weight or skeletal or visceral morphology were observed in an inhalation developmental toxicity study in rats up to the concentration of 1910 ppm. Therefore, tetrahydrothiophene is considered of low priority for further testing for effects on reproduction (OECD Guideline 414 (Prenatal Developmental Toxicity Study in rabbits)).*"

However, ECHA notes that this adaptation does not meet the specific rules for adaptation according Annex X, Section 8.7., column 2 or the general rules for adaptations according to Annex XI. ECHA notes that in the ECHA Guidance on information requirements and chemical safety assessment (version 2.3, December 2013), Chapter R.7a, Section R.7.6.6.3 it is stated: "At ≥1000 t/y, a study in a second species will normally be required when the first study is negative, unless weight of evidence assessment or specific data e.g. toxicokinetic data provide scientific justification not to conduct the study in a second species. This could be the case if available data demonstrate that for example the rat is the most relevant species for extrapolating to humans or if the rabbit is not a suitable model for testing for developmental toxicity. ECHA notes that the Registrant has not provided such arguments. As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

In the updated dossier (submission number [redacted]) the registrant has sought to adapt this information requirement based on Annex XI, Section 3.2(b). ECHA acknowledges the registrant's comments on this endpoint. ECHA acknowledges that the Registrant has updated the technical dossier, including the CSR, adapting this information requirement based on Annex XI, section 3.2(b). Based on the information provided in the updated CSR (03/09/2014) all uses recorded in section 3 of IUCLID, including the life-cycle description are carried out under strictly controlled conditions and the risk management measures to ensure strictly controlled conditions are adequately described.

Based on the industrial uses described in the dossier, this end-point study could be waived based on adequately documented strictly controlled conditions. The CSR however states "Once injected in the gas, the life-cycle of tetrahydrothiophene is the same as for natural gas. It stops at combustion of the fuel. The registrant states that levels of tetrahydrothiophene are from 15 to 40mg/m^3 in natural gas when distributed." The Registrant goes on to conclude that because the concentration in natural gas does not exceed 0.1% w/w, according to Art. 14 of REACH, a quantitative chemical safety assessment only needs to be performed for those life-cycle steps before injection of tetrahydrothiophene into natural gas. This latter comment by the registrant cannot be used to waive the study based on Annex XI 3.2(b) as specified by the introductory paragraph of Annex XI section 3.2 and section 3.2(b). Based on this there is a data-gap. ECHA notes, however, that the stage in the life-cycle where the substance is used as a tracer in natural gas where consumer exposure is foreseeable (when EU citizens light their gas stove and hence momentary exposure to the substance before the gas ignites) is not included as a use in the technical registration dossier or the CSR, while it is an obvious use of the substance. Annex XI, section 3.2(b) requires that strictly controlled conditions are demonstrated throughout the life cycle of the substance. As explained above, this is not demonstrated. Consequently there remains a data-gap for this end-point.

The test in the first species was carried out by testing a rodent species and ECHA therefore considers that the test in a second species should be carried out in a non-rodent species. According to the test method EU B.31/OECD 414, the rabbit is the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rabbit as a second species to be used.

ECHA notes that the substance is liquid and there is at least one oral study available (for acute toxicity), thus, the route shall be oral. ECHA also notes that in 90-day inhalation study the NOAEC for local irritation is 51 ppm and for systemic effects 1442 ppm, further supporting the choice of the oral route to avoid additional stress of pregnant animals due to local irritation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD 414) in rabbits by the oral route.

B. Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 30 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested other studies (Two-generation reproductive toxicity study or Extended one-generation reproductive toxicity study, Annex X, Section 8.7.3, Skin sensitization, Annex VII, Section 8.3., Terrestrial toxicity studies Annexes IX and X, Section 9.4.). As these studies are not addressed in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated IUCLID5 dossier is 12 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

IV. Adequate identification of the composition of the tested material

In relation to the information required by the present decision, the sample of substance used for the new study must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new study is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new study must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the study to be assessed.

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://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[2] by Ofelia Bercaru, Head of Unit, Evaluation E3

[2] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.