EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000005121-89-03/F Helsinki, 8 October 2014

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

For pyrithione zinc, CAS No 13463-41-7 (EC No 236-671-3), 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 pyrithione zinc, CAS No 13463-41-7 (EC No 236-671-3), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Section 9.4.2 of Annex IX of the REACH Regulation relating to effects on soil micro-organisms. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year. This decision does not take into account any updates submitted after 12 June 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 10 September 2013.

On 22 October 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 18 November 2013 ECHA received comments from the Registrant. On 21 January 2014 the Registrant also submitted an update of the dossier with submission number [redacted]

The ECHA Secretariat considered the Registrant's comments and the updated dossier ([redacted]). The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 12 June 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.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

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

1. Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216).

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 **15 July 2015**.

Note for consideration by the Registrant:

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

III. Statement of reasons

Pursuate 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.

Effects on soil micro-organisms is a standard information requirement as laid down in Annex IX, section 9.4.2. of the REACH Regulation.

In the dossier initially addressed ([redacted]), the Registrant did not provide information fulfilling the information requirement of Annex IX, 9.4.2. but only included the statement *"No data"* in the relevant IUCLID field. In the Registrant´s comments and in the updated dossier ([redacted]), the Registrant proposed to adapt the information requirements of Annex IX, 9.4.2. using the following justification:
"According to REACH Annex IX section 9.4 column 2, studies assessing the effects on terrestrial organisms do not need to be conducted if indirect and direct exposure of the soil compartment is unlikely. Indirect exposure to Zinc Pyrithione (ZnPT) via the atmosphere is highly unlikely based on the substance's physical-chemical properties and chemical stability. Monitoring data revealed that there is practically no direct exposure of ZnPT to soil. Thus, the study on toxicity to soil microorganisms (REACH Annex IX section 9.4.2) is waived.

ZnPT exposure to the soil compartment is unlikely. There is practically no indirect and no direct exposure. Please see details below:

Indirect exposure
Indirect exposure of ZnPT to the soil compartment via the atmosphere is considered highly unlikely based on the substance's physical-chemical properties and chemical stability. ZnPT is a solid and the vapour pressure was estimated to be < 1E-6 Pa at 25 °C (see IUCLID section 4.6 for details), thus, volatilisation is unlikely. If released to air ZnPT absorbs UV light at 300 nm and therefore is susceptible to direct photolysis in sunlight, with a troposhperical half-life of 8.69 hours (see IUCLID section 5.1 for details).

Direct exposure – tier 1 assessment
ZnPT environmental exposure was estimated in a tier 1 assessment. To cover all possible scenarios and identify highest potential exposures, worst-case assumptions were made and several sub-scenarios as well as combined exposure included. Resulting exposure values are considered highly conservative and are used for risk assessment only.
The tier 1 assessment includes four exposure scenarios (ES) covering all relevant life cycle stages: manufacturing (ES 1 - synthesis of zinc pyrithione), formulation (ES 2- [redacted] *), [redacted] (ES 3 [redacted]) and use by consumers (ES 4 –dispersive use [redacted]). ES 2 covers formulation in large scale formulation plants and small scale formulation plants. ES 4 covers potential environmental exposure from the use [redacted] containing [redacted] % ZnPT via two different approaches, including exposure modelling based on formulation of [redacted] ZnPT at the local and regional level and exposure calculation based on [redacted] % market share in a local catchment. Further, combined exposures were assessed, assuming that formulation and use may occur in the same local catchment.*
Highest Predicted Environmental Concentrations in the soil compartment (PECsoil) were revealed for combined formulation (ES 2) and consumer use (ES 4) scenarios. Assuming formulation in a small scale formulation plant without own sewage treatment plant (STP) and consumer use of [redacted] ZnPT [redacted] taking place in the same catchment resulted in local PEC-values for agricultural soil averaged (180 days) of 2.11E-03 mg/kg ww for formulation and 6.5E-02 mg/kg ww for consumer use, with a combined PECsoil of 6.5E-02 mg/kg ww. Regional concentrations were very low and had no influence on the combined local and regional values obtained.

Direct exposure - monitoring data
As an assignment from the Swedish Environmental Protection Agency, the IVL Swedish Environmental Research Institute Ltd. published a "Screening Study" of zinc pyrithione (Swedish EPA, 2007; see section 13 for full report). The overall objectives of the screening were to determine the concentrations of the substances in a variety of media, to highlight important transport pathways, and to assess the possibility of current emissions. The screening programme included measurements in background areas and in the vicinity of potential point sources and/or "affected areas". Measurements were carried out in areas reflecting diffuse emission pathways from the society. Sample types were water (surface water, in and outgoing sewage water, industrial effluents, drinking water and landfill leachate) sediment, sludge, biota (fish) and human urine. A total of 124 samples were included of which 112 samples were analysed for ZnPT.
ZnPT was only detected in three water samples (representing ingoing water to STPs and one industrial effluent) in concentrations of 1.9, 17 and 32 µg/L. In no other samples was ZnPT detected, including sludge samples from 34 different STPs. Samples are considered representative for the geographical extent of use.
The report concludes that ZnPT is no problematic substance. With no ZnPT detected in sewage sludge, direct deposition of ZnPT to soils with the application of sludge from STPs is

highly unlikely. The results confirm that the tier 1 assessment produced highly overestimated exposure values to be used for risk assessment purposes only.

Summary and conclusion
The tier 1 exposure assessment allowed calculating highest potential ZnPT environmental exposure concentrations. Calculations are based on conservative assumptions and include all possible worst-case scenarios. Thus, even though estimated exposures are low overall, PECsoil-values obtained are considered conservative overestimates to be used for risk assessment purposes only.
In general, release to soil at the local scale will occur via application of sludge from an STP to agricultural soil and via atmospheric deposition of substances released to air and direct releases to soil from industrial settings are not assessed at the local scale, but only at the regional scale (ECHA Guidance CSR R.16, 2010). Based on the substance's physical-chemical properties and chemical stability atmospheric deposition is highly unlikely. There is practically no indirect exposure. Extensive monitoring detected no ZnPT in a total of 34 representative sludge samples analyzed. Thus, deposition of ZnPT to soils with the application of sludge from STPs is highly unlikely. There is practically no direct exposure. In summary indirect and direct exposure of ZnPT to the soil compartment are highly unlikely. Indirect exposure via the atmosphere is unlikely based on the substance's properties. Direct exposure can be practically excluded based on extensive monitoring data.

References
Swedish Environmental Protection Agency (2007) Results from the Swedish Screening Programme. Subreport 3: Zinc pyrithione and Irgarol 1051. IVL Report B1764."

The Registrant in his justification claims that a study on soil micro-organisms is not required because there is practically no direct or indirect exposure. According to column 2 of section 9.4 of Annex IX of the REACH Regulation, the study does not need to be conducted if direct and indirect exposure of the soil compartment is unlikely. However, ECHA does not consider that the Registrant has established that exposure of the soil compartment is unlikely for the following reasons;

- The technical dossier contains information indicating wide dispersive use (ERC 8a) for which exposure to soil cannot be ruled out.
- The calculated Predicted Environmental Concentrations (PECs) indicate that exposure to soil is not unlikely even though at a very low level.
- The Registrant states that the PECs are based on conservative assumptions and include all possible worst-case scenarios. However, EHCA notices that the Tier 1 default ERCs have been replaced by sPERCs and it is not clear to ECHA why the calculated PECs should be considered as worst-case scenarios.
- The Registrant refers to a monitoring study in which the substance was not detected in any of the analysed sludge samples. ECHA, however, notices that the monitoring study does not cover any degradation products of the substance. The degradation studies included in the technical dossier reports of several degradation products and these and any other degradation products need to be covered by the risk assessment as well.

In conclusion, ECHA does not consider that the Registrant has established that exposure to soil of the substance and its degradation products is unlikely. Furthermore, following section R.7.11.5.3. of ECHA Guidance Chapter R7c (version 1.1, November 2012), a soil microorganism toxicity test is triggered for this substance as inhibition of aquatic microbial activity has been observed according to studies reported in the technical dossier and considered reliable by the Registrant.

Thus, it follows that the Registrant has an information gap for the endpoint of Annex IX, 9.4.2 and is obliged to fulfil the information requirement.

Therefore, pursuant to Article 41(3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance: Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216).

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation. The Registrant is reminded of his responsibility and that of joint Registrants to ensure that the joint registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

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://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]
Leena Ylä-Mononen
Director of Evaluation