SUBSTANCE EVALUATION

CONCLUSION DOCUMENT

as required by REACH Article 48

for

2-(phenylmethoxy)naphthalene

EC No 405-490-3

CAS No 613-62-7

Evaluating Member State(s): Czech Republic

Dated: 18 December 2015

Evaluating Member State Competent Authority

Ministry of Environment of the Czech Republic
Vršovická 1442/65
Praha 10, 100 10

Tel: +420 2 6712 2129
Fax: +420-2-6731-0308
Email: Jarmila.Sladkova@mzp.cz

Year of evaluation in CoRAP: 2012

Before concluding the substance evaluation a draft decision to request further information was issued on: 04 April 2013 and 26 April 2013. This draft decision was terminated on 18 March 2015 after the lead registrant dossier was updated.

Please find (search for) further information on registered substances here:

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

DISCLAIMER

The Conclusion document has been prepared by the evaluating Member State as a part of the substance evaluation process under the REACH Regulation (EC) No 1907/2006. The information and views set out in this document are those of the author and do not necessarily reflect the position or opinion of the European Chemicals Agency or other Member States. The Agency does not guarantee the accuracy of the information included in the document. Neither the Agency nor the evaluating Member State nor any person acting on either of their behalves may be held liable for the use which may be made of the information contained therein. Statements made or information contained in the document are without prejudice to any further regulatory work that the Agency or Member States may initiate at a later stage.

Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work.

In order to ensure a harmonised approach, ECHA in cooperation with the Member States developed risk-based criteria for prioritising substances for substance evaluation. The list of substances subject to evaluation, the Community rolling action plan (CoRAP), is updated and published annually on the ECHA web site[1].

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by the Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. In this conclusion document, the evaluating Member State shall consider how the information on the substance can be used for the purposes of identification of substances of very high concern (SVHC), restriction and/or classification and labelling. With this Conclusion document the substance evaluation process is finished and the Commission, the registrants of the substance and the competent authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

CONTENTS

1. CONCERN(S) SUBJECT TO EVALUATION

2-(phenylmethoxy) naphthalene was originally selected for substance evaluation in order to clarify suspected risks about:

- long-term effects in the environment.

The substance was previously notified under NONS and previous assessments for lower tonnages and conclusions of the assessments were not consistent.

During the evaluation also other concerns were identified. The additional concerns were:

- provided data were insufficient to reach an unequivocal decision on PBT properties;

- occupational exposure.

2. CONCLUSION OF SUBSTANCE EVALUATION

The available information on the substance and the evaluation conducted has led the evaluating Member State to the following conclusions, as summarised in the table below.

Conclusions	**Tick box**
Need for follow up regulatory action at EU level *[if a specific regulatory action is already identified then, please, select one or more of the specific follow up actions mentioned below]*	X
Need for Harmonised classification and labelling	X
Need for Identification as SVHC (authorisation)	
Need for Restrictions	
Need for other Community-wide measures	
No need for regulatory follow-up action	

3. JUSTIFICATION FOR THE CONCLUSION ON THE NEED OF REGULATORY RISK MANAGEMENT

3.1. NEED FOR FOLLOW UP REGULATORY ACTION AT EU LEVEL

3.1.1. Need for harmonised classification and labelling

During the Substance evaluation decision-making process, a lead registrant on behalf of the newly established SIEF submitted an updated registration dossier. In the updated dossier, the following information was provided: 1) a waiver for freshwater/sediment simulation testing and a conclusion that the substance is very persistent; 2) a robust study summary and full study report for a fish bioaccumulation test performed in 1994; 3) a robust study summary for a fish early-life stage toxicity test conducted in 2005-6; 4) a chemical safety report including a revised exposure assessment; 5) robust study summaries for the endpoints a) Toxicity to reproduction, b) Developmental toxicity/teratogenicity, c) Long-term toxicity on aquatic invertebrates.

The Czech MSCA examined all of the data provided in the updated registration dossier.

Aquatic toxicity

The fish early life stage toxicity test was conducted in accordance with GLP to test guideline OECD 210 using a semi-static regime. The 32 day NOEC for effects on length and weight was 0.0048 mg/l based on nominal concentrations and 0.0016 mg/l based on time-weighted mean measured concentrations. No effects on hatching and survival rates were observed. The study is considered as reliable and the Czech MSCA used this result to derive the PNEC aquatic.

The study on long-term toxicity to Daphnia was conducted in accordance with GLP to test guideline OECD 202 using a semi-static regime. The 21 day NOEC for effects on reproduction was 0.036 mg/l. The reliability of this study is not clear as the effects were seen at a concentration above the water solubility (0.027 mg/l) and there was a sudden loss of test concentration at the end of the exposure period.

There is an algal toxicity study available for the substance, conducted in accordance with GLP to test guideline OECD 201. No significant effects on growth rate were observed and the 96h NOEC for growth rate is >0.09 mg/l based on mean measured concentrations. This study is considered to be reliable by the Czech MSCA.

The long-term aquatic toxicity to fish and the fact that the substance is not readily biodegradable indicate that it should be classified as Aquatic Chronic 1. However, the harmonised classification for this substance in Annex VI of Regulation EC 1272/2008 (the CLP Regulation) is Aquatic Chronic 4 H413 and Registrants have a legal obligation to use the harmonised classification. Thus a revision of the harmonized classification is appropriate for controlling the risks.

There is no link between potential update of the harmonised classification and labelling and other regulatory risk management processes as the substance was not identified as a PBT substance and no risks to workers or the environment were identified.

3.1.2. Need for Identification as a substance of very high concern, SVHC (first step towards authorisation)

Not applicable.

3.1.3. Need for restrictions

Not applicable.

3.1.4. Proposal for other Community-wide regulatory risk management measures

Not applicable.

3.2. NO FOLLOW-UP ACTION NEEDED

At the moment there is no follow up action needed under REACH Article 48 for the other concerns identified during substance evaluation.

The concern could be removed because	**Tick box**
Hazard and /or exposure was verified to be not relevant and/or	
Hazard and /or exposure was verified to be under appropriate control and/or	X
The registrant modified the applied risk management measures.	
other: <Please specify>	

PBT properties

The lead registrant included a waiver for freshwater/sediment simulation testing and concluded that the substance is very persistent vP.

Based on the fish early life stage toxicity test submitted, the substance meets the T criterion according to Annex XIII of REACH.

The lead registrant provided a robust study summary and full study report for a fish bioaccumulation test performed in 1994 in accordance with GLP and to test guideline OECD 305E. The Czech MSCA originally had concerns about interpretation of this study due to lack of information on the concentration of dispersants used and a missing declaration on the test validity. On review of the full study report, it was concluded that the study is reliable and the aquatic BCF is 180. Thus, the substance is not bioaccumulative or very bioaccumulative according to REACH Annex XIII and the substance is not considered as PBT.

Environmental and occupational exposure

An exposure assessment was required in order to clarify the concern related to exposure and high aggregated tonnage of the substance. The registrants were requested to provide information which relates to the most recent situation on tonnage produced or imported into the relevant markets in the Member States from the individual registrants and estimates or measurements of occupational exposure under the current situation and conditions.

During substance evaluation, it came to light that some registrants had already ceased production and it was confirmed by them immediately after receipt of the draft decision. Therefore the actual tonnage was much lower than estimated when the substance was included in CoRAP. Based on the assessment of the available data the Czech MSCA concluded that there is no concern regarding environmental and occupational exposure and consider the risk management measures recommended by the registrants based on self-classification as sufficient to control the risks.

Based on the available information, the Czech MSCA concludes that there is no concern regarding the subsequent life cycle stages handling of the product with substance as the substance in the final products is used in low concentration up to 1% and is bound to the paper surface by a polymer layer.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

Given that there are individual registrants who follow the valid harmonised classification and labelling, there is need for its revision to bring it in compliance with the available information. The CLH proposal should be submitted by the manufacturer or importer or downstream user according to Article 37(6) of Regulation (EC) No 1272/2008 to the competent authority in one of the Member States in which the substance is placed on the market.

Follow-up action	Date for intention	Actor
Proposal to revise the current harmonised classification and labelling	N/A	Member State directly, or prompted by submission from a manufacturer/importer/downstream user in accordance with Art. 37(6) of the CLP Regulation.