Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	Reaction mass of ethylbenzene and m-xylene and p-xylene
Chemical Group:	
EC Number:	905-562-9
CAS Number:	
Submitted by:	Germany
Date:	17/03/2015

Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

Contents

1 IDENTITY OF THE SUBSTANCE

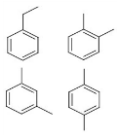
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	Reaction mass of ethylbenzene and m-xylene and p-xylene
IUPAC name:	N/A
Index number in Annex VI of the CLP Regulation	None available for registered substance, but relevant constituents covered by index numbers 601-023-00-4 (ethylbenzene) and 601-022-00-9 (xylenes).
Molecular formula:	C_8H_{10}
Molecular weight or molecular weight range:	106 g·mol^{-1}
Synonyms/Trade names:	

Type of substance ☐ Mono-constituent ☒ Multi-constituent ☐ UVCB

Structural formula: (The structural formula of the four main constituents are given)



1.2 Similar substances/grouping possibilities

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2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

No harmonised classification is available for the substance as a whole, but all of the individual constituents have CLH, cf. Table 2.

Table 2: Harmonised classification

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard state-ment code(s)		
601-023-00-4	ethylbenzene	202-849-4	100-41-4	Flam. Liq. 2; Acute Tox. 4*	H225; H332	-	-
601-022-00-9	o-xylene	202-422-2	95-47-6	Flam. Liq. 3; Acute Tox. 4*; Skin Irrit. 2	H226; H312; H315; H332	-	-
	m-xylene	203-576-3	108-38-3			-	-
	p-xylene	203-396-5	106-42-3			-	-

2.2 Self classification

Regarding human health, the registrant(s) have submitted the following self-classification in excess of the CLH given in Table 2 for the substance affected by this proposal:

Hazard classes/categories : Eye Irrit. 2 , Asp. Tox. 1, STOT SE 3, STOT RE 2 (with SCL ≥ 10 %)

Hazard statements: H304, H319, H335, H373 (ototoxicity)

For other similar substances, self-classifications vary between notifiers. Some notifiers have assigned a more severe hazard category for the hazard classes already covered by CLH. Others have included additional classification for Asp. Tox. 1, Eye Irrit. 2 or Eye Dam. 1, Skin Sens. 1, STOT SE 3 (respiratory irritation), and/or STOT RE 2 (ototoxicity).

In rare cases, also classification for carcinogenicity and/or reproductive toxicity have been proposed, but only by a small minority of notifiers.

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

None known.

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA dissemination site		
☐ 1 – 10 tpa	☐ 10 – 100 tpa	☐ 100 – 1000 tpa
☐ 1000 – 10,000 tpa	☒ 10,000 – 100,000 tpa	☐ 100,000 – 1,000,000 tpa
☐ 1,000,000 – 10,000,000 tpa	☐ 10,000,000 – 100,000,000 tpa	☐ > 100,000,000 tpa
☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential

☒ Industrial use	☒ Professional use	☒ Consumer use	☒ Closed System

The substance is used in industrial and professional settings during polymer and rubber processing and production and as an intermediate or fuel. Additional use of the substance includes lubricants, binders and release agents and functional fluids. Consumer use of the substance comprises a wide variety of product categories such as adhesives, sealants, lubricants, air care products, washing and cleaning agents etc.

4 OTHER COMPLETED/ONGOING REGULATORY PROCESSES THAT MAY AFFECT SUITABILITY FOR SUBSTANCE EVALUATION

☒ Compliance check, Final decision	☐ Dangerous substances Directive 67/548/EEC
☐ Testing proposal	☐ Existing Substances Regulation 793/93/EEC
☐ Annex VI (CLP)	☐ Plant Protection Products Regulation 91/414/EEC
☐ Annex XV (SVHC)	☐ Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	

5 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1 Legal basis for the proposal

☒ Article 44(2) (refined prioritisation criteria for substance evaluation)

☐ Article 45(5) (Member State priority)

5.2 Selection criteria met (why the substance qualifies for being in CoRAP)

☒ Fulfils criteria as CMR/ Suspected CMR

☒ Fulfils criteria as Sensitiser/ Suspected sensitiser

☐ Fulfils criteria as potential endocrine disrupter

☐ Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB

☒ Fulfils criteria high (aggregated) tonnage (*tpa > 1000*)

☒ Fulfils exposure criteria

☐ Fulfils MS's (national) priorities

5.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR ☐C ☐M ☐R	Suspected CMR[1] ☐C ☐M ☒R	☐ Potential endocrine disruptor
☐ Sensitiser	☒ Suspected Sensitiser[1]	
☐ PBT/vPvB	☐ Suspected PBT/vPvB[1]	☒ Other (please specify below) Suspected Neurotoxicant
Exposure/risk based concerns		
☒ Wide dispersive use	☒ Consumer use	☒ Exposure of sensitive populations
☐ Exposure of environment	☐ Exposure of workers	☐ Cumulative exposure
☒ High RCR	☒ High (aggregated) tonnage	☐ Other (please specify below)

[1] CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)
Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)
Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

There are several reasons for why this substance is proposed to be put on the CoRAP:

- Screening of the available toxicological data base has shown the possibility that the standard information requirements for reproductive toxicity might not have been fulfilled. For the xylene isomers, only a one-generation study appears to be available whereas at this stage it is unclear whether the results from the two-generation study performed with ethylbenzene can be read across to the xylene isomers. In addition, pre-natal developmental toxicity data only appear to have been performed in one species.
- The substance subject to this proposal also bears a potential to cause neurotoxic effects. In particular, the constituent ethylbenzene is known for its ototoxicity and in the view of the DE MSCA some further evaluation is need in order to clarify whether this endpoint has been adequately addressed in the risk characterisation by the registrants.
- A wide variety of consumer uses is listed in the registration dossier. Moreover, the substance is marketed at a high tonnage (while it is unclear at this stage, which part of that tonnage relates to consumer uses).
- In addition, a cursory assessment of the registration dossier raised concern that DNEL derivation by the registrant(s) has not been performed to REACH standards. In particular, the assessment factors used in the extrapolation from animal toxicity data to exposed humans appear to be smaller than the ones recommended by the corresponding ECHA guidance.
- As a consequence, RCRs calculated by the registrant(s) could be too optimistic and risk characterisation based on these DNELs might lead to an underestimation of risk of the general population.
- In view of all of the above points, there is concern that relevant toxicity of the substance under question with regard to reproductive or other endpoints might have been addressed inadequately in the risk assessment of the registrant(s) and, hence, that consumers might be put at risk.

5.4 Preliminary indication of information that may need to be requested to clarify the concern

☒ Information on toxicological properties	☐ Information on physico-chemical properties
☐ Information on fate and behaviour	☒ Information on exposure
☐ Information on ecotoxicological properties	☒ Information on uses
☐ Information ED potential	☐ Other (provide further details below)

At the current state of knowledge, it might become necessary to request further data on reproductive toxicity from the registrant(s). Moreover, if the concern regarding the RCRs calculated by the registrant(s) being unrealistically small is confirmed, a refined exposure assessment may become necessary for which additional data, e.g. with respect to a more adequate characterisation of consumer exposure, might need to be requested.

5.5 Potential follow-up and link to risk management

☒ Harmonised C&L	☒ Restriction	☒ Authorisation	☐ Other (provide further details)

If the evaluation of reproductive toxicity or neurotoxicity should result in the conclusion that CLH was required, preparing a CLH dossier would be the logical next step.

Furthermore, a detailed evaluation of consumer uses and RCRs will demonstrate whether restriction or authorisation should be considered or whether no further risk management options appear indicated.