CONSULTATION NUMBER 0094-01

Third party submission of information on alternatives for

Industrial use of MOCA as a curing agent/chain extender in cast polyurethane elastomer production

PUBLIC VERSION

Legal name of submitter(s): *LANXESS Deutschland GmbH*

TABLE OF CONTENTS

1. ALTERNATIVE ID AND PROPERTIES

Isobutyl 4-chloro-3,5-diaminobenzoate, EC no. 251-311-5, CAS no. 32961-44-7, trade name Addolink® 1604.

Substance ID	EC Number	CAS Number	Properties
Isobutyl 4-chloro-3,5-diaminobenzoate, Addolink® 1604	251-311-5	32961-44-7	Aquatic Chronic 3, H412

2. TECHNICAL FEASIBILITY

Applicants claim:

"The cure time compared with MOCA means that it is not a suitable alternative reagent for some products.
Additionally, several moulders reported cracks on the finished product meaning that the product was not fit for purpose. Colour was previously a problem, however synthesis has developed but it is still not possible to produce a completely white elastomer."

Our customers report that Addolink® 1604 is only slightly less reactive than MOCA. The pot life of Addolink® 1604 is 3 times longer (compared to MOCA) which is a big advantage for casting of large parts. After melting at 80 - 90 °C, Addolink® 1604 can be stored for 10 hours at 110 °C.

3. ECONOMIC FEASIBILITY

Applicants claim:

"The price is 5-7 times that of MOCA. This is one of the reasons why this alternative is only used in an estimated 1 % of the world-wide market."

The price for Addolink® 1604 is higher than that of MOCA. This is due to the multi-step synthesis of Addolink® 1604.
For that substance LANXESS Deutschland GmbH has active business to numerous small, midsize and large companies in Europe. About half of our customers of Addolink® 1604 are small or medium enterprises. Further companies are already in the process to evaluate Isobutyl 4-chloro-3,5-diaminobenzoate as an alternative to existing systems.

4. HAZARDS AND RISKS OF THE ALTERNATIVE

Applicants claim:

"The classification according to the ECHA dissemination tool for 1604 is given in Table 11 above. It does not have harmonised classification and labelling, but is not considered a CMR, PBT, vPvB or endocrine disrupting substance by those registrants who have submitted CLP notifications. There, consequently, could be an overall risk reduction for workers in using this substance."

LANXESS Deutschland GmbH (formerly Rhein Chemie Rheinau GmbH) is the elected Lead registrant for Isobutyl 4-chloro-3,5-diaminobenzoate, EC no. 251-311-5, CAS no. 32961-44-7. Even though the REACH dossier has not yet been submitted sufficient data to conclude on classification is available, see references. Taking into account these data Isobutyl 4-chloro-3,5-diaminobenzoate should (only) be classified as

Aquatic Chronic 3, H412.

LANXESS Deutschland GmbH notices that this classification is in contrast to approx. one third of the CLP notifications, according to which the substance should not be classified or only be classified for human health effects (Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319, STOT SE 3, H335). However, as no information regarding the impurity profile of the CLP notified substances is provided on the ECHA web page it is difficult to identify what caused the indicated health effects.
The classification Aquatic Chronic 3, H412 refers to the substance as manufactured and, therefore, should be considered the only relevant classification when evaluating Isobutyl 4-chloro-3,5-diaminobenzoate, EC no. 251-311-5, CAS no. 32961-44-7 as an alternative to 2,2'-Dichloro-4,4'-methylenedianiline, EC no. 202-918-9, CAS no. 101-14-4 [= MOCA, MbOCA] as a curing agent/chain extender in cast polyurethane elastomer production.

5. AVAILABILITY

Applicants claim:

"During interviews it was mentioned that the production of this substance causes significantly higher pollution and waste water compared with MOCA (Suzhou's MOCA production currently has zero emissions). Furthermore it was also stated that the factory that produces 1604 in China has been forced to cease production due to these high levels of pollution. Indeed in communications with some distributors they have stated that they cannot currently reliably source this product.
Therefore, it is questionable whether the availability of this substance is sustainable. The problems related to the production of this substance are likely to be drivers of the poor price elasticity."

In 2015 LANXESS Deutschland GmbH switched to a new reliable supplier for Isobutyl 4-chloro-3,5-diaminobenzoate, EC no. 251-311-5, CAS no. 32961-44-7. It is now manufactured by a non-European company that mainly produces pharmaceuticals for the European market. This supplier is certified according to ISO 9001, ISO 14001, ISO 18001 and works according to OHSAS rules. All single process steps for production of Addolink® 1604 were evaluated as such for environmental risks before starting regular business for that product. The currently expected availability of the substance is up to 10 tons per month, if needed.

6. CONCLUSION ON SUITABILITY AND AVAILABILITY OF THE ALTERNATIVE

LANXESS Deutschland GmbH has a reliable source for Isobutyl 4-chloro-3,5-diaminobenzoate, EC no. 251-311-5, CAS no. 32961-44-7 that does not raise concerns regarding pollution or waste water. For that substance LANXESS Deutschland GmbH has active business to numerous small, midsize and large companies in Europe. Further companies are already in the process to evaluate Isobutyl 4-chloro-3,5-diaminobenzoate as an alternative to existing systems.

The data gathered for ongoing REACH registration of the substance allow for a classification as Aquatic Chronic 3, H412. Therefore, using Isobutyl 4-chloro-3,5-diaminobenzoate as alternative for MOCA can significantly reduce risks for environment and workers.

REFERENCES

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2. Isobutyl 4-chloro-3,5-diaminobenzoate: In vitro Eye Irritation Test, human cornea model test, ENVIGO, December 2016

3. Isobutyl 4-chloro-3,5-diaminobenzoate: Local Lymph Node Assay in the Mouse, ENVIGO, October 2016

4. Study on the toxicity towards algae of Isobutyl 4-chloro-3,5-diaminobenzoate according to OECD-Test Guideline 201, SGS Institut Fresenius GmbH, September 2016

5. Study on the acute toxicity towards Daphnia of Isobutyl 4-chloro-3,5-diaminobenzoate according to OECD-Test Guideline 202, SGS Institut Fresenius GmbH, September 2016

6. Study on the ready biodegradability of Isobutyl 4-chloro-3,5-diaminobenzoate according to OECD-Test Guideline 301 B, SGS Institut Fresenius GmbH, August 2016