

ANNEX XV REPORT

**AN ASSESSMENT OF WHETHER THE USE OF
MUSK XYLENE IN ARTICLES SHOULD BE
RESTRICTED IN ACCORDANCE WITH
ARTICLE 69(2) OF REACH**

SUBSTANCE NAME(S): musk xylene

IUPAC Name(s): 5-tert-butyl-2,4,6-trinitro-m-xylene

EC NUMBER(S): 201-329-4

CAS NUMBER(S): 81-15-2

CONTACT DETAILS:

EUROPEAN CHEMICALS AGENCY

Annankatu 18,

P.O. Box 400, 00121

Helsinki,

Finland

tel: +358-9-686180,

www.echa.europa

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A. Conclusions

A.1 Conclusions based on the assessment

Musk xylene is a vPvB substance according to Article 59 of REACH; it has been included on the candidate list (28/10/2008; ED/67/2008) and included into Annex XIV of REACH (Commission Regulation (EU) No 143/2011) with a sunset date of 21 August 2014.

ECHA has gathered information on the uses of Musk Xylene in articles from various sources. According to the records there are no registrations for Musk Xylene, there are no SiA notifications made under Article 7(2) and there have been no applications for authorisation (AfAs) made for the substance.

Following an assessment of the available evidence, ECHA considers that there is no use of the substance in articles. Therefore, under Article 69(2), ECHA's view is that the requirements to develop and submit an Annex XV dossier for restriction are not met.

This conclusion was supported by the EFFA (European Flavour and Fragrance and Association) and IFRA (International Fragrance Association) who submitted a comment in the call for evidence on the Dossier.

A.2 Targeting

The report is targeted on the potential use of Musk xylene in articles and whether or not such use should be restricted.

This targeting is based on the requirement of Article 69(2) that requires ECHA to consider if the use of the substance in articles is adequately controlled and prepare an Annex XV dossier for an appropriate restriction if this is not the case.

A.3 Summary of the justification

A.3.1 Identified hazard and risk

Information on uses

There is no production of musk xylene in the European Union (EU). Musk xylene is used as fragrance and fragrance enhancer in fragrance mixtures for detergents, fabric softeners, fabric conditioners, cleaning agents, air fresheners and other household products. Its use appears to be decreasing in Europe. Exports of musk xylene in mixtures are likely to be minimal (RPA 2008).

Quantities of musk xylene used in articles are likely to be negligible, if any, as musk xylene is used in mixtures, rather than articles.

According to the records there are no registrations for Musk Xylene indicating there are uses as an article, there are no SiA notifications made under Article 7(2) and there have been no applications for authorisation submitted.

Information on hazards

Musk xylene is concluded to be a vPvB substance according to Article 59, it has been included on the candidate list and into Annex XIV of REACH. It is classified in Regulation 1272/2008 (CLP) as: Expl. 1.1 H201; Carc. 2 H351; Aquatic Acute 1 H400; Aquatic Chronic 1 H410.

Information on emissions/release

There is no information available on emission of Musk xylene from articles.

Characterisation of risk

No risk has been identified for the use of Musk xylene in articles.

A.3.2 Justification that action is required on a Union-wide basis

No restriction is proposed.

A.2.3 Justification that the proposed restriction is the most appropriate Union-wide measure

No restriction is proposed.

B. Information on hazard and risk

B.1 Identity of the substance(s) and physical and chemical properties

B.1.1 Name and other identifiers of the substance(s)

Chemical name: Musk xylene
EC Number: 201-329-4
CAS Number: 81-15-2
IUPAC Name: 1-tert-butyl-3,5-dimethyl-2,4,6-trinitrobenzene

B.1.2 Composition of the substance(s)

Chemical name: Musk xylene
EC Number: 201-329-4
CAS Number: 81-15-2
IUPAC Name: 1-tert-butyl-3,5-dimethyl-2,4,6-trinitrobenzene
Molecular Formula: C₁₂H₁₅N₃O₆
Structural Formula: -
Molecular Weight: 297.3
Typical proportion%: >99
Real proportion (range) in %: 99-100

B.1.3 Physicochemical properties

REACH ref Annex	Property	Value	Reference
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VII, 7.1	Physical state at 20° C and 101.3 kPa	Solid, powder	
VII, 7.2	Melting / freezing point	112-114°C	Treff, 1926; Le Fèvre and Le Fèvre, 1935; Opfer- Schaum and Piristi, 1944
VII, 7.3	Boiling point	Not applicable	Tas and Van de Plassche, 1996; Givaudan, 1990.
VII, 7.5	Vapour pressure	0.00003 Pa at 20°C	Grain 1990; Tas and Van de Plassche, 1996
VII, 7.7	Water solubility	0.15 mg/l	Tas and Van de Plassche, 1996; Schramm et al., 1996
VII, 7.8	Partition coefficient noctanol/water (log value)	4.9	Rudio, 1996; Schramm et al., 1996; Tas and Van de Plassche, 1996; Johnson et al., 1984

B.1.4 Justification for grouping

Not relevant

B.2 Manufacture and uses

B.2.1 Manufacture, import and export of a substance

There is no manufacture of musk xylene in the European Union (EU); it is only imported. Several European companies have terminated their productions in the last decade. Producers in China are now the most important source for the European imports (EC 2005).

The EU Risk Assessment Report (EC 2005) estimated the EU import volume was around 67 tonnes per year (in 2000). While there are no up-to-date data for current imports, a review of use patterns by companies in the EU would suggest that this tonnage has decreased significantly (RPA 2008).

There have been no registrations to date for Musk xylene although there was a pre-registration submitted for the substance with the envisaged deadline of 30/11/2010.

B.2.2 Uses

Musk xylene is used as fragrance and fragrance enhancer in fragrance mixtures for cosmetic products and household products such as detergents, fabric softeners, fabric conditioners, cleaning agents, air fresheners (RPA 2008).

No detailed information is available on the amount of musk xylene which is imported or exported as substances in articles (RPA 2008). Quantities are however, likely to be negligible, if any, as musk xylene is used in mixtures, rather than articles. This is supported by the lack of notifications received by ECHA in relation to the use of musk xylene in articles (<http://echa.europa.eu/documents/10162/2b5afb3a-3438-4226-88ea-bd38f8ea0085>).

B.2.3 Uses advised against by the registrants

The substance is not registered.

B.2.4 Description of targeting

Targeting is based on the hazard for which the substance was included on Annex XIV.

B.3 Classification and labelling

Classification according to CLP

Expl. 1.1 H201; Carc. 2 H351; Aquatic Acute 1 H400; Aquatic Chronic 1 H410

Classification according to the Classification and Labelling Inventory

There have been 942 notifications to the C&L inventory all reproducing the harmonised classification with no additional endpoints covered.

B.4 Environmental fate properties

Not relevant

B.5 Human health hazard assessment

Not relevant

B.6 Human health hazard assessment of physicochemical properties

Not relevant

B.7 Environmental hazard assessment

Not relevant

B.8 PBT and vPvB assessment

B 8.1 Assessment of PBT/vPvB Properties – Comparison with the Criteria of Annex XIII

Musk xylene is concluded to be a vPvB substance (ECHA 2008).

B 8.2 Emission Characterisation

A review of use patterns by companies in the EU would suggest that the use tonnage of 67 tonnes in 2000 has decreased significantly. For the purposes of the mass balance, the figure of 67 tonnes per year is considered to be a *high estimate* and around 25 tonnes per year, which is considered to be a *reasonable estimate* (RPA 2008).

For the high estimate it is assumed that around 54 tonnes (or 80%) of this tonnage is used in detergents, cleaning products and fabric softeners, while cosmetics (i.e. toiletries, colognes, shampoos, etc.) and other uses account for 13 tonnes (or 20%). There is no information on emissions from articles (service life or waste phase) and this is assumed to be negligible at most (RPA 2008).

B.9 Exposure assessment

B.9.1 General discussion on releases and exposure

Not relevant for this dossier as no use in articles has been identified.

B.9.1.1 Summary of the existing legal requirements

Musk xylene is permitted for use in cosmetics products (except oral care products) in the European Union in the framework of the Cosmetics Regulation¹. The permitted quantities are: up to 1% in fine fragrances; up to 0.4% in eau de toilette; up to 0.03% in other products.

Under REACH, Musk xylene was proposed for SVHC listing by NL in 30/06/2008, the substance was listed in the candidate list 28/10/2008 (ECHA 2008)² and included into Annex XIV in 2011 (EC 2011).

REACH has several requirements for substances on the candidate list including notification of its presence in Articles if $\geq 0.1\%$ and 1 tonne per year (Article 7(2)) and that suppliers must inform their customers on request if an article contains more than 0.1% by weight of musk xylene (Article 33(b)).

The entry in Annex XIV for Musk Xylene Authorisation set a last application date of 21/1/2013 and a sunset date of 21/8/2014. No applications for use of the substance have been received to date.

B.10 Risk characterisation

Not relevant for this dossier as no use in articles has been identified.

B.11 Summary on hazard and risk

Information on uses

¹ Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

² included in the candidate list for authorisation by the ECHA's decision ED/67/2008 on 28 October 2008, after agreement of the Member State Committee.

There is no production of musk xylene in the European Union (EU). Musk xylene is used as fragrance and fragrance enhancer in fragrance mixtures for detergents, fabric softeners, fabric conditioners, cleaning agents, air fresheners and other household products. Its use appears to be decreasing in Europe.

According to the records there are no registrations for Musk Xylene indicating there are uses as an article, there are no SiA notifications made under Article 7(2) and there have been no applications for authorisation submitted with Article Service Life.

Quantities of musk xylene used in articles are likely to be negligible, if any, as musk xylene is used in mixtures, rather than articles.

Information on hazards

Musk xylene is concluded to be a vPvB substance according to Article 59, it has been included on the candidate list and into Annex XIV of REACH.

Information on emissions

There is no information available on emission of Musk xylene from articles.

Characterisation of risk

No risk has been identified for the use of Musk xylene in articles.

C. Available information on alternatives

Not relevant

D. Justification for action on a Community-wide basis

No restriction is proposed.

E. Justification why the proposed restriction is the most appropriate Community-wide measure

Not applicable for the report.

F. Socio-economic Assessment of Proposed Restriction

Not applicable for the report.

G. Stakeholder consultation

The draft Annex XV report was subject to a Call for evidence from 13 May 2015 to 15 July 2015 (8 weeks). One comment was received from the EFFA (European Flavour and Fragrance and Association) and IFRA (International Fragrance Association) supporting ECHA's conclusion.

H. Other information

Not relevant.

References

- EC (2005) Risk Assessment Report Vol.55, 2005 on: 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene), CAS#: 81-15-2, EINECS#: 201-329-4. Publication: EUR 21506 EN.
- EC (2011) Commission regulation (EU) no 143/20011 of 17 February 2011 amending Annex XIV of REACH.
- ECHA (2008) Agreement of the Member State Committee on identification of 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene) as a substance of very high concern.
- RPA (2008) Data on manufacture, import, export, uses and releases of musk xylene (CAS n° 81-15-2) as well as information on potential alternatives to its use Report prepared for ECHA