

1 June 2009

Background document for 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)

Document developed in the context of ECHA's first Recommendation for the inclusion of substances in Annex XIV

1. Identity of the substance

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

2. Background information

2.1. Intrinsic properties

Musk xylene was identified as a Substance of Very High Concern (SVHC) meeting the criteria of a vPvB substance pursuant to Article 57(e) and was therefore included in the candidate list for authorisation following ECHA's decision ED/67/2008 on 28 October 2008.

2.2. Imports, exports, manufacture and uses

2.2.1. Volume(s), imports/exports

The substance is not manufactured in the EU but imported as a pure substance from outside EU. The imported volume corresponds largely to the volume used within the EU as the export of the substance or the finished products out of the EU is considered to be minimal. The volume of uses was reported as 67 tonnes in 2000. However, a clear decrease has been observed since then (RPA, 2008). This is mainly due to the phasing out of the use of musk xylene in detergents and cleaning products industry for more than 10 years (RCOM, 2009). Within the time frame of the study no updated information became available on the actual imported volumes. A reasonable estimate of approximately 25 tonnes/year was extrapolated based on the decreasing trend from the past (22% decrease between 1998 and 2000).

Furthermore, there is no detailed information about the presence of musk xylene in articles imported or exported. However, it is likely to be negligible as musk xylene is mainly used in preparations rather than articles.

In conclusion, no actual data on the volume of musk xylene used in the EU is available. Based on the decreasing trend observed in the recent past the volume currently used is estimated to approximately 25 tonnes/year.

2.2.2. *Manufacture and uses*

2.2.2.1. Manufacture and releases from manufacture

At present no manufacturing of musk xylene is taking place within the EU.

2.2.2.2. Uses and releases from uses

Musk xylene belongs to the family of synthetic musks which are substances used to emulate the aroma produced by natural musk. Musk ingredients are a significant ingredient for fragrance formulation both as fragrance and fragrance enhancers used in most fragrance mixtures for detergents, fabric softeners, fabric conditioners, cleaning agents, air fresheners and other household products (RPA, 2008).

It is assumed in the report (RPA, 2008) that 80% of the overall tonnage is used in detergents, cleaning products and fabric softeners and 20% of this tonnage is used in toiletries, colognes, shampoos, etc. This corresponds to 20 and 5 tonnes when taking into account the more reasonable estimate for the use volume (25 tonnes/year).

The number of EU relevant sites formulating and compounding of the substance is estimated at less than 10. The releases from these point sources are thought to be negligible compared to the overall diffuse releases coming from the use of consumer products containing the substance (EC, 2005).

The main releases come from the use by consumers of end products containing the substance. It is assumed (as a worst case using the EUSES software) that 100% of the EU use volume is released into waste water and that no substance remains on the fabric, skin or surfaces or has evaporated. For detergents it is further assumed (RPA, 2008) that 75% of the musk xylene ends up in domestic wastewater while 25% ends up in industrial wastewater. For the private use of the substance and the regional scale it is considered that 20% of the releases go directly to the surface water whereas 80% go via a municipal Sewage Treatment Plant (STP). When in the STP it is assumed that 43% is discharged directly to the surface waters and 57% is adsorbed to sludge. This sludge can later on be incinerated, landfilled or spread on agricultural soil. Within the study, it is estimated that 25 tonnes/year is released into the environment (13 tonnes/year to water and 12 tonnes per year to sludge) (RPA, 2008).

2.2.2.3. Geographical distribution and conclusions in terms of (organisation and communication in) supply chain

There is no specific information regarding the geographical distribution of the different sites where the substance is compounded and formulated into preparations. The only information available is that the number of sites is rather small (less than 10 sites) (RPA, 2008).

According to the available information, the substance is imported, compounded into the fragrance (at less than 10 sites in the EU) and then formulated into a large number of end products mainly destined for consumer use.

There is no specific information regarding the use by consumers but as the end products are mainly for private use one can expect a wide distribution of the end products in the EU. According to the available information, the consumption is higher in southern countries than in northern countries (EC, 2005). No update of these market characteristics could be obtained in the short term of the RPA study.

Therefore, based on the information provided by the study (RPA, 2008) it can be concluded that:

- the supply chain of this substance does not contain many levels (from the manufacturer/importer to the last actor affected by a possible authorisation decision).
- the supply chain does not contain EU manufacturers but contains a high number of downstream users (formulators and professional users) as well as private users (consumers).
- the supply chain contains limited types of industry branches but producing a large number of different products. In addition, these industry branches are well organised in effective industry associations (cosmetics industry, detergents and cleaning products industry and fragrances formulators).

Furthermore, the available information has shown that the “self regulation” of musk xylene that has taken place during the last decade, has not drastically changed the supply chains compared to the previous market situation.

In conclusion, according to the available information, the supply chains for musk xylene are rather simple.

2.3. Availability of information on alternatives¹

According to available information, the EU detergents and cleaning products industry has been phasing out the use of musk xylene in their products for more than 10 years. In particular, there is information available on synthetic musks (nitromusks, polycyclic musks, macrocyclic musks and alicyclic musks) which may, in theory, be considered to be alternatives to musk xylene (taking into account existing restrictions on their use in certain products, e.g. cosmetics) (RPA, 2008).

Fragrances/perfumes are usually made up of top, middle and base notes. The base notes are usually the strongest scent and last longer than the top and middle notes (which are perceived shortly after application of the perfume). Base notes are, therefore, chosen because of their fixative properties, strength and/or scent. Musk xylene is one of a number of base notes which may be employed to ‘fix’ aromas in a range of consumer products. In discussing the alternatives to musk xylene, it is important to bear in mind that while, in theory, all the above mentioned synthetic musks possess what is often referred to as a “*typical musky odour*”, in practice, the

¹ Please note that this information was not used for the prioritisation.

odour profile for each compound is different and the resulting fragrance is a function of the manufacturing process as much as the type and quantity of musk compound used.

It also has to be noted that, from the data available, there is a wide variability in the level of information (and validity of data sources) on the hazard properties of these possible alternatives and, as such, drawing definitive conclusions on whether overall risks to human health and the environment would be reduced if these substances were used to substitute musk xylene, is not straightforward (for instance for alicyclic and macrocyclic musks) (RPA, 2008). Thus, further investigations would be needed in order to assess the suitability of the possible alternative substances.

To conclude, there appears to be available information on potential alternatives for all the various end-products in which musk xylene is used. However, some information suggests that, for certain specific uses, it would be more complicated to replace musk xylene. This is the case, for instance, where the identified potential alternative may have an impact on the specific properties that musk xylene confers to certain end products affecting, e.g., the odour profile of the fragrance.

Nevertheless it is also clear that the reduction of the use of musk xylene is currently on-going in the EU as an autonomous process without any regulatory pressure due to consumer pressure (RPA, 2008).

2.4. Existing specific Community legislation relevant for possible exemption

No data available.

2.5. Any other relevant information (e.g. for priority setting)

No data available.

3. Conclusions and justification

3.1. Prioritisation

No actual data on the volume of musk xylene used in the EU is available. Based on the decreasing trend observed in the recent past the volume currently used is estimated to approximately 25 tonnes/year.

Musk xylene is a vPvB substance which is mainly used in preparations for consumer use such as e.g. detergents, cleaning products, fabric softeners as well as in toiletries, colognes and shampoos. These uses, which can be assumed to occur widespread all over the EU and to result in nearly 100% release of the substance, are wide-dispersive.

Hence, although the volume used is presumably relatively low, ECHA recommends to include 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene) in Annex XIV.

3.2. Recommendation for Annex XIV entry

3.2.1. *Transitional arrangements*

Based on the available information, it is anticipated that the preparation of applications for authorisation would be facilitated by the relative homogeneity and the limited number of actors in the supply chains.

Furthermore, the available information indicates an already ongoing substitution of musk xylene with alternative substances as an autonomous process (due to pressure by consumers). There appears also to be information on the limitation of the currently available alternatives for certain uses. Therefore, the available information on potential alternatives facilitates preparing an analysis of alternatives for uses for which actors wish to apply for.

Consequently, the available information suggests that potential applicants would be well prepared to develop an application, in particular with respect to the analysis of alternatives.

Hence, in the light of the available information, ECHA recommends the following early transitional arrangements:

- *Latest application date:*
24 months after the entry into force of the Decision to include the substance in Annex XIV
- *Sunset date:*
42 months after the entry into force of the Decision to include the substance in Annex XIV

3.2.2. *Review periods for certain uses*

Neither the available information for musk xylene nor the comments following the public consultation of 14 January 2009 provide information that would support defining review periods for any uses in accordance with article 58(1)(d).

ECHA therefore recommends not to include any review periods for uses of musk xylene.

3.2.3. *Exempted (categories of) uses*

During the public consultation of 14 January 2009 no requests were made for exempting certain uses of musk xylene.

On the basis of the available information, ECHA does not see any grounds for recommending any exemptions of uses for musk xylene.

3.2.4. *Application of authorisation to product and process oriented research and development (PPORD)*

Neither the available information for musk xylene nor the comments following the public consultation of 14 January 2009 provide information that would support introducing exemptions from the authorisation requirement for product and process

oriented research and development (PPORD) on the basis of Article 56(3) of the REACH Regulation.

Therefore ECHA does not recommend to exempt the use of musk xylene in PPORD from authorisation.

3.3 Possible route for authorisation

The substance meets the criteria in Article 57(e). Therefore, pursuant to article 60(3) of the REACH Regulation, it would appear that an authorisation can only be granted in accordance with Article 60(4) ('socio-economic route')

4. 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.

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.

RCOM (2009): "*Responses to comments*" document. Document compiled from the commenting period 14.01-14.04.2009.