AGREEMENT OF THE MEMBER STATE COMMITTEE
ON IDENTIFICATION OF 5-TER-BUTYL-2,4,6-TRINITRO-M-XYLENE
(MUSK XYLENE)
AS A SUBSTANCE OF VERY HIGH CONCERN

According to Articles 57 and 59 of
Regulation (EC) No 1907/2006[1]

Adopted on 8 October 2008

This agreement concerns

Substance name: 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)

EC number: 201-329-4

CAS number: 81-15-2

Molecular formula: $C_{12}H_{15}N_3O_6$

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

The Netherlands presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (30 June 2008, submission number AK010882-50) on identification of 5-tert-Butyl-2,4,6-trinitro-m-xylene (musk xylene) as a substance of very high concern because of its vPvB properties.

The Annex XV dossier was circulated to Member States on the 30 June 2008 and the Annex XV report was made available to Interested Parties on the ECHA website on the same date according to Articles 59(3) and 59(4).

Comments were received from both Member States and Interested Parties on the proposal.

The dossier was referred to the Member State Committee on 15 September and was discussed in the meeting of the Committee on 7 – 8 October 2008.

Agreement of the Member State Committee in accordance with Article 59(8):

5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene) is identified as a substance of very high concern because it fulfils the criteria of Article 57 (e) of Regulation (EC) No 1907/2006 (REACH).

UNDERLYING ARGUMENTATION
FOR IDENTIFICATION OF SUBSTANCE OF VERY HIGH CONCERN

Persistence:

Musk xylene is not considered to be persistent in sediment. The half-life due to biodegradation in two estuarine sediments is estimated to be 60 days or less, based on the extractable part in the sediment phase. In this interpretation of the results of the simulation studies the observed irreversible binding to sediment is considered as dissipation. Musk xylene seems to degrade under anaerobic conditions.

Musk xylene is considered to be very persistent in water. In estuarine water, the half-life of musk xylene due to biodegradation appears to be longer than 150 days. The dissipation in the water simulation study can almost completely be attributed to volatilisation from the system (as the parent compound). When irradiated, musk xylene is subject to photolysis. This process appears to be rather efficient. However, its relevancy should be evaluated as a general issue, which has to be covered in new guidance to be developed in the near future. For the time being this route of degradation is considered to have no relevant influence on the overall persistence of musk xylene in the environment.

The estimated half-life in air due to reaction with radicals is estimated to be in the order of 13 days. This half-life might be an overestimation of the half-life in air because photolysis can be a substantial degradation pathway as well and this process is not taken into account in the estimation of the half-life. In water this process is very fast but in apolar solvents the half-life for photolysis is in the order of six hours under constant irradiation with maximum solar intensity. Consequently, the half-life in air due to direct photolysis is estimated to be more than one day. As calculated by the multimedia model, musk xylene will evaporate to air, which is confirmed by the observations in both the water and the water/sediment simulation tests. Therefore, a significant long-range transport can not be excluded. Hence, significant amounts of musk xylene will reach the sea and ocean water compartments. For this reason the degradation rate in marine water becomes essential in determining the persistency of musk xylene. In a deep water column, in the absence of sunlight and sediment, musk xylene is persistent.

Bioaccumulation:

Next to very persistent musk xylene is also considered to be very bioaccumulative based on the results of the critical BCF-study in fish. Musk xylene can therefore be considered to be a vPvB substance.

Conclusion:

Musk xylene fulfils the vP and the vB criteria.

Reference:

1. Support Document 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene) (Member State Committee, 8 October 2008)