Annex XV Dossier

Diarsenic Trioxide

EC Number: 215-481-4

CAS Number: 1327-53-3

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR CAT 1 OR 2, PBT, vPvB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN

Submitted by: France

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PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR CAT 1 OR 2, PBT, VPVB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN

Substance Name: Diarsenic Trioxide

EC Number: 215-481-4

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- *It is proposed to identify the substance as a CMR according to Article 57 (a), (b) and/or (c).*

Summary of how the substance meets the CMR (Cat 1 or 2), PBT or vPvB criteria, or is considered to be a substance of an equivalent level of concern

Diarsenic Trioxide has been identified as a CMR according to the 19th ATP to Directive 67/548/EEC, updated in the 25th ATP to Directive 67/548/EEC, in which the diarsenic trioxide has been classified as a carcinogen Cat 1/ R45: May cause cancer and then has been included in the Annex I of the Directive 67/548/EEC.

Registration number(s) of the substance or of substances containing the substance:

JUSTIFICATION

1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifiers of the substance

Chemical Name:	Diarsenic Trioxide
EC Name:	215-481-4
CAS Number:	1327-53-3
IUPAC Name:	dioxodiarsoxane

1.2 Composition of the substance

Chemical Name:	Diarsenic trioxide
EC Number:	215-481-4
CAS Number:	1327-53-3
IUPAC Name:	dioxodiarsoxane
Molecular Formula:	As_2O_3
Structural Formula:	
Molecular Weight:	197.84
Typical concentration (% w/w):	>= 99%
Concentration range (% w/w):	See typical concentration

1.3 Physico-chemical properties

Table 1: Summary of physico-chemical properties

REACH ref Annex, §	Property	IUCLID section	Value
VII, 7.1	Physical state at 20°C and 101.3 kPa	3.1	Solid
VII, 7.2	Melting/freezing point	3.2	315°C/193°C
VII, 7.3	Boiling point	3.3	477°C
VII, 7.5	Vapour pressure	3.6	850.10^{-12} hPa at 20°C
VII, 7.7	Water solubility	3.8	
VII, 7.8	Partition coefficient n-octanol/water (log value)	3.7 partition coefficient	No data available
XI, 7.16	Dissociation constant	3.21	

2 MANUFACTURE AND USES

- Used as decolorizing agent for glass and enamels.
- Used as refining and oxidizing agent for manufacturing special glass and lead crystal formulations.
- Was used in Europe as wood preservative (in industrial installations using vacuum or pressure for impregnation with CCA (copper, chromium, arsenic)) but no dossiers were notified for this use under the Directive 98/8/EC. But it should be noted that treated wood could be imported according to the Directive 2006/139/EC of 20 December 2006 as regards restrictions on the marketing and use of arsenic compounds for the purpose of adapting its Annexe I to technical progress.
- Used as a hydrogen recombination poison for metallurgical studies.
- Used as a starting point for the preparation of elemental arsenic, arsenic alloys and arsenide semiconductors.
- Use as a cytostatic in the treatment of refractory promyelocytic (M3) subtype of acute myeloid leukemia. The drug is available as Trisenox ampules; each containing 10mg to be diluted for i.v. infusion. Diarsenic trioxide is also used to treat leukemia in patients who have not responded to other medications.

In France, the consumption of diarsenic trioxide is estimated at approximatively 1000 t/y.

Based on the data in the SPIN database, the table 2 relate the total use of diarsenic trioxide in Nordic countries (*biocides and heavy metals contained in articles are not inluded in SPIN)*

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Table 2**:** Total Use of diarsenic trioxide in Nordic countries (FIN, DK, N and S)

Year	**Total use (tonnes)**
2000	67
2001	45
2002	39
2003	72
2004	39
2005	< 100 kg

3 CLASSIFICATION AND LABELLING

3.1 Classification in Annex I of Directive 67/548/EEC

According to the 19th ATP to Directive 67/548/EEC, updated in the 25th ATP to Directive 67/548/EEC, the diarsenic trioxide has been classified as a carcinogen Cat 1/ R45: May cause cancer and then has been included in the Annex I of the Directive 67/548/EEC.

Its Annex I to Directive 67/548/EEC Index number is 033-003-00-0

The Diarsenic Trioxide is classified, according to Directive 67/548/EEC, as:

- R45: May cause cancer.
- R28: Very toxic if swallowed.
- R34: Causes burns.
- R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety Phrases:

- S53: Avoid exposure - obtain special instructions before use.
- S45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
- S60: This material and its container must be disposed of as hazardous waste.
- S61: Avoid release to the environment. Refer to special instructions/Safety data sheets.

3.2 Self classification(s)

INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS

1 INFORMATION ON EXPOSURE

Please refer to Section 2 of the Justification part of this report, since the exposure is directly related to the uses.

2 INFORMATION ON ALTERNATIVES

2.1 Alternative substances

For the wood preservatives use, it is possible to substitute the diarsenic trioxide by cupric hydroxycarbonate or by Benzalkonium Chloride (quaternary ammonium).

2.2 Alternative techniques

No information available

3 RISK-RELATED INFORMATION

Not available

REFERENCES

- ECB ClassLab database http://ecb.jrc.it/classification-labelling/search-classlab/
- Fiche toxicologique de l'INRS FT89 : Trioxyde de diarsenic. 2006
- Annex I of Directive 97/548/EEC
- Commission Directive 2006/139/EC of 20 December 2006 amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of arsenic compounds for the purpose of adapting its Annexe I to technical progress, 2006.
- INERIS - Fiche de données toxicologiques et environnementales des substances chimiques : Arsenic et ses dérivés inorganiques. 2006
- Integrated Pollution Prevention and Control (IPPC), Reference Document on Best Available Techniques in the Glass Manufacturing Industry, European Commission, December 2001.
- Medical Management Guidelines for Arsenic Trioxide, US Agency for toxic Substances and Disease registry, 2007.
- Substances in Preparations in Nordic Countries database (SPIN)
- European Commission (2000) IUCLID Dataset, CAS 1327-53-3, 18.2.2000.