17 December 2010

Background document for Diarsenic pentaoxide

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

1. Identity of the substance

Chemical name:	Diarsenic pentaoxide
EC Number:	215-116-9
CAS Number:	1303-28-2
IUPAC Name:	1,3-dioxodiarsoxane 1,3-dioxide

2. Background information

2.1. Intrinsic properties

Diarsenic pentaoxide was identified as a Substance of Very High Concern (SVHC) according to Article 57(a) as it is classified according to Annex VI, part 3, Table 3.2 of Regulation (EC) No 1272/2008 as a carcinogen, category 1[1], R45 (may cause cancer) and was therefore included in the candidate list for authorisation on 28 October 2008, following ECHA's decision ED/67/2008.

2.2. Imports, exports, manufacture and uses

2.2.1. Volume(s), imports/exports

According to information received from industry during public consultation (WVM, RCOM 2010), there seems to be no current manufacture or import of the substance in the EU. This presumption is supported by the fact that ECHA did not receive registration dossiers for the substance. It seems that diarsenic pentaoxide is currently not manufactured and used in the EU in volumes ≥ 1 t/yr.

[1] This corresponds to a classification as carcinogen 1A, H350 (may cause cancer) in Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 (List of harmonised classification and labelling of hazardous substances)

2.2.2. Manufacture and uses

2.2.2.1. Manufacture and releases from manufacture

According to information provided by industry (WVM, RCOM 2010), diarsenic pentaoxide seems neither to be manufactured nor imported in the EU**.**

2.2.2.2. Uses and releases from uses

Glass and Glass Products

It is uncertain whether diarsenic pentaoxide is currently used in the manufacture of special glass. The European glass industry trade association has suggested that diarsenic pentaoxide is not used within Europe (CPIV, 2008a) and this statement has been made again by industry in the context of the public consultation on ECHA's recommendation to include diarsenic pentaoxide in Annex XIV (WVM, RCOM 2010). However, according to information provided by the Italian Competent Authority, diarsenic pentaoxide may be used in the small scale manufacture of decorative glass for arts and crafts in manufactories. Given that ECHA did not receive registration dossiers for diarsenic pentaoxide, it can be assumed that any usage within the EU is likely to be small.

Industry (CPIV and WVM; RCOM 2010) considers all raw materials used in the melting phase of the glass as isolated intermediates for the production of a new substance, i.e. glass. In their opinion, this applies equally to As_2O_5 as the oxide is completely and immediately transferred in a non-crystalline or vitreous inorganic macromolecular structure due to the high temperature of the melt, thereby completely changing its chemical speciation and properties.

However, if diarsenic pentaoxide would be used in the manufacture of glass, it would be used as a decolourising, opacifying and fining agent. These uses do not seem to be uses of the substance as an intermediate in accordance with the agreed definitions (Definition of intermediates, 2010):

> *An intermediate is used in the manufacturing of another substance where it is itself transformed into that other substance. […] Whenever a substance (A) used in a chemical processing is not used in the manufacturing of another substance (B) in order to be itself transformed into that other substance (B), it is necessarily used in order to achieve another function than transformation, either as part of the manufacturing of another substance (B) (e.g. as catalyst, processing agent, solvent), or as part of another activity (e.g. as an individual step in the production process of an article). While this other function may still involve chemical modification of the substance (A) used in the process, this type of use cannot be considered as the manufacturing of another substance (B) from the transformation of substance (A). Therefore, as soon as the main aim of the chemical process is not to transform a substance (A) into another substance (B), or when substance (A) is not used for this main aim but to achieve another function, substance (A) used for this activity should not be regarded as an intermediate under REACH.*

As diarsenic pentaoxide would not be used in the synthesis of glass itself but as processing agent for modifying the properties of glass (degassing, decolourisation,

etc.), it consequently could not be considered as an intermediate in the sense of the above definition.

According to information provided by WVM (RCOM, 2010), the glass sector applies in general strict exposure restriction conditions as it uses several materials with CMR properties. With respect to the high toxicity of the material, it is emptied and handled under strictly controlled conditions (SCC) in industrial facilities. However, it is well recognized that different from the industrial glass sector, SCC is not guaranteed for the artisan handmade glass sector where supply of the material and mixing often occur under suboptimal conditions.

Information provided by the Italian Competent Authority indicates problems with preventing occupational exposure in the manufacturing of hand-made decorative glass for arts and crafts. Biological monitoring of workers in glass manufactories in the Murano district of Venice, carried out through urinary arsenic measurement, revealed that workers employed in the mixture preparation and in the furnace work are still significantly exposed to arsenic despite the technical preventive measures adopted (mean concentrations of different As species in urine samples of workers are 2-3 times higher than the upper limit of reference for the non exposed population (Montagnani et al., 2006). Main problems are apparently the dustiness of As_2O_3,(or As_2O_5, if used) which is mixed with the other glass raw materials in form of fine powder and the high volatility of As_2O_3 (As_2O_5) at its sublimation temperature (at least 20% loss of the As added), which lead to inhalative exposure. About 80 manufactories with ca. 800 – 1000 workers are manufacturing arsenic containing art glass.

The situation in the Murano region may have improved in the last years, as biomonitoring data on arsenic exposure of glass makers between 1996 and 2006 indicate. These data collected by the Stazione Sperimentale del Vetro (SSV) suggest that arsenic exposure of workers manufacturing arsenic containing glass or making articles of it may have decreased between 1996 and 2006 by roughly two thirds to approximately 5-7 µg As /g creatinine, which is below the Italian limit value (Eurometaux, SSV, RCOM 2010).

Many items of special glass may be collected and, possibly, recycled. However, it is of note that the collection and physical sorting of different glasses is unlikely to lead to significant exposures to arsenic (at least within the EU) (RPA, 2009).

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

As already mentioned in section 2.2.1, manufacture and import of diarsenic pentaoxide appear not to take place in the EU. It is uncertain whether the substances is at all used. If there are uses, they appear to take place in volumes < 1 t/yr.

Based on the information provided, it can be concluded that:

1) If the substance is used, its supply chain may include only few levels (from the manufacturer/importer to the last actor affected by a possible authorisation decision).

2) the supply chain seems to comprise only one industry branch (glass industry), which is well organised in effective industry associations.

Therefore, if the substance is used at all, it can be concluded that the supply chain for diarsenic pentaoxide is of rather low complexity: the substance may be manufactured or imported in volumes < 1 t/yr and used for the manufacture of glass.

2.3. Availability of information on alternatives

Use in Glass Processing
Diarsenic pentaoxide as decolourising agent in glass has various established alternative non-arsenic substances including:

- antimony trioxide (decolourising agent for glass and an opacifier in ceramics and enamels);
- selenium (particularly in lead crystal); and
- cerium oxide (in special glass and as an opacifier in enamels/ceramics).

The industry has indicated that arsenic acid may also be used for this purpose - albeit under different processing conditions (CPIV 2008; CPIV, 2009).

Given the range and diversity of alternatives to the use of arsenates, it is expected that alternatives would be available with suitable technical and economic characteristics for most applications. Although it is accepted that there are alternatives for most domestic (lead crystal) applications, the glass industry has highlighted a number of applications where there are technical difficulties in replacing arsenic in special glass (CPIV, 2008):

- pharmaceutical packaging glass which would require further investigation into the suitability of any alternative materials;
- although some glass-ceramic hobs (cooker tops) are now arsenic-free, producing clear glass hobs remains a difficult challenge;
- some optical filter glass relies on the intrinsic properties (i.e. optical wavelengths) of arsenic for which there are no alternatives; and
- use of alkali-free glass in opto-electronic applications.

Many of the alternatives to the use of arsenic in glass processing may be considered potentially harmful to human health and the environment. By way of example, antimony trioxide is the subject of an (as yet unpublished) EU Risk Assessment Report under the Existing Substances Regulation[2].

[2] European Chemical Substances Information System: Diantimony Trioxide (CAS 1309-64-4).

2.4. Existing specific Community legislation relevant for possible exemption

Wood Preservative (CCA)
Especially the use of arsenic treated wood has been extensively covered by other regulations. Although initially it was considered suitable for general indoor and outdoor use, increasing concerns over its use led to a series of regulatory actions including:

Directive 89/677/EEC (amending for the eighth time Directive 76/769/EEC on Marketing and Use restrictions) stipulated that arsenic compounds may not be used as substances and constituents of preparations intended for use in the preservation of wood unless solutions of inorganic salts of the CCA type were used in industrial installations using vacuum or pressure to impregnate wood.

Several years later, **Directive 2003/2/EC** (adapting Directive 76/769/EEC to technical progress for the tenth time) restricted the use of CCA-treated timber to a limited number of end uses where structural integrity is required for human or livestock safety and skin contact by the general public is unlikely. This had to be implemented by 30th June 2004. These limited end uses account for a small proportion of the requirement for treated timber.

Another issue of importance to the evolution of the EU markets for wood treatment formulations is the **Biocidal Products Directive (98/8/EC)**. Arsenic pentaoxide was notified by industry as an active substance following the provisions of the Directive; however, a dossier was not eventually submitted. This effectively prevents the use of arsenic in wood preservatives in the EU (but see points on imports below).

Directive 2006/139/EC (adapting Directive 76/769/EEC to technical progress), prescribes that arsenic shall not be used in the preservation of wood. Under Point 20 of Annex 1 to Directive 76/769/EEC as amended by Directive 2006/139/EC, CCA type C cannot be used to treat wood in the EU due to the fact that it has not been authorised under Directive 98/8/EC. A request for authorisation could, however, be made in the future in line with the requirements of Directive 98/8/EC (EC, 2008).

Pharmaceuticals. The use of arsenic compounds in medicinal products for human or veterinary use is regulated within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC and Directive 2001/83/EC {Art. 2(5a)} and is exempt from authorisation.

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

No data available.

3. Conclusions and justification

3.1. Prioritisation

Based on the information available before public consultation on the recommendation of ECHA to include diarsenic pentaoxide in Annex XIV, ECHA concluded that the substance may potentially be supplied to uses in the scope of authorisation in amounts < 10 t/yr and that it may be used in the glass industry, where it can replace diarsenic trioxide. However, according to information received from industry during public consultation, there seems to be no current manufacture or import of the substance in the EU. This presumption is supported by the fact that ECHA did not receive registration dossiers for the substance. It seems that diarsenic pentaoxide is currently not manufactured and used in the EU in volumes ≥ 1 t/yr.

The European glass industry trade association has suggested that diarsenic pentaoxide is not used for glass manufacture within Europe. However, information provided by the Italian Competent Authority indicates that the substance may be used for manufacturing decorative glass for arts and crafts. If the latter was the case, the same problems with the control of occupational exposure may occur as for the use of diarsenic trioxide (see section 2.2.2.2).

Verbal-argumentative approach

On the basis of the prioritisation criteria, diarsenic pentaoxide may have a low priority. However, as it can be used to replace As_2O_3 in at least some of its applications, it should be grouped together with diarsenic trioxide and considered as a group for prioritisation.

Scoring approach

Score			Total Score
Inherent properties (IP)	Volume (V)	Uses - wide dispersiveness (WDU)	(= IP + V + WDU)
1 (Carcinogen, cat. 1)	Range: 0 - 1 (No to low volume)	The substance might not be used. Score: 0 If the substance is used, these uses occur at a presumably low to medium number of sites in the artisan glass industry. Occupational exposure may be significant. Scoring: Medium number of sites where the substance is used. Score: 2. Potentially significant exposure of workers in (parts of) the glass industry. Score: 3. Overall maximum score: 2 * 3 = 6	Range: 1 - 8

Conclusion, taking regulatory effectiveness considerations into account

On the basis of the prioritisation criteria, diarsenic pentaoxide may have a low priority. However, as it can be used to replace As_2O_3 in at least some of its applications, diarsenic pentaoxide should be grouped and prioritised together with diarsenic trioxide.

4. References

CPIV (2008): CPIV Answer to the Questionnaire of Arsenic Uses in the Glass Industry, detailed response to RPA consultation, dated October 2008.

CPIV (2008a): CPIV Answer to the Questionnaire of Arsenic Uses in the Glass Industry, detailed response to RPA consultation, dated October 2008.

CPIV (2009): Responses to additional RPA questions, dated January 2009.

Definition of intermediates, 2010: Definition of intermediates as agreed by Commission, Member States and ECHA on May 4 2010. http://guidance.echa.europa.eu/docs/guidance_document/clarificationintermediates_201005_en.pdf

EC (2008): Draft Reference Document on Best Available Techniques in the Glass Manufacturing Industry, Draft of February 2008 (updating the previous BREF dated December 2001), European Commission, available from: http://ec.europa.eu/environment/ippc/brefs/gls_d1_0208.pdf

Montagnani, R, M Campagna, S Gasparello, A Hreiglich, P Apostoli (2006): L'esposizione ad arsenico nella produzione artigianale della bacchetta di vetro. Risultati del monitoraggio biologico e indicazioni preventive. G Ital Med Lav Erg 2006; 28:2, 158-162.

RCOM, 2010: RESPONSES TO COMMENTS DOCUMENT (RCOM) FOR DIARSENIC PENTAOXIDE (EC NUMBER: 215-116-9)

RPA (2009): Data on manufacture, import, export, uses and releases of: diarsenic trioxide (CAS no: 1327-53-5); diarsenic pentaoxide (CAS no: 1303-28-2); lead hydrogen arsenate (CAS no: 7784-40-9); and triethyl arsenate (CAS no: 15606-95-8), as well as information on potential alternatives to their use. Report prepared for ECHA.