

ANNEX XV REPORT

AN ASSESSMENT OF WHETHER THE USE OF DIARSENIC TRIOXIDE AND DIARSENIC PENTAOXIDE IN ARTICLES SHOULD BE RESTRICTED IN ACCORDANCE WITH ARTICLE 69(2) OF REACH

SUBSTANCE NAME: Diarsenic trioxide

IUPAC Name: Dioxodiarsoxane

EC NUMBER: 215-481-4

CAS NUMBER: 1327-53-3

SUBSTANCE NAME: Diarsenic pentaoxide

IUPAC Name: 1,3-dioxodiarsoxane 1,3-dioxide

EC NUMBER: 215-116-9

CAS NUMBER: 1303-28-2

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A. Conclusions

A.1 Conclusions based on the assessment

Diarsenic trioxide and diarsenic pentaoxide have 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 May 2015.

ECHA has gathered information on the uses of diarsenic trioxide and diarsenic pentaoxide in articles from various sources. This includes information gathered during the SVHC listing and recommendation for the inclusion of substances in Annex XIV, uses identified in the REACH registrations and information in the received applications for authorisation and substances in articles (SiA) notifications.

Following an assessment of the available evidence, ECHA considers that there is no use of these substances that would lead to a non-adequately controlled risk from diarsenic trioxide or diarsenic pentaoxide concentrations in articles that are not already regulated under other legislation. 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 tested in a call for evidence to last from 9 November 2016 to 9 January 2017. One response was received supporting ECHA's conclusion that no restriction under Article 69(2) was necessary.

A.2 Targeting

This dossier is targeted on the potential release and exposure of diarsenic trioxide and diarsenic pentaoxide from articles and whether or not such use should be restricted.

This targeting is based on the Article 69(2) of REACH Regulation 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 uses, hazard, exposure/emissions and risk

Information on uses

Based on the information gathered during the SVHC listing and recommendation for the inclusion of substances in Annex XIV, uses identified in the REACH registrations and information in the received applications for authorisation, the uses of diarsenic trioxide include:

- Production of glass
- Paints and varnishes
- Purification of metal impurities in the zinc manufacture
- Processing aid in the gold electroplating
- Processing aid in the production of ammonia

- Wood preservation
- Pharmaceutical preparations
- Production of alloys
- Electronic components

Even if many of the uses described above do not lead to presence of diarsenic trioxide or diarsenic pentaoxide in the articles, they are briefly discussed in this report to justify their exclusion from further assessment.

Diarsenic pentaoxide has been reported to be used in the production of glass (ECHA, 2010b). However, it is not clear if this use still exist.

Information on hazards

Diarsenic trioxide and diarsenic pentaoxide were included in Annex XIV based on its carcinogenic properties (Carc. 1A). Other human health endpoints are not relevant for this dossier.

Diarsenic trioxide is classified in Regulation 1272/2008 (CLP) as: Acute Tox. 2 H300; Skin Corr. 1B H314; Carc. 1A H350; Aquatic Acute 1 H400; Aquatic Chronic 1 H410.

Diarsenic pentaoxide is classified in Regulation 1272/2008 (CLP) as: Acute Tox. 3 H301; Acute Tox. 3 H331; Carc. 1A H350; Aquatic Acute 1 H400; Aquatic Chronic 1 H410.

Information on emissions/release

Not relevant - there is no use of these substances that would lead to a non-adequately controlled risk from diarsenic trioxide or diarsenic pentaoxide concentrations in articles that are not already regulated under other legislation.

Characterisation of risk

Not relevant - there is no use of these substances that would lead to a non-adequately controlled risk from diarsenic trioxide or diarsenic pentaoxide concentrations in articles that are not already regulated under other legislation.

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 substances and physical and chemical properties

B.1.1 Name and other identifiers of the substances

Diarsenic trioxide

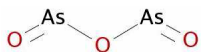
Chemical name:	Diarsenic trioxide
EC Number:	215-481-4
CAS Number:	1327-53-3
IUPAC Name:	Dioxodiarsoxane

Diarsenic pentaoxide

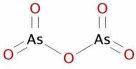
Chemical name:	Diarsenic pentaoxide
EC Number:	215-116-9
CAS Number:	1303-28-2
IUPAC Name:	1,3-dioxodiarsoxane 1,3-dioxide

B.1.2 Composition of the substance(s)

Diarsenic trioxide

Chemical name:	Diarsenic trioxide
EC number:	215-481-4
CAS number:	1327-53-3
IUPAC name:	Dioxodiarsoxane
Molecular formula:	As ₂ O ₃
Structural formula:	
Molecular weight:	197.84
Typical proportion %:	>=99
Concentration range %:	99-100

Diarsenic pentaoxide

Chemical name:	Diarsenic pentaoxide
EC number:	215-116-9
CAS number:	1303-28-2
IUPAC name:	1,3-dioxodiarsoxane 1,3-dioxide
Molecular formula:	As ₂ O ₅
Structural fomula:	
Molecular weight:	229.84
Typical concentration (% w/w):	>=99
Concentration range (% w/w):	See typical concentration

B.1.3 Physicochemical properties*Diarsenic trioxide*

REACH ref Annex	Property	Value
VII, 7.1	Physical state at 20°C and 101.3 kPa	Solid
VII, 7.2	Melting / freezing point	315°C/193°C
VII, 7.3	Boiling point	477°C
VII, 7.5	Vapour pressure	850.10 ⁻¹² hPa at 20°C
VII, 7.7	Water solubility	
VII, 7.8	Partition coefficient noctanol/water (log value)	No data available
XI, 7.16	Dissociation constant	

Source: SVHC support document for diarsenic trioxide (ECHA, 2008a)

Diarsenic pentaoxide

REACH ref Annex	Property	Value
VII, 7.1	Physical state at 20°C and 101.3 kPa	
VII, 7.2	Melting / freezing point	315°C
VII, 7.3	Boiling point	
VII, 7.5	Vapour pressure	

VII, 7.7	Water solubility	1.5 Kg (16°C)
VII, 7.8	Partition coefficient noctanol/water (log value)	
XI, 7.16	Dissociation constant	

Source: SVHC support document for diarsenic pentaoxide (ECHA, 2008b)

B.1.4 Justification for grouping

Not relevant.

B.2 Manufacture and uses

B.2.1 Manufacture, import and export of a substance

According to Background document for diarsenic trioxide in the context of ECHA's recommendation for the inclusion of substances in Annex XIV (ECHA, 2010a), diarsenic trioxide manufacturing volumes within the EU were estimated at 1 820 t/y. Amounts imported are in the range of 500 – 600 t/y and those disposed of are around 200 t/y. This results in a total volume placed on the global market of 2 200 t/y. The largest part of this volume (1 100-1 200 t/y) is exported outside the EU in form of diarsenic trioxide and a smaller part (70-100 t/y) in form of the wood-preserved Copper-Chromium-Arsenic (CCA). According to ECHA substance database, the substance is manufactured and/or imported in the European Economic Area in 100 - 1 000 tonnes per year.

Most diarsenic trioxide is produced as a by-product from the copper primary materials smelting and refining (and to a smaller extent from lead production). This means that the manufacture of diarsenic trioxide depends largely on the production volume of these metals and the arsenic impurity levels in the ores, which can vary quite considerably. (ECHA, 2010a)

There are no information available on current manufacture or import of diarsenic pentaoxide in the EU and ECHA has received no registrations on the substance. However, it cannot be excluded that the substance is still used in the manufacture of special glass. If the substance is still used, it may be manufactured or imported in volumes less than 1 tonne per year. (ECHA, 2010b)

B.2.2 Uses

In 2010, the main uses of diarsenic trioxide were in the purification of metal impurities in the zinc manufacture, in production of glass and for manufacturing other chemicals and ultra-pure arsenic metal. Other identified uses were in wood preservation, paints and varnishes, pharmaceutical preparations, alloys, and electronic components. Some uses were already at that time declining rapidly due to regulatory initiatives in the EU. (ECHA, 2010)

Related to these uses, ECHA has received applications for authorisation only for the manufacture of zinc by electrolysis (2 applications for this use). In addition, applications have been received for use as a processing aid in the gold electroplating and the

production of ammonia. Based on the information in the authorisation applications, the volume used within the EU for these uses is in the range of 100 to 1 000 t/y. According to registration information diarsenic trioxide may still be used also as an intermediate in manufacture of glass, ultra-pure arsenic metal and other metals.

There are no SiA notifications made under Article 7(2) for diarsenic trioxide.

It cannot be excluded that diarsenic pentaoxide is still used in the manufacture of special glass. If the substance is still used, it is used volumes less than 1 tonne per year. (ECHA, 2010b). Furthermore, there is one SiA notification for diarsenic pentaoxide for circuits and PCBs (printed circuit boards) incorporated in electronic controller equipment. It is not clear if the substance is still used in these equipments. ECHA has not received any applications for authorisation for this substance.

B.2.3 Uses advised against by the registrants

There are no uses advised against in the registrations.

B.2.4 Description of targeting

This restriction report is targeted on the potential release and exposure of diarsenic trioxide and diarsenic pentaoxide from articles and whether or not such use should be restricted. Furthermore, targeting is based on the hazard for which the substances were included on Annex XIV, i.e. carcinogenicity.

B.3 Classification and labelling

Classification according to CLP

Diarsenic trioxide

Acute Tox. 2 H300; Skin Corr. 1B H314; Carc. 1A H350; Aquatic Acute 1 H400; Aquatic Chronic 1 H410

Diarsenic pentaoxide

Acute Tox. 3 H301; Acute Tox. 3 H331; Carc. 1A H350; Aquatic Acute 1 H400; Aquatic Chronic 1 H410.

Classification according to the Classification and Labelling Inventory

There have been 324 notifications to the C&L inventory for diarsenic trioxide most of them reproducing the harmonised classification. Some of them have a lower hazard class for certain endpoints or they are deviating e.g. on the pictograms. 69 notifications cover an additional endpoint of Eye Dam. 1.

For diarsenic pentaoxide there have been 33 notifications to the C&L inventory most of them reproducing the harmonised classification.

B.4 Environmental fate properties

Not relevant

B.5 Human health hazard assessment

Diarsenic trioxide and diarsenic pentaoxide were included in Annex XIV based on its carcinogenic properties (Carc. 1A). Other human health endpoints are not relevant for this dossier. In developing its opinions on the application for authorisation, RAC confirmed that it is not possible to determine a DNEL for the carcinogenic (category 1A) properties of the substance in accordance with Annex I of the REACH Regulation.

B.6 Human health hazard assessment of physicochemical properties

Not relevant

B.7 Environmental hazard assessment

Not relevant

B.8 PBT and vPvB assessment

Not relevant

B.9 Exposure assessment**B.9.1 General discussion on releases and exposure**

For this report only releases and exposure from articles are relevant. When identified uses do not lead to diarsenic trioxide or diarsenic pentaoxide being present in articles, there is no potential for releases or exposure and no need for further assessment of that use. The following uses have been reported for diarsenic trioxide. Diarsenic pentaoxide has been used for production of glass in the past and may have been used also for some of the other uses.

Production of glass

Diarsenic trioxide is used for the manufacture of special glass and crystal glass where it may act as network former, decolourisation agent, fining agent or an opacifying agent. As arsenic from diarsenic trioxide is bound in the matrix and not present as diarsenic trioxide in the article, this use is not further assessed in this dossier. (ECHA, 2010a)

Paints and varnishes (enamels)

Diarsenic trioxide is used in small quantities in enamels. Due to the matrix effect, the hazard properties of the enamel are clearly different from the constituting compounds. Diarsenic trioxide is not present as diarsenic trioxide anymore in the article, this use is not further assessed in this dossier. (ECHA, 2010a)

Purification of metal impurities in the zinc manufacture

Diarsenic trioxide is completely consumed by the chemical reactions in the process. Furthermore, the majority of arsenic constituents from the process are in the end bound to inorganic waste material as ferric arsenate. This use does not lead to production of articles and is therefore not further assessed in this dossier. (Applications for authorisation)

Processing aid in the gold electroplating

A mixture containing diarsenic trioxide is used as grain refiner for gold plating to ensure uniform and homogenous gold thickness on the etched circuits and good plating quality

with high current density conditions. The process is catalytic in nature so that the final product does not contain any diarsenic trioxide. Therefore, this use is not further assessed in this dossier. (Applications for authorisation)

Processing aid in the production of ammonia

Diarsenic trioxide is used to strip the carbon dioxide from the synthesis gas before the final synthesis of ammonia (as CO₂ is a pollutant for the catalyst use for ammonia synthesis) and to generate clean CO₂ which can be used in the production of urea. This use does not lead to production of articles and is therefore not further assessed in this dossier. (Applications for authorisation)

Wood preservation

Historically Copper-Chromium-Arsenic based wood preservatives were a major use for diarsenic trioxide. However, the use falls under the scope of the Biocides Directive and therefore not further assessed in this dossier. (ECHA, 2010a)

Pharmaceutical preparations

The use of arsenic compounds in medicines in EU disappeared by the mid-1990s. However, the use of arsenic has reappeared following extensive studies in China. The use of arsenic compounds in medicinal products for human or veterinary use are within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC and Directive 2001/83/EC and therefore not further assessed in this dossier. (ECHA, 2010a)

Production of alloys

The reported uses of arsenic for producing alloys are actually all based on arsenic metal (ECHA, 2010a), and this use is not further assessed in this dossier.

Electronic components

The reported applications for the production of ultrapure Gallium Arsenide, Arsenic as a dopant, and Selenium based alloys are also all applications of arsenic metal (ECHA, 2010a), and these uses are not further assessed in this dossier.

B.9.1.1 Summary of the existing legal requirements

The use of arsenic in wood preservation is covered by Biocidal Products Regulation (EU/528/2012) and by entry 19 of annex XVII of REACH.

The use of arsenic compounds in pharmaceuticals is covered by Regulation (EC) No 726/2004, Directive 2001/82/EC and Directive 2001/83/EC.

Under REACH, diarsenic trioxide was proposed for SVHC listing by France in 30/06/2008, the substance was listed in the candidate list 28/10/2008 (ECHA 2008)¹ 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

¹ 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.

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 entries in Annex XIV for diarsenic trioxide and diarsenic pentaoxide Authorisation set a last application date of 21/11/2013 and a sunset date of 21/05/2015.

B.10 Risk characterisation

Not relevant for this dossier as no uses have been identified where diarsenic trioxide is present in articles.

C. Available information on alternatives

Not relevant, as no restriction is proposed

D. Justification for action on a Community-wide basis

Not relevant, as no restriction is proposed

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

Not relevant, as no restriction is proposed

F. Socio-economic Assessment of Proposed Restriction

Not relevant, as no restriction is proposed

G. Stakeholder consultation

The Annex XV report was subject to a Call for evidence from xx xxx 2015 to xx xxx 2015 (8 weeks). [To be updated following CfE.]

H. Other information

Not relevant.

References

Applications for authorisation

The applications for authorisation received by ECHA on diarsenic trioxide (and diarsenic pentaoxide) are available at <https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations>

- ECHA (2008a) Member State Committee support document for identification of diarsenic trioxide as a substance of very high concern available at <https://www.echa.europa.eu/documents/10162/8730b910-c1d4-4b87-b3e3-a94ce47fbc9b>
- ECHA (2008b) Member State Committee support document for identification of diarsenic pentaoxide as a substance of very high concern available at <https://echa.europa.eu/documents/10162/91206b72-787f-4a2d-aa80-9d6f1f22fc55>
- ECHA (2010a) Background document for Diarsenic trioxide - document developed in the context of ECHA's second Recommendation for the inclusion of substances in Annex XIV available at <https://echa.europa.eu/documents/10162/46eb55f6-b2ba-43e6-ad28-3064b89e93a5>
- ECHA (2010b) Background document for Diarsenic pentaoxide - document developed in the context of ECHA's second Recommendation for the inclusion of substances in Annex XIV (updated version of 1 July 2010) available at <https://echa.europa.eu/documents/10162/7c25d3da-407a-4165-a83f-8ccb1bf14ede>