

**ANNEX XV REPORT**

**AN ASSESSMENT OF WHETHER THE USE OF  
ARSENIC ACID IN ARTICLES SHOULD BE  
RESTRICTED IN ACCORDANCE WITH ARTICLE  
69(2) OF REACH**

**SUBSTANCE NAME: Arsenic acid**

**EC NUMBER: 231-901-9**

**CAS NUMBER: 7778-39-4**

**VERSION NUMBER: 1.0**

**DATE: 14 December 2021**

## About the report

This report is prepared according to Article 69(2) of REACH Regulation (EC) No. 1907/2006, which after the sunset date has passed for a substance included on the Authorisation List (Annex XIV), requires ECHA to consider if risks from the use of the substance in articles are adequately controlled and, if this is not the case, prepare an Annex XV restriction dossier.

In general, ECHA gathers information on potential risks to human health and/or the environment for identified uses of the substance in articles from various sources. Information is gathered (if available) from authorisations, applications for authorisations, recommendation for inclusion in Annex XIV and substance of very high concern (SVHC) identification. Uses identified in the REACH registrations and in substances in articles notifications (in accordance with Article 7(2) of REACH<sup>1</sup> and the Waste Framework Directive (SCIP database<sup>2</sup>)) are also investigated. Information on possible uses of the substance in articles that were not identified during the screening phase can be gathered through a subsequent call for evidence launched via ECHA's website.

In most cases, risks stemming from the incorporation of the substance into an article are not in the scope of this investigation as incorporation of a substance in articles has to be authorised, unless this use is exempted in accordance with Article 56(1) of REACH<sup>3</sup>. The incorporation process carried out in third countries is outside the scope of EU legislation. However, it should be noted that articles if imported to the EU are within the scope of this investigation. The incorporation is regarded to cover two type of uses<sup>4</sup>:

- a) The substance is incorporated into an article during its production, or
- b) The substance, alone or in a mixture is incorporated into/onto an existing article (isolated or incorporated in a complex object) at a later stage (e.g. coatings, primers, adhesives, sealants) and become an integral part of the article (or of the complex object).

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<sup>1</sup> Producers and importers have to notify ECHA the substances listed on the Candidate list which are present in their articles, if both the following conditions are met: i) the substance is present in their relevant articles above a concentration of 0.1% w/w; ii) the substance is present in these relevant articles in quantities totalling over 1 tonne per year. Companies have to notify no later than six months after the inclusion of the substance in the Candidate List. For further details see:

<https://echa.europa.eu/regulations/reach/candidate-list-substances-in-articles/notification-of-substances-in-articles>.

<sup>2</sup> In accordance with the Waste Framework Directive (WFD), companies supplying articles containing substances on the Candidate List in a concentration above 0.1% w/w on the EU market have to submit information on these articles to ECHA, from 5 January 2021. The information provided is included in the SCIP database, i.e., Substances of Concern In articles as such or in complex objects (Products): <https://echa.europa.eu/scip>.

<sup>3</sup> Q&A ID: 0564: <https://echa.europa.eu/support/qas-support/qas> Note that ECHA will investigate for this report whether applications for authorisation cover the incorporation of the substance into an article.

<sup>4</sup> [https://echa.europa.eu/documents/10162/23036412/articles\\_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c](https://echa.europa.eu/documents/10162/23036412/articles_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c)

It is to be noted that there are several specific exemptions from the authorisation requirements<sup>5</sup>, while only few exemptions are envisaged in case of restrictions. These include manufacture and placing on the market or use of a substance in scientific research and development, risks to human health of the use of the substance in cosmetic products and when a substance is used as an on-site isolated intermediate.

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<sup>5</sup> [https://echa.europa.eu/documents/10162/13640/generic\\_exemptions\\_authorisation\\_en.pdf/9291ab2a-fe2f-418d-9ce7-4c5abaaa04fc](https://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf/9291ab2a-fe2f-418d-9ce7-4c5abaaa04fc)

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## A. Conclusions

### A.1. Conclusions based on the assessment

Arsenic acid has been included on the candidate list (19/12/2011; ED/77/2011) and into Annex XIV of REACH (Commission Regulation (EU) No 895/2014 of 14 August 2014) with a sunset date of 22/08/2017 due to its carcinogenic (category 1A) properties. According to REACH, ECHA needs to consider whether the use of the substance listed in the Annex XIV in articles poses a risk to human health or to the environment that is not adequately controlled. In such cases, ECHA prepares a restriction dossier which conforms to the Annex XV to REACH.

ECHA has gathered information on the uses of arsenic acid in articles from various sources. This includes information gathered during the SVHC listing and recommendation for the inclusion of this substance in Annex XIV, uses identified in the REACH registrations and information in the submitted (1) application for authorisation, substances in articles notifications (in accordance with Article 7(2) of REACH and the Waste Framework Directive) and various external database searches. Following an assessment of the available evidence, there appears to be two EU uses of arsenic acid to produce articles. One is an industrial use of arsenic acid for the treatment of copper foil used in the manufacture of Printed Circuit Board. An application for authorisation has been submitted and granted for this use<sup>6</sup>.

In addition, less than 1 tonne per year of arsenic acid is used in the special glass industry as an intermediate, which means that it is exempt from REACH Authorisation. This use would only be exempted from REACH Restriction if the intermediate is manufactured and used at the same site (on-site isolated intermediate; Article 68(1) of REACH). From the available information it appears that this is not the case here, which would make it a transported isolated intermediate. This use could be covered by a REACH Restriction, if there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of the substance, which needs to be addressed on a Union-wide basis.

Submissions under the Waste Framework Directive indicate that there is arsenic acid in imported articles likely in quantities less than one tonne per year per supplier in the following categories of articles or complex objects:

- a) Spark-ignition and compression-ignition internal combustion piston engines, electrical ignition (Combined Nomenclature (CN) chapters and headings: 8407, 8408, 8511);
- b) Valves and similar appliances for pipes, boiler shells, tanks, vats or the like (CN chapter and heading: 8481) and
- c) Instruments and appliances used in medical, surgical, dental or veterinary sciences (CN chapter and heading: 9018, 9031, 9033).

ECHA considers that there is no EU use of arsenic acid in articles that would lead to a non-adequately controlled risk that are not already regulated under REACH Authorisation. However, based on available information from the SCIP database, there appears to be a presence of arsenic acid in articles being imported to the EU. This database information being the only information on arsenic acid in articles, ECHA concludes that before any further action on the substance it will

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<sup>6</sup> <https://ec.europa.eu/docsroom/documents/44426>

monitor the presence of the substance in articles via SCIP (Substances of Concern In articles as such or in complex objects) and Substances in Articles notifications.

The information in the SCIP database allows the users of the articles to assess the risk from their uses and take appropriate risk reduction measures, as information is available throughout the whole lifecycle of products and materials, including at the waste stage.

The call for evidence was organised from 03/02/2021 to 17/03/2021. The European Special Glass Association provided information on the use and tonnage of arsenic acid in the special glass industry. This information is added to the relevant parts of this report. Furthermore, the SCIP information is included in the report after the call.

It should be noted that like for other inorganic salts of metals, any hazard would likely come from the metal (arsenic in this case) and if arsenic were to be found in articles (e.g. following analytical analysis during an enforcement campaign), it would be difficult for enforcement authorities to know whether this would be coming from arsenic acid or different arsenic salts.

## **A.2. Targeting**

This report is targeted on the potential release of arsenic acid from articles or exposure to arsenic acid when used in articles throughout its lifecycle (including the waste stage) and whether or not such use should be restricted. The report is focused on human health hazard due to which the substance is placed on the Annex XIV. Other hazards are not taken into account in this report.

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 poses a risk to human health or the environment that is not adequately controlled and prepare an Annex XV dossier for an appropriate restriction if this is the case. The incorporation of an Annex XIV substance into an article is a use which is subject to the authorisation requirement<sup>7</sup>.

## **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 the substance in Annex XIV, uses identified in the REACH registrations and information in the received application for authorisation for which authorisation has been granted, the (current and previous) uses of arsenic acid include:

- Intermediate use in the production of basic alloys
- Intermediate use in the production of certain special glass types
- Production of copper foil for printed circuit boards

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<sup>7</sup> Q&A ID No 564: [https://echa.europa.eu/support/qas-support/qas?p\\_p\\_id=journalqasearch\\_WAR\\_journalqaportlet&p\\_p\\_lifecycle=0&p\\_p\\_state=normal&p\\_p\\_mode=view&p\\_p\\_col\\_id=column-1&p\\_p\\_col\\_pos=2&p\\_p\\_col\\_count=3](https://echa.europa.eu/support/qas-support/qas?p_p_id=journalqasearch_WAR_journalqaportlet&p_p_lifecycle=0&p_p_state=normal&p_p_mode=view&p_p_col_id=column-1&p_p_col_pos=2&p_p_col_count=3)

Submissions under the Waste Framework Directive indicate that there is arsenic acid in imported articles likely in quantities less than one tonne per year per supplier in the following categories of articles or complex objects:

- a) Spark-ignition and compression-ignition internal combustion piston engines, electrical ignition (Combined Nomenclature (CN) chapters and headings: 8407, 8408, 8511);
- b) Valves and similar appliances for pipes, boiler shells, tanks, vats or the like (CN chapter and heading: 8481) and
- c) Instruments and appliances used in medical, surgical, dental or veterinary sciences (CN chapter and heading: 9018, 9031, 9033).

#### *Information on hazards*

Arsenic acid is included in Annex XIV based on its carcinogenic (category 1A) properties. Other endpoints are not relevant for this dossier.

Arsenic acid (and its salts) are classified in Regulation 1272/2008 (CLP) as: Carc. 1A H350; Acute Tox. 3 H331; Acute Tox. 3 H301; Aquatic Acute 1 H400; Aquatic Chronic 1 H410.

The opinion of the RAC on the evaluation of the occupational exposure limits (OELs) for arsenic acid and its inorganic salts (RAC, 2017) states that “Despite mechanistic indications of a threshold mode of action, the available data do not allow the identification of a threshold”.

#### *Information on emissions/release/exposure*

There are indications that arsenic acid is in imported articles, however before any further action on the substance ECHA will monitor the presence of the substance in articles via SCIP (Substances of Concern In articles as such or in complex objects) and Substances in Articles notifications.

#### *Characterisation of risk*

There are indications that arsenic acid is in imported articles, however before any further action on the substance ECHA will monitor the presence of the substance in articles via SCIP (Substances of Concern In articles as such or in complex objects) and Substances in Articles notifications.

### **A.3.2. Justification that action is required on a Union-wide basis**

No restriction is proposed at present.

### **A.3.3. Justification that the proposed restriction is the most appropriate Union-wide measure**

No restriction is proposed at present.

## B. Information on hazard and risk

### B.1. Identity of the substance and physical and chemical properties

#### B.1.1. Name and other identifiers of the substance

*Arsenic acid*

Chemical name: Arsenic acid

EC Number: 231-901-9

CAS Number: 7778-39-4

IUPAC Name: Arsenic acid

#### B.1.2. Composition of the substance(s)<sup>8</sup>

*Arsenic acid*

Chemical name: Arsenic acid

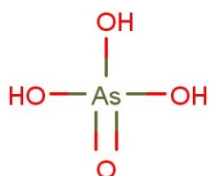
EC Number: 231-901-9

CAS Number: 7778-39-4

IUPAC Name: Arsenic acid

Molecular formula: AsH<sub>3</sub>O<sub>4</sub>

Structural formula: Source, ECHA



Molecular weight: 141.94

Typical proportion %: >80% (w/w)

Concentration range %: 90-100% (w/w)

#### B.1.3. Physicochemical properties

Arsenic acid, anhydrous, CAS Nr. 7778-39-4 has not been isolated but is only found in solution where it is largely ionised. Its hemihydrate form, arsenic acid, hemihydrate (As<sub>2</sub>H<sub>8</sub>O<sub>9</sub>), with CAS Nr. 7774-41-6 does form stable crystals.

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<sup>8</sup> Synonyms can be found from Brief profile available on ECHA's website: <https://echa.europa.eu/brief-profile/-/briefprofile/100.029.001>



**Table 1: Physicochemical properties of arsenic acid**

REACH ref Annex	Property	Value
VII, 7.1	Physical state at 20°C and 101.3 KPa	Liquid, solid
VII, 7.2	Melting / freezing point	35.5°C
VII, 7.3	Boiling point	160°C at 1013 hPa
VII, 7.5	Vapour pressure	12.58 hPa at 15°C
VII, 7.7	Water solubility	302 g/L at 12.5°C
VII, 7.8	Partition coefficient n-octanol/water (log value)	
XI, 7.16	Dissociation constant	pKa 2 = 7.089 +/- 0.01

Source: SVHC support document for arsenic acid (ECHA, 2011).

#### B.1.4. Justification for grouping

In the context of this article 69(2) screening, no group has been assessed; only the Annex XIV substance arsenic acid.

### B.2. Manufacture and uses

#### B.2.1. Manufacture, import and export of the substance

According to the background document for arsenic acid in the context of ECHA's recommendation for the inclusion of substances in Annex XIV (ECHA, 2012), arsenic acid was imported in a tonnage of 100-1000 t/y partly as aqueous solution in 2010. ECHA does not have more recent information on this imported tonnage figure (as of 10 December 2020).

No manufacture was reported at the time of the 4<sup>th</sup> recommendation. However, in 2014 a further transported isolated intermediate registration dossier was submitted, which included a "manufacturing of arsenic acid" lifecycle stage reported at 100-1000 t/y. The registration also includes the intermediate (precursor) use of arsenic acid at industrial sites, with the sector of use indicated as 'manufacture of basic metal, including alloys". This 2014 dossier is still the last registration dossier received by ECHA for arsenic acid (as of 5 May 2021).

It should be noted that the manufacturing lifecycle stage (including synthesis, transfer and storage steps) is not subject to the authorisation process. Furthermore, the manufacture of the substance may be possible for the uses exempted from authorisation (ECHA, 2015), and for the export.

#### B.2.2. Uses in articles

##### Special glass

According to the background document for arsenic acid in the context of ECHA's recommendation for the inclusion of substances in Annex XIV (ECHA, 2012), the main use (97 % of the uses) (Annex XV, ECHA 2011) in EU was as a fining agent in the manufacture of speciality glass for removing bubbles from the glass melt. This use of the substance appeared to be similar to the use of diarsenic trioxide As<sub>2</sub>O<sub>3</sub> in glass making (Background document for As<sub>2</sub>O<sub>3</sub> Annex XV, ECHA, 2010).

During the call for evidence (CfE) of this report in Feb-Mar 2021, The European Special Glass Producers Association (ESGA<sup>9</sup>) (CfE, 2021) clarified that arsenic acid is used by a low number of companies to produce some special glass types for specific articles. The main and essential applications of those glass types are reported to be for articles in e.g. aerospace and military sectors. According to ESGA, some of these applications require high quality glass with specific properties only brought about by arsenic acid: low electric conductivity, high transparency, high homogeneity. As a side but beneficial effect, the transformation of arsenic acid (As V) into trivalent arsenic (As III) is associated to a release of oxygen (fining effect) which leads to a very efficient removal of bubbles from glass, thereby removing the need to complexify the process and to use other substances as refining agents. ESGA confirm this use as an intermediate and based on the information available to ECHA it appears to be an transported isolated intermediate use, which in accordance with REACH article 3(15) means that the substance is transformed into another substance and therefore is not expected to be present in the final article.

The ESGA (CfE, 2021) indicated that to the best of its knowledge, the tonnage band for use of arsenic acid by the special glass industry was between 100 t/y and 1,000 t/y until 2019. However the ESGA reports that since 2020, it is below 1 t/y for arsenic acid. The reduction in tonnage is due to a change of process together with a change of substance for applications for which it was possible, after heavy research and investments. According to ESGA, the remaining tonnage (less than 1 t/y) is necessary to provide to essential applications (see above) certain highly specific properties not obtainable otherwise.

### **Copper foil for printed circuit boards**

According to the background document for arsenic acid in the context of ECHA's recommendation for the inclusion of substances in Annex XIV (ECHA, 2012), the second known use of arsenic acid is in the production of copper foil for printed circuit boards (electronic components sector). In 2015, an authorisation has been applied for (and granted with Commission Implementing Decision of 7.6.2019, C(2019) 4134 final)<sup>10</sup> for this use. This AfA describes how the rolls of base foil, or drums foil, are processed through a sequence of chemical and electro-chemical processing steps. The final processes apply protective chemical conversion coatings that prevent corrosion to both surface of the foil during storage or lamination. Arsenic acid is used as adjuvant that prevents the formation of hydrogen during the electrochemical reactions. In the AfA, the technical function is as a surface agent and the tonnage is reported as 3.25 tonnes per year, all imported. As stated in the opinion by RAC and SEAC (RAC and SEAC, 2017), it is important to recognise that the final product, the copper foils, do not contain arsenic acid. Any arsenic acid is either included on a matrix (which has a key role in the electrolytic treatment of the copper foils) or precipitated in undefined arsenic forms by rinsing. The RAC and SEAC opinion described how the aqueous effluents are subject to on-site wastewater treatment before release to municipal sewer. RAC considers the RMMs to be generally appropriate and effective in limiting the risks to workers and the general population and no additional conditions for authorisation are proposed. This is also reflected in the Commission decision.

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<sup>9</sup> The Glass Industry is composed of five subsectors: container glass, flat glass, domestic glass, continuous filament glass and special glass. Special glass is the smallest sector in terms of production. It produces mainly high value products of very specific applications. More information can be found on the Glass Alliance Europe (GAE) webpage ([Glass Applications - Glass Alliance Europe](#))

<sup>10</sup> <https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/12449/term>

The condition of the authorisation related to the tonnage is that the amount of arsenic acid used by the authorisation holder in the authorised use does not exceed 1 tonne per year until 2020, 800 kg per year until 2022 and 700 kg per year until 2024. This authorisation has a review period which shall expire on 22 August 2024 and the latest submission date for the review report is 22 March 2023. It is important to note that the AfA has been submitted to allow enough time to phase out arsenic acid in this use and ECHA has been informed that the applicant does not intend to submit a further AfA after the review date.

The recycling or waste handling of articles where the specific substance is incorporated are not expected to cause exposure to humans (workers or indirectly exposed via the environment) as the concentrations of the substance are low as described in the authorisations.

The use information in two more recent registration dossiers (falling under the joint submission) were consistent with what was considered in the background document for arsenic acid in the context of ECHA's recommendation for the inclusion of substances in Annex XIV (ECHA, 2012). A 2014 registration dossier also included the intermediate (precursor) use of arsenic acid at industrial sites, with the sector of use indicated as 'manufacture of basic metal, including alloys'.

One downstream user report was also received in 2012, with use information also consistent with the joint submission use information.

To date no application for authorisation (AfA) has been received for the main use (glass making) reported above. It is assumed this is because this use is considered as an intermediate use and/or it has been phased out following inclusion of arsenic acid on the Authorisation List (Annex XIV), similar to that done for diarsenic trioxide and diarsenic pentaoxide (IT CA, 2017).

### **Substance in article notifications (SiA) and submissions under the Waste Framework Directive (SCIP)**

To date no SiA notifications have been made under Article 7(2) for arsenic acid.

The data submitted by suppliers of articles to the SCIP database identify the presence of arsenic acid, in a concentration above 0.1% w/w in articles as such or in complex objects, in particular in the following categories of articles or complex objects:

- d) Spark-ignition and compression-ignition internal combustion piston engines, electrical ignition (Combined Nomenclature (CN) chapters and headings: 8407, 8408, 8511);
- e) Valves and similar appliances for pipes, boiler shells, tanks, vats or the like (CN chapter and heading: 8481) and
- f) Instruments and appliances used in medical, surgical, dental or veterinary sciences (CN chapter and heading: 9018, 9031, 9033).

From the data submitted to the SCIP database, it seems that the presence of that substance results from the use or incorporation of the following type of mixtures containing arsenic acid in their composition, during the production or assembling of the articles or complex objects listed above:

- fibre, leather, rubber and polymerised materials preservatives (European product categorisation system ([EuPCS](#)) code: PP-BIO-9);
- candles - scented and unscented (EuPCS code: PC-AIR-7).

In addition, suppliers of articles also submitted data referring to the presence of arsenic acid in articles made of steel, carbon steel (non-alloy steel), and other materials such as rubber and elastomers.

Submissions under the Waste Framework Directive indicate that arsenic acid is used in imported articles likely in quantities less than one tonne per year per supplier<sup>11</sup>.

### **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 Annex XV, Article 69(2) report is targeted on the potential release of arsenic acid from articles and exposure to arsenic acid when used in articles and whether or not such use should be restricted. Furthermore, targeting is based on the hazard for which the substance was included in the Annex XIV, i.e. carcinogenicity. It is to be noted however, that according to article 56 of REACH, incorporation of an Annex XIV substance in articles falls under the authorisation procedure. This is further explained in the Q&A ID no 564 (see footnote 1).

## **B.3. Classification and labelling**

### **Classification according to CLP**

*Arsenic acid*

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

### **Classification according to the Classification and Labelling Inventory**

There have been 14 notifications (in 4 aggregations) to the C&L inventory for arsenic acid. 4 of them reproducing the harmonised classification (above). 6 of them are deviating i.e. dropping the aquatic acute 1. 4 of the notifications add additional self-classifications i.e. Skin Corr. 1C, Eye Dam.1, Repr 2.

## **B.4. Environmental fate properties**

Not relevant.

## **B.5. Human health hazard assessment**

Arsenic acid was included in Annex XIV based on its carcinogenic properties (Carc. 1A). Other human health endpoints are not relevant for this dossier. In the context of applications for authorisations, RAC has established a reference dose response relationship for carcinogenicity of the 3 inorganic arsenic compounds diarsenic pentoxide, diarsenic trioxide and arsenic acid (RAC, 2013) in which the risk estimates were derived (see Table 2 below). In terms of bioavailability, it is stated that "Data on the speciation of arsenic under different exposure

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<sup>11</sup> The SiA notification needs to be done when the substance is present in articles in quantities totalling over 1 tonne per year and ECHA has not received any SiA notifications as.

conditions are inadequate to permit any differentiation, therefore the risk assessments below are considered to apply to all forms of inorganic arsenic, in the absence of data to the contrary”.

**Table 2: Excess lifetime cancer risk**

Population/route	Parameters	Excess lifetime lung cancer mortality risk	Excess lifetime risk of lung tumours
Workers	40 year working life (8h/day, 5d/week)	$1.4 \times 10^{-4}$ per $\mu\text{g As}/\text{m}^3$	
General population	70 years (24 h/day every day); 89-year life expectancy	$1.0 \times 10^{-3}$ per $\mu\text{g As}/\text{m}^3$	
Dermal exposure	BMDL <sub>0.5</sub> = 3 $\mu\text{g As}/\text{kg}/\text{day}$ (0.5% excess risk of cancer)		$1.7 \times 10^5$ per $\mu\text{g As}/\text{m}^3$ bw/day
Oral exposure (general population)	BMDL <sub>0.5</sub> = 3 $\mu\text{g As}/\text{kg}/\text{day}$ (0.5% excess risk of cancer)		$1.7 \times 10^{-3}$ per $\mu\text{g As}/\text{kg}$ bw/day

The opinion of the RAC on the evaluation of the occupational exposure limits (OELs) for arsenic acid and its inorganic salts (RAC, 2017) states that “Despite mechanistic indications of a threshold mode of action, the available data do not allow the identification of a threshold”.

In developing its opinion 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 from articles and the exposure during the use of the substance in articles are relevant. When identified uses do not lead to arsenic acid being present in articles, there is no potential for releases or exposure from articles and no need for further assessment of that use.

It should be noted that, like for other inorganic salts of metals, any hazard would likely come from the metal ion (i.e. arsenic in this case) and if arsenic were to be found in articles (e.g.

following analytical analysis as part of an enforcement campaign), it would be difficult for enforcement authorities to know whether this would be coming from arsenic acid or different arsenic salts.

The following uses have been reported for arsenic acid.

#### Production of glass

In the EU, arsenic acid was used in the industrial Special Glass Sector, in particular in the manufacture of black and white ceramic glass. The available registration data indicated closed processes for the use in glass making (Process category (PROC) 1 and PROC 3), but also included transfer processes (PROCs 8a and 8b) where the opportunity for exposure could arise.

ECHA currently has no grounds for concern regarding releases from glass articles or exposure during the use of the arsenic acid in glass articles based on the information above, the available information on the use of arsenic acid in the production of glass (see Section B.2.2) and that no SiA notifications have been submitted for arsenic acid in glass articles.

Note: any risk associated with potential exposure of workers to the arsenic acid, when used as a transported isolated intermediate in the production of glass, was not in the scope of this screening report.

#### Production of copper foils in printed circuit boards

The rolls of base foil, or drums foil, are processed through a sequence of chemical and electro-chemical processing steps. The 'Releases' section (9.1.1.2) of the Chemical Safety Report (AfA, 2017) states "It is assumed that 99.9% of the substance [arsenic acid] is consumed during the scenario. About 30% are included as arsenic on a matrix (copper sheets), whereas about 70% precipitate in undefined arsenic forms (e.g. as arsenic oxide and arsenic hydroxide) and become part of a waste sludge". However, the RAC and SEAC opinion (RAC, SEAC, 2017) on this AfA states that "it is important to recognise that the final product, the copper foils, do not contain arsenic acid. Any arsenic acid is removed from the finished articles by rinsing".

ECHA has not investigated the exposure from the recycling or waste handling of articles where the specific substance is incorporated. However, these are not expected to cause exposure to humans (workers or humans indirectly exposed via the environment) or to the environment as the concentrations of the substance in articles are reported to be negligible or low (below 0.1%) as described in the authorisations.

#### **B.9.1.1. Summary of the existing legal requirements**

The use of arsenic in wood preservation is covered by [entry 19 of annex XVII of REACH](#).

Arsenic acid is subject to the Prior Informed Consent (PIC) Regulation (649/2012) and is listed in Part 1 of Annex I are subject to the export notification procedure.

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

As a consequence of its classification as a carcinogen category 1A arsenic acid is covered by the following downstream legislation (Section 21 CLP Guidance Document, ECHA 2019);

- Chemical Agents Directive 98/24/EC and the Carcinogens and Mutagens Directive 2004/37/EC meaning that employers are obligated to minimize worker exposure to

this substance as far as possible and must arrange for medical surveillance of workers exposed to these substances. There is also an EU occupational exposure limit (OEL) of 0.01 mg/m<sup>3</sup> for arsenic acid;

- Commission Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food. Such materials and articles must not contain arsenic acid;
- Regulation (EU) 2017/745 on medical devices and Regulation 2017/746 on in vitro medical devices (to replace Directive 93/42/EEC on medical devices and Directive 98/79/EC on in vitro Diagnostic Medical Devices from 2022). Under these new regulations, such devices must not contain arsenic acid;
- Regulation (EU) 528/2012) concerning the making available on the market and use of biocidal products. Arsenic acid meets the exclusion criteria;
- Regulation (EC) 1107/2009 on authorisation and marketing of pesticides. Arsenic acid meets the non-approval criteria;
- Regulation (EC) 1223/2009 on cosmetic products. The use of arsenic acid in such products is prohibited. Arsenic acid meets the non-approval criteria;
- Regulation (EC) 66/2010 on the EU Ecolabel. An ecolabel will not be awarded to goods containing arsenic acid;
- Commission Decision (EU) 2016/1332 establishing the ecological criteria for the award of the EU ecolabel for furniture:
  - Paints, primers or varnishes used on wood or wood-based materials shall not contain substances based on arsenic (and other heavy metals cadmium, lead, chromium (VI), mercury and selenium) at concentration exceeding 0.01% w/w for each individual metal in the in-can paint, primer or varnish formulation.
  - Chemical testing requirement limit of  $\leq 1.0$  mg/kg for arsenic in leather, textiles and coated fabric covering material. Different limits for chromium, cobalt, lead, nickel, antimony, cadmium, copper and mercury.
  - Pigments in dyeing and printing processes based on arsenic (and cadmium, lead, chromium VI, mercury, and antimony) shall not be used.
- Directive 2009/48/EC on the safety of toys. As a consequence of its harmonised classification as a carcinogen category 1A, arsenic acid is restricted in toys if certain conditions. Recital 22 states that limit values for arsenic, cadmium, chromium VI, lead, mercury and organic tin, which are particularly toxic, and which should therefore not be intentionally used in those parts of toys that are accessible to children, should be set at levels that are half of those considered safe according to the criteria of the relevant Scientific Committee, in order to ensure that only traces that are compatible with good manufacturing practise will be present.

The following migration limits of **arsenic** from toys or components of toys, shall not be exceeded:

Element	mg/kg in dry, brittle, powder-like or pliable toy material	mg/kg in liquid or sticky toy material	mg/kg in scraped-off toy material
Arsenic	3,8	0,9	47

Under REACH, arsenic acid was proposed for SVHC listing by Norway on 01/08/2011, the substance was listed in the candidate list 19/12/2011 (ECHA 2011) and included into Annex XIV in 2014 (EC 2014).

REACH has several requirements for substances on the candidate list including notification of its presence in articles if >0.1% and 1 tonne per year (Article 7(2)) and that suppliers must inform their customers on request if an article contains more than 0.1% by weight of arsenic acid (Article 33(b)).

The entries in Annex XIV for arsenic acid authorisation set a last application date of 22/02/2016 and a sunset date of 22/08/2017.

Arsenic acid, as a substance or in a mixture, is restricted with entry 28 of Annex XVII in REACH (placing on the market for supply to the general public), being placed on the Appendix 1.

Information on existing legislations in European Union relevant for arsenic acid is available on ECHA's website under EU Chemicals Legislation Finder (EUCLEF): <https://echa.europa.eu/fi/legislation-obligation/-/obligations/100.029.001>.

## B.10. Risk characterisation

Not relevant - there is no use of these substances that would lead to a non-adequately controlled risk from arsenic acid concentrations in articles that are not already regulated under REACH Authorisation.

## C. Available information on alternatives

For the authorised use of arsenic acid in the production of copper foil for printed circuit boards, the RAC and SEAC opinion (RAC & SEAC, 2017) on the AFA mentioned above reports:

“The applicant states that the company has been working for the past 10 years on developing a production process that is free of arsenic acid. The applicant provided a report on the testing of several potential alternatives under different test conditions (including temperature, density, copper concentration and chloride concentration). They have carried out literature reviews and laboratory tests in order to find a promising substitute. Based on this work they identified candidates for substitution that were taken forward in the semi-industrial tests. This R&D work resulted in the identification of a suitable alternative, the identity of which is claimed confidential, while the final test report is available in French and is confidential as well. For this reason, the term “alternative (A)” is used in this opinion when referring to the arsenic acid-free alternative.

Over the past five years the applicant has industrialised alternative (A). Currently, about 30% of the copper foil production of the applicant is arsenic acid free, and copper foils for new products are systematically manufactured without the use of arsenic acid. The applicant has shown that they have implemented a flexible production line for both arsenic acid and arsenic acid free manufacture. According to the substitution schedule provided by the applicant all



copper foil will be produced without the use of arsenic acid by 2030. The applicant has informed its customers that, after 2030, it will no longer sell copper foils produced with arsenic acid. The timeline for this remaining substitution has been documented in the application (AoA, 2015).

This AfA has been submitted to allow sufficient time to phase out arsenic acid in this use and ECHA has been informed that the applicant does not intend to submit a further AfA after the review date of (21/02/2023)."

## **D. Justification for action on a Community-wide basis**

Not relevant, as no restriction is proposed at present.

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

Not relevant, as no restriction is proposed at present.

## **F. Socio-economic Assessment of proposed restriction**

Not relevant, as no restriction is proposed at present.

## **G. Stakeholder consultation**

The Annex XV report was subject to a call for evidence from 03 February 2021 to 17 March 2021. Comments were received from one stakeholder, the European Special Glass Association and these have been taken into account in the relevant parts of this report.

## **H. Other information**

Not relevant.

## References

### *SVHC identification*

ECHA (2011) Member State Committee support document for identification of arsenic acid as a substance of very high concern available at <https://echa.europa.eu/documents/10162/bc77d03b-2f02-4084-8fab-2b8d586f342a>

### *Recommendation for the inclusion of substances in Annex XIV*

ECHA (2010) 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 (2012) Background document for arsenic acid - 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/10162/3eabf798-7459-4ef5-a2c3-5e1e0f3f4f52>

### *Applications for authorisation*

RAC (2013) Application for authorisation: establishing a reference dose response relationship for carcinogenicity of inorganic arsenic compounds available at: [https://echa.europa.eu/documents/10162/13579/rac\\_carcinogenicity\\_dose\\_response\\_as\\_en.pdf/57b6e1ba-51b6-4fbf-b9c5-ca3ba952dd9f](https://echa.europa.eu/documents/10162/13579/rac_carcinogenicity_dose_response_as_en.pdf/57b6e1ba-51b6-4fbf-b9c5-ca3ba952dd9f)

ECHA (2015) Generic exemptions from the authorisation requirement available at: [https://echa.europa.eu/documents/10162/13640/generic\\_exemptions\\_authorisation\\_en.pdf](https://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf)

AfA (2015) The application for authorisation received by ECHA on arsenic acid are available at [https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/12449/term?viewsubstances\\_WAR\\_echarevsubstanceportlet\\_SEARCH\\_CRITERIA\\_EC\\_NUMBER=231-901-9&viewsubstances\\_WAR\\_echarevsubstanceportlet\\_DISS=true](https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/12449/term?viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=231-901-9&viewsubstances_WAR_echarevsubstanceportlet_DISS=true)

AoA (2015) Analysis of alternatives available at: <https://echa.europa.eu/documents/10162/6e3e0878-4bd9-4d34-952a-5370a4d09d02>

RAC & SEAC (2017) Consolidated version of RAC and SEAC opinion on the application for authorisation for industrial use of arsenic acid for the treatment of copper foil used in the manufacture of Printed Circuit Boards is available here: <https://echa.europa.eu/documents/10162/a93efe3c-bf63-729b-bb93-1aff96d3e02a>

IT CA (2017) Substitution of diarsenic trioxide in Murano glass” presentation available at: [https://echa.europa.eu/documents/10162/23551137/maria\\_letizia\\_policci\\_en.pdf/f927879f-bf38-0343-387e-06474a93f21d](https://echa.europa.eu/documents/10162/23551137/maria_letizia_policci_en.pdf/f927879f-bf38-0343-387e-06474a93f21d)

#### *Authorisation*

EC (2019) Authorisation Decisions List, European Commission (including authorisation for arsenic acid) at: <https://ec.europa.eu/docsroom/documents/42566>

#### *Article 69(2) assessment*

ECHA (2016) 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: <https://echa.europa.eu/documents/10162/8adf8f94-1348-4a26-8fe6-79a38f90e532>

#### *OEL*

RAC (2017) Opinion of the Committee for Risk Assessment on the evaluation of the occupational exposure limits (OELs) for arsenic acid and its organic salts available at: [https://echa.europa.eu/documents/10162/13641/opinion\\_arsenic\\_en.pdf/dd3eb795-108e-5d3a-6847-dddccc021a9dc](https://echa.europa.eu/documents/10162/13641/opinion_arsenic_en.pdf/dd3eb795-108e-5d3a-6847-dddccc021a9dc)

#### *Guidance documents*

ECHA (2019) Introductory Guidance on the CLP Regulation available at: [https://echa.europa.eu/documents/10162/23036412/clp\\_introduutory\\_en.pdf/b65a97b4-8ef7-4599-b122-7575f6956027](https://echa.europa.eu/documents/10162/23036412/clp_introduutory_en.pdf/b65a97b4-8ef7-4599-b122-7575f6956027)