Pentavalent arsenate salts: Human health tier II assessment

12 September 2013

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Arsenenic acid, sodium salt	15120-17-9
Arsenic acid (H3AsO4), monopotassium salt	7784-41-0
Arsenic acid (H3AsO4), sodium salt	7631-89-2
Arsenic acid (H3AsO4), disodium salt	7778-43-0
Arsenic acid (H3AsO4), disodium salt, heptahydrate	10048-95-0
Arsenic acid (H3AsO4), trisodium salt	13464-38-5
Arsenic acid (H3AsO4), dipotassium salt	21093-83-4

Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.

This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on this program please visit:**www.nicnas.gov.au**

Disclaimer

ACRONYMS & ABBREVIATIONS

Grouping Rationale

The pentavalent arsenate salts in this report include the sodium and potassium salts of arsenic acid (CAS No. 7778-39-4), which have been assessed separately (NICNAS). Members in this group are compounds with arsenic in an oxidation state of +5. These chemicals are chemically related to arsenic pentoxide, which is the anhydrous form of arsenic acid. Therefore, when data are not available for a specific chemical in this group, data from the previous assessment of arsenic pentoxide and arsenic acid (NICNAS) will be used to assess the chemical group's hazard profile.

According to ATSDR (2007) the pentavalent arsenates are less toxic than trivalent arsenites. A differentiating factor between the toxicity of trivalent and pentavalent arsenic compounds is the degree to which the chemicals can actively diffuse across the cell membrane (Jomova et al, 2011). Inorganic pentavalent arsenates are not able to diffuse across the cell membrane as efficiently as the trivalent arsenites. Once the pentavalent salts do cross the cell membrane, they are reduced by glutathione (GSH) to trivalent arsenites. In addition, pentavalent arsenate salts can also substitute for phosphate in biological processes of glycolysis (energy generation) and respiration, therefore affecting the efficiency and output of these critical processes (Jomova et al, 2011).

Import, Manufacture and Use

Australian

No specific Australian use, import, or manufacture information has been identified for chemicals in this group.

International

The following international uses have been identified through Galleria Chemica and the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

The chemicals have reported commercial use including:

- in printing textiles.

The chemicals have reported site-limited use including:

- in the textile, tanning, and paper industries;
- as a laboratory reagent; and
- in producing other arsenates and germicides.

The chemicals have reported non-industrial use including:

- in insecticides.

Restrictions

Australian

The chemicals, belonging to the group entry 'arsenic', are listed in the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons—SUSMP) in Schedule 7 with the below entry for industrial uses:

'ARSENIC **except**:

(a) when separately specified in this Schedule;

(b) when included in Schedule 4 or 6;

(c) as selenium arsenide in photocopier drums;

(d) as 10,10'-oxydiphenoxarsine in silicone rubber mastic containing 120 mg/kg or less of arsenic;

(e) as 10,10'-oxydiphenoxarsine contained in polyvinyl chloride and polyurethane extruded and moulded articles containing 160 mg/kg or less of arsenic other than when included in articles:

(i) in contact with food stuffs, animal feeds or potable water;

(ii) of clothing and footwear in contact with the skin;

(iii) used as infant wear; or

(iv) intended for use as packaging materials;

(f) in animal feeds containing 75 g/tonne or less of arsenic; or

(g) in paints containing 0.1 % or less of arsenic calculated on the non-volatile content of the paint.'

Schedule 7 chemicals are labelled with 'Dangerous Poison'. These are substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply.

"Arsenic and its compounds " are restricted hazardous chemicals under Schedule 10 (Prohibited carcinogens, restricted carcinogens and restricted hazardous chemicals) of the Work Health and Safety (WHS) regulations (WHS, 2011). Specifically, use is restricted in:

- abrasive blasting at a concentration of greater than 0.1 % as arsenic; and
- for spray painting.

International

International restrictions include:

- European Union (EU) Cosmetic Directive 76/768/EEC Annex II: List of substances which must not form part of the composition of cosmetic products.
- Health Canada List of Prohibited and Restricted Cosmetic Ingredients ("Hotlist").
- New Zealand Cosmetic Products Group Standard—Schedule 4: Components cosmetic products must not contain.

Existing Worker Health and Safety Controls

Hazard Classification

The chemicals in this group are classified as hazardous with the following risk phrases for human health in the Hazardous Substances Information System (HSIS) (Safe Work Australia):

Carc. Cat. 1; R45 (Carcinogenicity)

T; R23/25 (Acute toxicity)

Exposure Standards

Australian

The chemicals in this group belong to the group entry arsenic and soluble compounds (as arsenic) which have an exposure standard of 0.05 mg/m³ time weighted average (TWA).

International

The following exposure standards are identified (Galleria Chemica):

An exposure limit (TWA) of 0.01–0.5 mg/m³ in different countries such as USA (Alaska, Hawaii), Canada (Yukon), Norway and Switzerland.

Health Hazard Information

The hazard assessment of this group of chemicals is based on data available for sodium arsenate (CAS No. 7631-89-2) and potassium arsenate (CAS No.7784-41-0). Sodium and potassium salts of arsenic acid are comparatively (compared with other arsenic acid salts (lead, calcium and gallium)) more soluble and hence absorbed at a greater rate through mucosal surfaces (gastrointestinal tract and/or respiratory tract) (IPCS, 1997). When data are not available for a specific chemical in this group, data available for the mono-arsenate salts and previous assessment of arsenic pentoxide (CAS No. 1303-28-2) and arsenic acid (CAS No. 7778-39-4) (NICNAS) have been used to assess the hazard profile for this chemical group.

Toxicokinetics

Studies on laboratory animals, as well as on humans, have indicated that approximately 90 % of ingested inorganic (trivalent or pentavalent) arsenic is absorbed from the gastrointestinal tract (IPCS, 1992). In the lungs, water-soluble arsenates are rapidly absorbed through mucosal surfaces. As with most inorganic arsenic compounds, the chemicals are considered to be poorly absorbed through the skin and dermal exposure is of less significance compared with inhalation exposure (IPCS, 1992).

The pentavalent arsenates are reduced by glutathione (GS1H) to trivalent arsenites and then methylated to form methylarsonic acid (MMA) and dimethylarsinic acid (DMA), which can then be eliminated in urine (Jomova et al, 2011). The half-life of arsenates in humans is dependent on the dose administered, and is estimated to be 1–3 days after short-term exposure (IPCS, 1992).

Acute Toxicity

Oral

This group of chemicals is classified as hazardous with the risk phrase ‘Toxic if swallowed’ (T; R25) in HSIS (Safe Work Australia).

No data are available for this group of chemicals. However, data available for arsenic pentoxide and arsenic acid support this classification (NICNAS).

Dermal

No data are available for this group of chemicals. However, data available for arsenic pentoxide and arsenic acid (NICNAS) support a hazard classification for this group of chemicals.

Inhalation

The chemical is classified as hazardous with the risk phrase ‘Toxic by inhalation’ (T; R23) in HSIS (Safe Work Australia).

No data are available for this group of chemicals. However, data available for arsenic pentoxide and arsenic acid support this classification (NICNAS).

Observation in humans

Acute oral toxicity has been observed in humans and poisoning data indicate that the intensity of toxic effects of sodium arsenate (CAS No. 7631-89-2) is dependent on the dose ingested. Acute incidents of sodium arsenate poisoning (ant killer powder) through ingestion has been reported to cause nausea, vomiting, diarrhoea, abdominal pain and death (IPCS, 1992).

Inhaling dusts generated from arsenic compounds while handling or during mechanical shaping can cause rhinitis, pharyngitis, laryngitis and tracheobronchitis (IPCS, 1997).

Corrosion / Irritation

Skin Irritation

The pentavalent arsenate salts are not expected to be skin irritants.

No significant dermal irritation was noted in guinea pigs exposed to aqueous solutions containing 4000 mg/L arsenic in the form of arsenate (ATSDR, 2007). However, due to the high pH of trisodium arsenate, this chemical may have irritant or corrosive properties.

Eye Irritation

No data are available.

Sensitisation

Skin Sensitisation

Sodium arsenate was not a sensitiser when assessed through the guinea pig maximisation test (IPCS, 1997). Based on this evidence and assessment of arsenic acid and arsenic pentoxide (NICNAS), it is not expected that the pentavalent arsenate salts will induce skin sensitisation.

Repeated Dose Toxicity

Oral

Chemicals in this group cause serious damage to health from repeated oral exposure with a no observed adverse effect level (NOAEL) of 62.5 ppm (equivalent to 3.1 mg/kg bw/day) reported for disodium hydrogen arsenate (CAS No. 7778-43-0). The available data on disodium hydrogen arsenate and read-across data from the assessment of arsenic pentoxide and arsenic acid warrant a hazard classification for repeated dose toxicity (refer to **Recommendation** section).

In a two-year oral gavage study, disodium hydrogen arsenate (CAS No. 7778-43-0) was administered to Osborne Mendel rats. A NOAEL of 62.5 ppm (equivalent to 3.1 mg/kg bw/day) was reported. Effects observed at higher concentrations (125, 250 and 400 ppm) include reduced survival, enlargement of the bile duct and reduced weight. Histopathological findings indicated focal necrosis and fibrosis in the bile duct (REACH).

In a further two-year oral gavage study, disodium hydrogen arsenate (CAS No. 7778-43-0) was administered to beagle dogs at doses of 5, 25, 50 or 125 ppm. One out of six dogs died in the highest dose group (125 ppm). Weight loss was a common feature across all dose groups, with an average reduction of 44–61 % in the high dose groups. Haematologically, beagles in the high dose group developed slight to moderate anaemia (REACH).

Dermal

No data are available.

Inhalation

No data are available.

Observation in humans

Available data on the pentavalent arsenate salts indicate that repeated dermal or occupational dermal exposure to the chemicals can result in eczema, pigmentation (darkening or loss of pigmentation), diffuse hair loss, scaling of the palms and soles, brittle nails, loss of hair and nails, localised swelling and/or thickened skin (IPCS, 1997).

Repeated and/or occupational inhalation exposure to the pentavalent arsenates has been reported to cause changes in lung function (pneumoconiosis and breathlessness) and nasal septum perforation (IPCS, 1997).

Genotoxicity

No data are available for this group of chemicals. However, data available for arsenic pentoxide and arsenic acid (NICNAS) support a hazard classification for this group of chemicals.

Carcinogenicity

Chemicals in this group are classified as hazardous—Category 1 carcinogenic substance—with the risk phrase ‘May cause cancer’ (T; R45) in HSIS (Safe Work Australia). The available data support this classification.

The International Agency for Research on Cancer (IARC) has classified arsenic and inorganic arsenic compounds, including pentavalent arsenates, as ‘carcinogenic to humans’ (Group 1) (IARC, 2012).

IARC (2012) concluded that there is sufficient evidence in humans for carcinogenicity in the lungs, urinary bladder and skin, and a positive association for cancer in the kidney, liver and prostate (IARC, 2012).

Reproductive and Developmental Toxicity

Available data from a study performed similarly to OECD Test Guideline (TG) 414 suggest developmental toxicity at a lowest observed adverse effect level (LOAEL) of 4.8 mg/kg bw/day. The available data are sufficient to recommend a hazard classification for reproductive and developmental toxicity (refer **Recommendation** section).

In a study performed similarly to OECD TG 414, a pentavalent arsenate salt (CAS No. 10048-95-0) was administered orally on gestation days seven and eight to groups of pregnant LM/Bc/Fnn mice at dose levels of 0, 4.8, 9.6 and 14.4 mg/kg bw/day (REACH). It was reported that maternal toxicity was indicated by reduced body weights and liver weights in dams of all treatment groups. Maternal body weight reduction did not follow a dose-dependent trend. While histopathology was not reported, the study report attributed reduced liver weights to hepatotoxicity. In the litters, there was a dose-dependent increase in neural tube defects, specifically exencephaly at all treatment doses. There was also a trend between arsenate dose and the number of litters displaying skeletal abnormalities. Mean foetal weight of all arsenate treated groups was also significantly reduced (REACH). The lowest observed adverse effect level (LOAEL) for developmental effects in this study was 4.8 mg/kg bw/day. While some maternal effects were observed at this dose, the observed developmental effects are considered to be too severe to be due to secondary maternal effects discussed above.

In a study assessing the teratogenicity of disodium hydrogen arsenate heptahydrate (CAS No. 10048-95-0), pregnant Wistar rats were injected once between 7–12 days of gestation intraperitoneally with the chemical at 20, 30, 40 or 50 mg/kg bw/day (REACH). At autopsy, the most frequently seen soft-tissue malformations were eye defects (anophthalmia and microphthalmia), exencephaly, renal agenesis and gonadal agenesis. Furthermore, bones were missing in 63 % of the test foetuses examined for skeletal defects (REACH). A similar study conducted in Swiss Webster mice injected once with the chemical at one of days 6–12 of gestation resulted in increased foetal resorptions in litters from females treated on days 11 and 12. Additionally, foetal weights and a spectrum of foetal anomalies were noted in litters treated on days 6–11. Foetal malformations induced were day-dependent and included exencephaly, micrognathia, protruding tongue, agnathia, open eye, exophthalmos, anophthalmia,

missing pinna, cleft lip, hydrocephalus, umbilical hernia, eventration, ectrodactyly, micromelia and shortened or twisted tail and twisted limb, or both. Skeletal defects such as fused vertebrae and fused and forked ribs were also observed (REACH).

In a further study, pregnant murine strain (LM/BSc) mice were injected intraperitoneally with sodium arsenate (CAS No. 7778-43-0) at 40 mg/kg bw/day during gestation day seven and eight. This caused exencephaly in 90–100 % of the exposed foetuses. Further analysis showed that the chemical altered the expression of genes, specifically, that sodium arsenate inhibits cell proliferation (REACH).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include systemic long-term effects (carcinogenicity, genotoxicity and developmental toxicity), harmful effects following repeated exposure, and systemic acute effects (acute toxicity from oral, dermal and inhalation exposure).

Public Risk Characterisation

Given the uses identified for this group of chemicals, it is unlikely that the public will be exposed. Hence, the public risk from these chemicals is not considered to be unreasonable.

These chemicals are currently listed on Schedule 7 of the SUSMP. Schedule 7 chemicals are not available for general public use. The current controls are considered adequate to minimise the risk to public health.

Occupational Risk Characterisation

Given the critical systemic long-term and systemic acute health effects, this group of chemicals may pose an unreasonable risk to workers unless adequate control measures to minimise dermal, ocular and inhalation exposure to the chemical are implemented. This group of chemicals should be appropriately classified and labelled to ensure that a person conducting a business or undertaking (PCBU) at a workplace (such as an employer) has adequate information to determine appropriate controls.

The data available support an amendment to the hazard classification in HSIS (refer to **Recommendation** section).

NICNAS Recommendation

Assessment of the chemical is considered to be sufficient, provided that the recommended amendment to the classification is adopted, and labelling and all other requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Regulatory Control

Work Health and Safety

The pentavalent arsenate salts are recommended for classification and labelling under the current approved criteria and adopted GHS as below. This assessment does not consider classification of physical hazards and environmental hazards.

Due to the pH of trisodium arsenate (CAS No. 13464-38-5), the chemical may have irritant or corrosive properties. This should be taken into consideration when classifying the chemical and products or formulations containing the chemical.

The classification proposed below is based on the human health hazard assessment of arsenic acid and arsenic pentoxide (NICNAS). It should be used as a default for all members of the group, subject to the previous paragraph concerning trisodium arsenate. If empirical data become available for any member of the group indicating that a lower (or higher) classification is appropriate, for the specific chemical, this may be used to amend the default classification for the chemical.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Toxic if swallowed (T; R25)* Harmful in contact with skin (Xn; R21) Toxic by inhalation (T; R23)*	Toxic if swallowed - Cat. 3 (H301) Harmful in contact with skin - Cat. 4 (H312) Toxic if inhaled - Cat. 3 (H331)
Repeat Dose Toxicity	Danger of serious damage to health by prolonged exposure (Xn; R48)	May cause damage to organs through prolonged or repeated exposure - Cat. 2 (H373)
Genotoxicity	Muta. Cat 3 - Possible risk of irreversible effects (Xn; R68)	Suspected of causing genetic defects - Cat. 2 (H341)
Carcinogenicity	Carc. Cat 1 - May cause cancer (T; R45)*	May cause cancer - Cat. 1A (H350)
Reproductive and Developmental Toxicity	Repro. Cat 3 - Possible risk of harm to the unborn child (Xn; R63)	Suspected of damaging the unborn child - Cat. 2 (H361d)

[a] Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)].

[b] Globally Harmonized System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third Edition.

[*] Existing Hazard Classification. No change recommended to this classification

Advice for industry

Control measures

Control measures to minimise the risk from oral, dermal and inhalation exposure to the group of chemicals should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemical is used. Examples of control measures which may minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- using local exhaust ventilation to prevent the chemical from entering the breathing zone of any worker;
- health monitoring for any worker who is at risk of exposure to the chemical if valid techniques are available to monitor the effect on the worker's health;
- air monitoring to ensure control measures in place are working effectively and continue to do so;
- minimising manual processes and work tasks through automating processes;
- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and

- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemical.

Guidance on managing risks from hazardous chemicals are provided in the *Managing risks of hazardous chemicals in the workplace—Code of practice* available on the Safe Work Australia website.

Personal protective equipment should not solely be relied upon to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selecting personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Obligations under workplace health and safety legislation

Information in this report should be taken into account to assist with meeting obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

- ensuring that hazardous chemicals are correctly classified and labelled;
- ensuring that (material) safety data sheets ((m)SDS) containing accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of the chemical are prepared; and
- managing risks arising from storing, handling and using a hazardous chemical.

Your work health and safety regulator should be contacted for information on the work health and safety laws in your jurisdiction.

Information on how to prepare an (m)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the *Preparation of safety data sheets for hazardous chemicals— Code of practice* and *Labelling of workplace hazardous chemicals—Code of practice*, respectively. These codes of practice are available from the Safe Work Australia website.

A review of the physical hazards of this group of chemicals has not been undertaken as part of this assessment.

References

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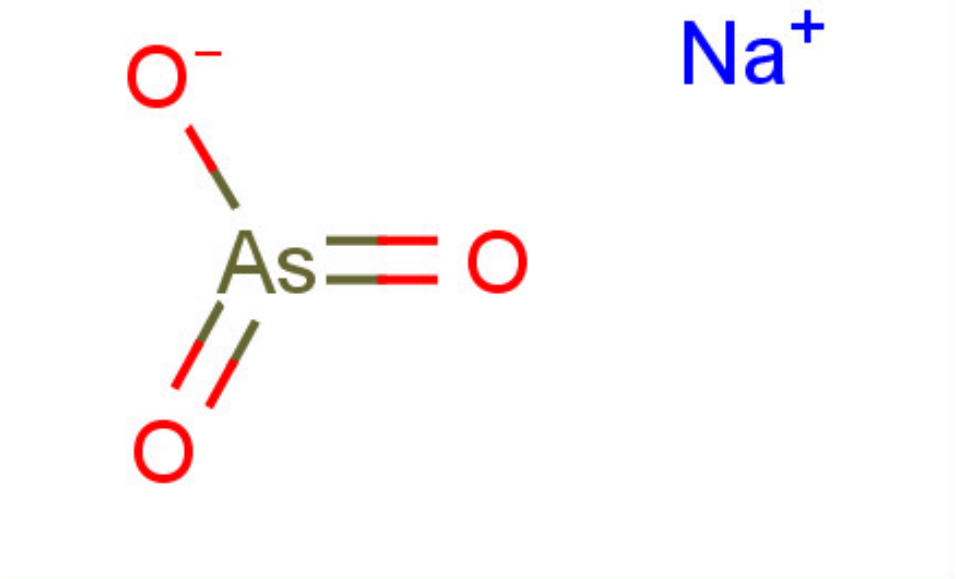
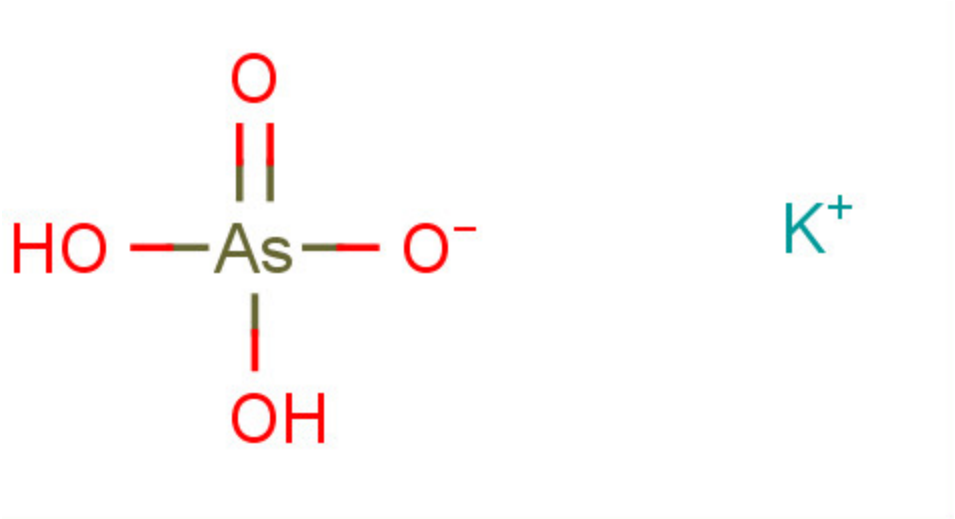
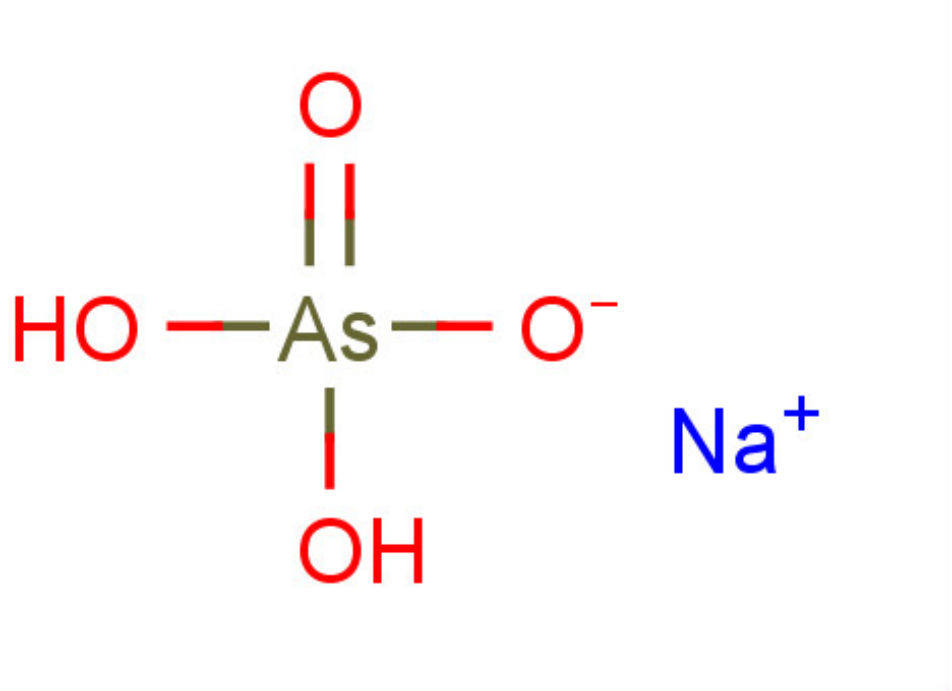
Last Update 12 September 2013

Chemical Identities

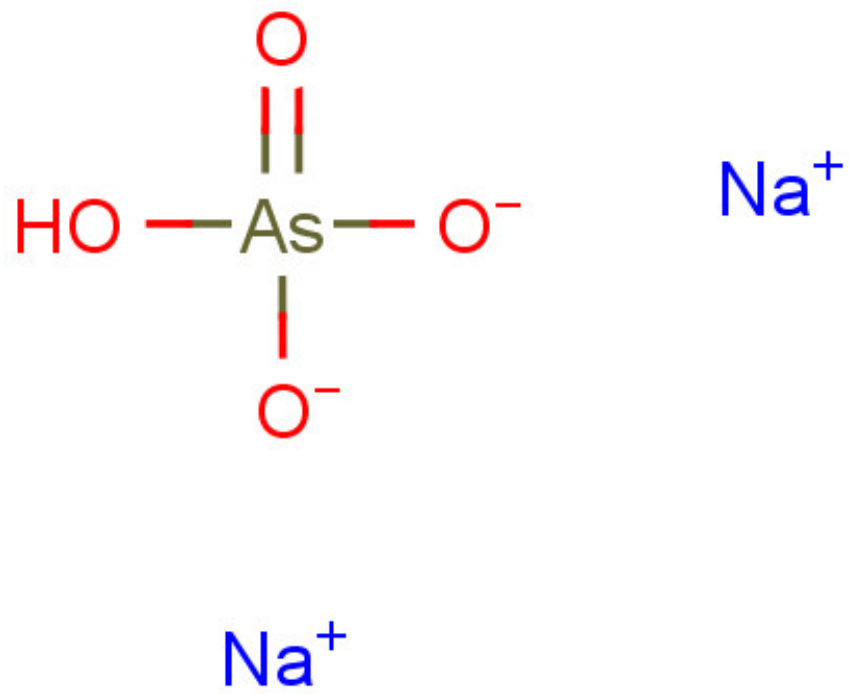
Chemical Name in the Inventory and Synonyms	**Arsenenic acid, sodium salt** Sodium metaarsenate Sodium arsenate Sodium monohydrogen arsenate
CAS Number	15120-17-9
Structural Formula	
Molecular Formula	AsHO3.Na
Molecular Weight	145.91

Chemical Name in the Inventory and Synonyms	**Arsenic acid (H3AsO4), monopotassium salt** Potassium arsenate Macquer's salt Monopotassium dihydrogen arsenate
CAS Number	7784-41-0
Structural Formula	
Molecular Formula	AsH3O4.K
Molecular Weight	180.34

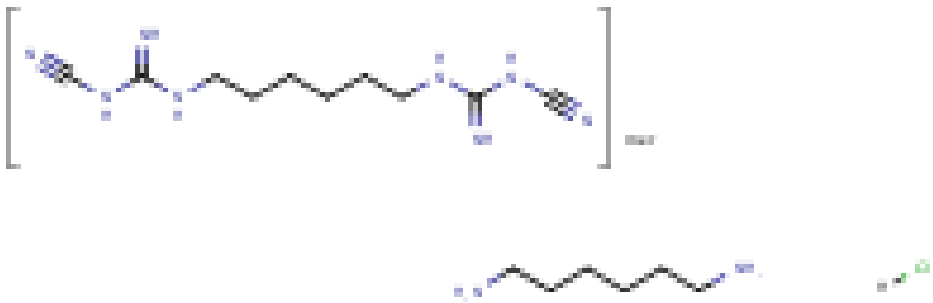
Chemical Name in the Inventory and Synonyms	**Arsenic acid (H3AsO4), sodium salt** Sodium arsenate Sodium orthoarsenate Sodium arsenate,dodecahydrate Arsenic acid
CAS Number	7631-89-2
Structural Formula	

	
Molecular Formula	AsH3O4.xNa
Molecular Weight	163.92

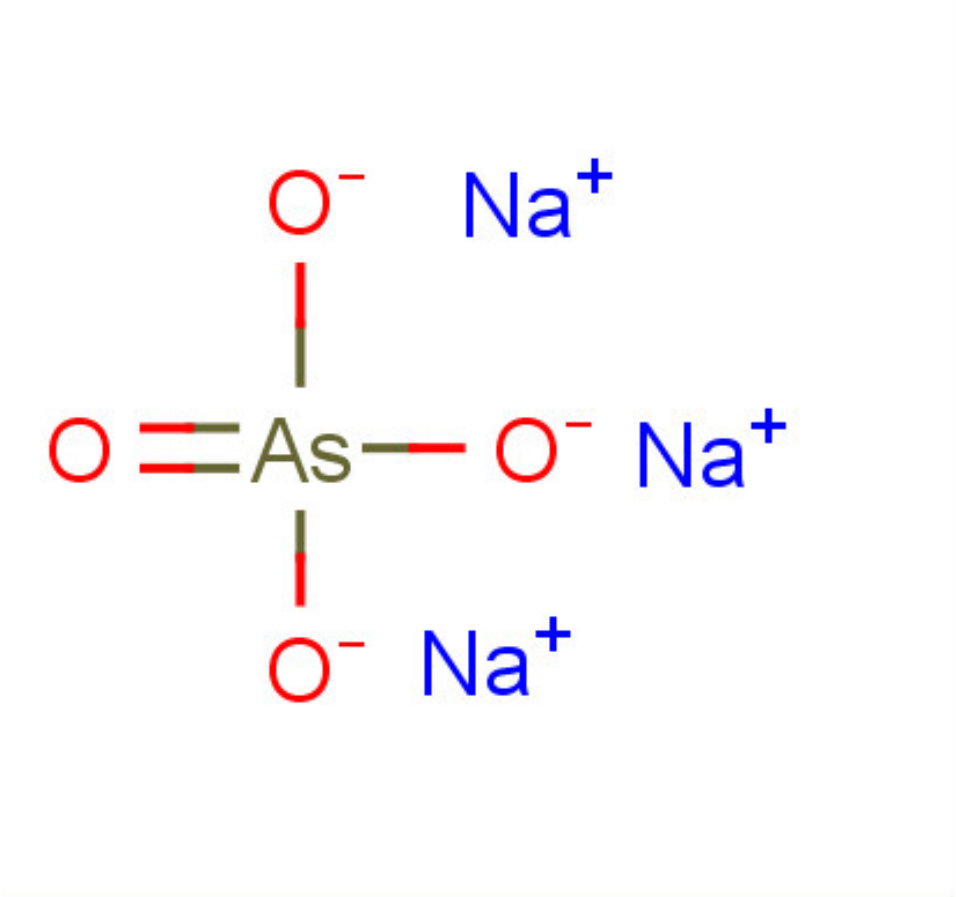
Chemical Name in the Inventory and Synonyms	**Arsenic acid (H3AsO4), disodium salt** Sodium arsenate Dibasic sodium arsenate Disodium arsenic acid Disodium hydrogen arsenate Sodium biarsenate
CAS Number	7778-43-0
Structural Formula	

	
Molecular Formula	AsH3O4.2Na
Molecular Weight	185.91

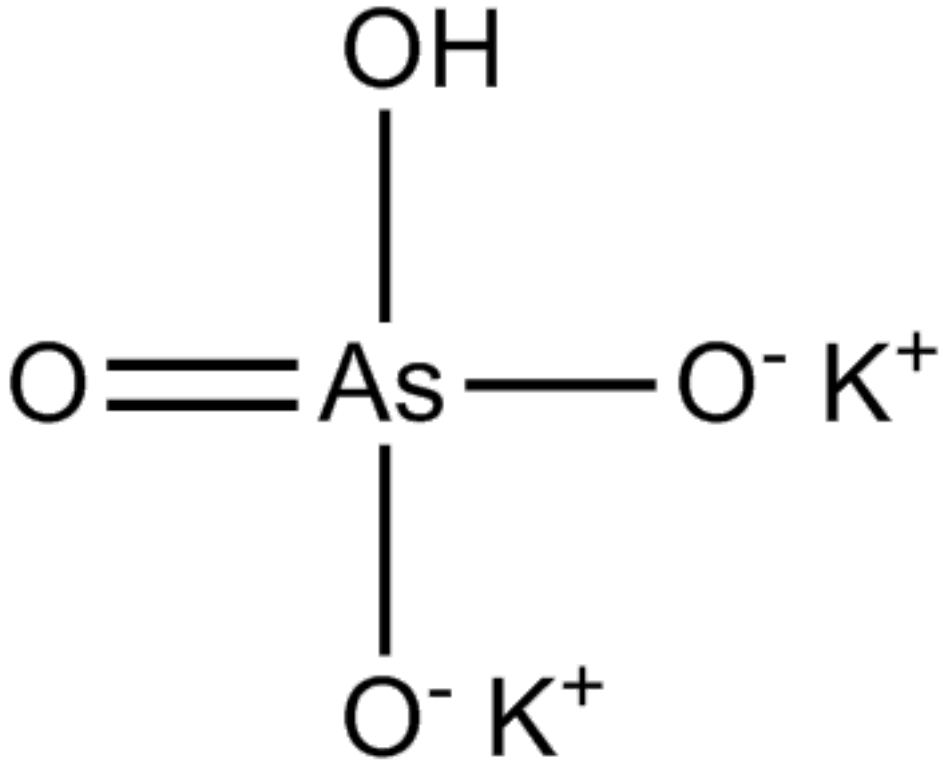
Chemical Name in the Inventory and Synonyms	**Arsenic acid (H3AsO4), disodium salt, heptahydrate** Dibasic sodium arsenate (Na2HAsO4.7H2O) Sodium acid arsenate, heptahydrate Disodium hydrogen arsenate heptahydrate
CAS Number	10048-95-0
Structural Formula	

	
Molecular Formula	AsH3O4.7H2O.2Na
Molecular Weight	312.01

Chemical Name in the Inventory and Synonyms	**Arsenic acid (H3AsO4), trisodium salt** Trisodium arsenate Arsinotrihydroxy-1-one, sodium salt, sodium salt, sodium salt
CAS Number	13464-38-5
Structural Formula	

	
Molecular Formula	AsH3O4.3Na
Molecular Weight	207.89

Chemical Name in the Inventory and Synonyms	**Arsenic acid (H3AsO4), dipotassium salt** Potassium arsenate (K2HAsO4) Dipotassium hydrogen arsenate
CAS Number	21093-83-4
Structural Formula	

	
Molecular Formula	AsH3O4.2K
Molecular Weight	218.5

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