

MATERIAL SAFETY DATA SHEET

Version No: MSDS/Arsenic-AUS/DP-001

Effective Date: 10th January 2022

Arsenic Trioxide Accord 10 mg/10 mL

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: Arsenic Trioxide Accord 10 mg/10 mL concentrated injection.

Intended Use:	Pharmaceutical product.
Details of the Supplier of the Safety Data Sheet	
Sponsor: Accord Healthcare Pty Ltd Level 24, 570 Bourke Street, Melbourne, VIC, 3000, Australia Telephone: 1800 222 673 (hours 8:30am – 4:30pm)	

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture:

Product definition: Mixture
Classification according to Regulation (EC) No. 1272/2008[CLP/GHS]: Carc 1A, H350

Label elements:

Hazard pictograms:



Signal Word: Danger
Hazard statements: H350 – May cause cancer.

Precautionary statements:

Prevention: P201 – Obtain special instructions before use.
P280 – Wear protective gloves. Wear protective clothing. Wear eye or face protection.

Response: P308 + P313 – IF exposed or concerned: Get medical attention/advice.

Storage: P405 – Store locked up.

Disposal: P501 – Dispose of contents/container in accordance with all local, regional, national and international regulations.

Hazardous ingredients: Diarsenic trioxide.

Supplemental label elements: Not applicable.

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Other hazards: None known.

SECTION 3 – COMPOSITION, INFORMATION ON INGREDIENTS

Hazardous:

Product/Ingredient name	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Diarsenic trioxide	1327-53-3	215-481-4	Carc. 1A (H350)	<0.25

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16.

SECTION 4 - FIRST AID MEASURES

Description of First Aid Measures:

Eye Contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.

Skin Contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Ingestion: Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If unconscious, place in recovery position and get

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medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Protection of first aiders: No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

Most Important Symptoms and Effects, Both Acute and Delayed:

Over-exposure signs/symptoms: None known.

Indication of the Immediate Medical Attention and Special Treatment Needed:

Notes to Physician: Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

SECTION 5 - FIRE FIGHTING MEASURES

Extinguishing Media:

Suitable extinguishing media: Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media: Do not use water jet.

Special Hazards Arising from the Substance or Mixture:

Hazards from the substance or mixture: In a fire or if heated, a pressure increase will occur, and the container may burst.

Hazardous thermal decomposition products: None known.

Advice for Fire-Fighters:

Special protective actions for fire-fighters: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves).

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SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures:

For non-emergency personnel: No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Avoid breathing vapour or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency personnel: If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental Precautions: Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and Material for Containment and Cleaning Up:

Measures for Cleaning / Collecting: Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Additional Consideration for Large Spills: Stop leak if without risk. Move containers from spill area. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilt product.

SECTION 7 - HANDLING AND STORAGE

Precautions for Safe Handling:

Protective measures: Put on appropriate personal protective equipment (see Section 8).

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Avoid exposure - obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapour or mist. If during normal use the material presents a respiratory hazard, use only with adequate ventilation or wear appropriate respirator.

Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene:

Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

Conditions for Safe Storage, Including any Incompatibilities:

Storage Conditions:

Store in accordance with local regulations. Shelf life: 2 years. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Specific end use(s):

Not available.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters:

Occupational exposure limits

Product/ingredient name	Exposure limit values
Diarsenic trioxide	TWA: 0.1 mg/m ³ , (as As) 8 hours.

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DNELs/DMELs

Product/ingredient name	Type	Exposure	Value	Population	Effects
Diarsenic trioxide	DNEL	Long term Oral	2.2 µg/kg bw/day	General population	Systemic
	DNEL	Long term Inhalation	2.5 µg/m ³	General population	Systemic
	DNEL	Long term Inhalation	5 µg/m ³	Workers	Systemic
	DNEL	Long term Dermal	112 µg/kg bw/day	General population	Systemic
	DNEL	Long term Dermal	112 µg/kg bw/day	Workers	Systemic

PNECs

No PNECs available.

Exposure Controls:

Engineering controls:

If user operations generate dust, fumes, gas, vapour or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

Environmental exposure controls:

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Personal protection measures:

Hygiene measures:

Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection:

Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

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Hand protection:	Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
Body protection:	Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Skin protection:	Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Respiratory protection:	Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid. [Clear.]
Colour:	Colourless.
Odour:	Not available.
Odour Threshold:	Not available.
pH:	7.7 to 8.3
Melting/Freezing Point (°C):	Not available.
Initial Boiling Point and boiling range (°C):	Not available.
Flash Point (°C):	Not available.
Evaporation Rate (Gram/s):	Not available.
Flammability (solid, gas):	Not applicable.
Upper/lower flammability or explosive Limits:	Not available.
Vapor Pressure (kPa):	Not available.
Vapor Density (g/ml):	Not available.
Relative Density:	Not available.
Solubility(ies):	Not available.
Partition Coefficient: n-octanol/water:	Not available.
Auto-ignition Temperature (°C):	Not available.

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Decomposition Temperature (°C): Not available.
Viscosity: Not available.
Explosive properties: Not available.
Oxidising properties: Not available.
Solubility in water: Not available.

SECTION 10 - STABILITY AND REACTIVITY

Reactivity: No specific test data related to reactivity available for this product or its ingredients.

Chemical Stability: The product is stable.

Possibility of Hazardous Reactions: Under normal conditions of storage and use, hazardous reactions will not occur.
Under normal conditions of storage and use, hazardous polymerisation will not occur.

Conditions to Avoid: No specific data.

Incompatible Materials: Reactive or incompatible with oxidizing materials.

Hazardous Decomposition Products: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11 - TOXICOLOGY INFORMATION

Information on Toxicological Effect:

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Diarsenic trioxide	LD50 Oral	Rat	10 mg/kg	-

Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapours) (mg/l)	Inhalation (dusts and mists) (mg/l)
Arsenic trioxide	10000	N/A	N/A	N/A	N/A
Diarsenic trioxide	10	N/A	N/A	N/A	N/A

Specific Effects:

General: No known significant effects or critical hazards.

Carcinogenicity: May cause cancer. Risk of cancer depends on duration and level of exposure.

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Mutagenicity: No known significant effects or critical hazards.
Teratogenicity: No known significant effects or critical hazards.
Developmental effects: No known significant effects or critical hazards.
Fertility effects: No known significant effects or critical hazards.

SECTION 12 - ENVIRONMENTAL IMPACT INFORMATION

Toxicity:

Product/ingredient name	Result	Species	Exposure
Diarsenic trioxide	Acute EC50 34.7 mg/l Fresh water	Algae – Scenedesmus subspicatus	72 hours
	Acute EC50 2.5 mg/l Fresh water	Daphnia – Daphnia magna - Neonate	48 hours
	Acute EC50 3380 µg/l Marine water	Fish – Terapon jarbua – Juvenile (Fledgling, Hatchling, Weanling)	96 hours
	Chronic EC10 9.4 mg/l Fresh water	Algae – Scenedesmus subspicatus	72 hours
	Chronic IC10 1.3 mg/l Fresh water	Daphnia – Daphnia magna - Neonate	21 days

Bio-accumulative potential:

Product/ingredient name	LogP _{ow}	BCF	Potential
Diarsenic trioxide	-	0.143	low

Persistence and Degradability: No data available
Mobility in Soil No data available
Results of PBT and vPvB assessment: This mixture does not contain any substances that are assessed to be a PBT or vPvB.
Other adverse effects: No known significant effects or critical hazards.

SECTION 13 - DISPOSAL INFORMATION

Waste treatment methods:

Product

Methods of disposal:

The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and nonrecyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with

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jurisdiction.

Hazardous waste: The classification of the product may meet the criteria for a hazardous waste.

Packaging

Methods of disposal: The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions: This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14 - TRANSPORTATION INFORMATION

	ADR/RID	ADN	IMDG	IATA
UN number	Not regulated	Not regulated	Not regulated	Not regulated
UN proper shipping name	-	-	-	-
Transport hazard class(es)	-	-	-	-
Packing group	-	-	-	-
Environmental hazards	No	No	No	No

Special precautions for user:

Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

SECTION 15 - REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Diarsenic trioxide (1327-53-3) is found on the following regulatory lists:

Australia Exposure Standards

Australia Work Health and Safety Regulations
2016 - Hazardous chemicals (other than lead)
requiring health monitoring

Australia Hazardous Substances Information
System - Consolidated Lists

International Agency for Research on Cancer
(IARC) - Agents Classified by the IARC

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Monographs

Australia Inventory of Chemical Substances
(AICS)

Substances of very high concern

Ingredient name	Intrinsic property	Status	Reference number	Date of revision
Diarsenic trioxide	Carcinogen	Candidate	ED/67/2008	12/17/2010

Restrictions of the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles:

Restricted to professional users.

Australian inventory:

All components are listed or exempted.

SECTION 16 - OTHER DATA

Abbreviations and acronyms:

ATE = Acute Toxicity Estimate
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No.1272/2008]
DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level
EUH statement = CLP-specific Hazard statement
N/A = Not available
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
RRN = REACH Registration Number
vPvB = Very Persistent and Very Bioaccumulative

Key literature references and sources for data:

Regulation (EC) No. 1272/2008 [CLP]; European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), concluded in Geneva on 30 September 1957 plus amendments (Uniform text: Journal of Laws 27/2009 pos. 162 plus amendments); European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN); Occupational exposure limits; International regulations

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Carc. 1A, H350	Calculation method

Full text of abbreviated H statements

H300	Fatal if swallowed.
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H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H350	May cause cancer.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Full text of classifications [CLP/GHS]

Acute Tox. 2, H300	ACUTE TOXICITY (oral) – Category 2
Aquatic Acute 1, H400	SHORT-TERM (ACUTE) AQUATIC HAZARD – Category 1
Aquatic Chronic 1, H410	LONG-TERM (CHRONIC) AQUATIC HAZARD – Category 1
Carc. 1A, H350	CARCINOGENICITY – Category 1A
Eye Dam. 1, H318	SERIOUS EYE DAMAGE/EYE IRRITATION – Category 1
Skin Corr. 1B, H314	SKIN CORROSION/IRRITATION – Category 1B

Training advice: Ensure operatives are trained to minimise exposures. Training staff on good practice.

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

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