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# Metaraminol 10mg/ml Solution for Injection / Infusion

## Phebra Pty Ltd

Chemwatch Hazard Alert Code: **2**

Chemwatch: **5464-11**
Version No: **2.1**
Safety Data Sheet according to WHS Regulations (Hazardous Chemicals) Amendment 2020 and ADG requirements

Issue Date: **28/04/2021**
Print Date: **10/02/2022**
S.GHS.AUS.EN.E

## SECTION 1 Identification of the substance / mixture and of the company / undertaking

### Product Identifier

| | |
|---|---|
| **Product name** | Metaraminol 10mg/ml Solution for Injection / Infusion |
| **Chemical Name** | Not Applicable |
| **Synonyms** | Not Available |
| **Chemical formula** | Not Applicable |
| **Other means of identification** | Not Available |

### Relevant identified uses of the substance or mixture and uses advised against

| | |
|---|---|
| **Relevant identified uses** | This medicine is used for treatment of acute hypotension due to loss of vasoconstictor tone as may occur during spinal anaesthesia and as an adjunct to accepted remedial procedures. May be given either by intravenous infusion or by direct intravenous injection after dilution. |

### Details of the supplier of the safety data sheet

| | |
|---|---|
| **Registered company name** | **Phebra** |
| **Address** | 17-19 Orion Road Lane Cove West NSW 2066 Australia |
| **Telephone** | +61 2 9420 9199\|1800 720 020 |
| **Fax** | +61 2 9420 9177 |
| **Website** | www.phebra.com |
| **Email** | msds@phebra.com |

### Emergency telephone number

| | |
|---|---|
| **Association / Organisation** | **Phebra** |
| **Emergency telephone numbers** | +61 401 264 004 |
| **Other emergency telephone numbers** | N/A |

## SECTION 2 Hazards identification

### Classification of the substance or mixture

**HAZARDOUS CHEMICAL. NON-DANGEROUS GOODS. According to the WHS Regulations and the ADG Code.**

**ChemWatch Hazard Ratings**

| | Min | Max |
|---|---|---|
| Flammability | 0 | |
| Toxicity | 2 | |
| Body Contact | 2 | |
| Reactivity | 0 | |
| Chronic | 0 | |

0 = Minimum
1 = Low
2 = Moderate
3 = High
4 = Extreme

| | |
|---|---|
| **Poisons Schedule** | S4 |
| **Classification [1]** | Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2A, Acute Toxicity (Oral) Category 4 |
| ***Legend:*** | *1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI* |

### Label elements

**Page 1 continued...**

| | |
|---|---|
| **Hazard pictogram(s)** |  |
| **Signal word** | **Warning** |

**Hazard statement(s)**

| | |
|---|---|
| **H315** | Causes skin irritation. |
| **H319** | Causes serious eye irritation. |
| **H302** | Harmful if swallowed. |

**Precautionary statement(s) Prevention**

| | |
|---|---|
| **P264** | Wash all exposed external body areas thoroughly after handling. |
| **P270** | Do not eat, drink or smoke when using this product. |
| **P280** | Wear protective gloves, protective clothing, eye protection and face protection. |

**Precautionary statement(s) Response**

| | |
|---|---|
| **P305+P351+P338** | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| **P337+P313** | If eye irritation persists: Get medical advice/attention. |
| **P301+P312** | IF SWALLOWED: Call a POISON CENTER/doctor/physician/first aider if you feel unwell. |
| **P302+P352** | IF ON SKIN: Wash with plenty of water. |
| **P330** | Rinse mouth. |
| **P332+P313** | If skin irritation occurs: Get medical advice/attention. |
| **P362+P364** | Take off contaminated clothing and wash it before reuse. |

**Precautionary statement(s) Storage**

Not Applicable

**Precautionary statement(s) Disposal**

| | |
|---|---|
| **P501** | Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation. |

## SECTION 3 Composition / information on ingredients

**Substances**

See section below for composition of Mixtures

**Mixtures**

| CAS No | %[weight] | Name |
|---|---|---|
| 33402-03-8 | 1-10 | metaraminol bitartrate |
| 7681-57-4 | <1 | sodium metabisulfite |
| 7647-14-5 | <1 | sodium chloride |
| 87-69-4 | <1 | tartaric acid |
| 1310-73-2 | <1 | sodium hydroxide |
| 7732-18-5 | >60 | water |
| ***Legend:*** | *1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 4. Classification drawn from C&L; * EU IOELVs available* | |

## SECTION 4 First aid measures

**Description of first aid measures**

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|---|---|
| **Eye Contact** | If this product comes in contact with the eyes:<br>▸ Wash out immediately with fresh running water.<br>▸ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.<br>▸ Seek medical attention without delay; if pain persists or recurs seek medical attention.<br>▸ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel. |
| **Skin Contact** | If skin contact occurs:<br>▸ Immediately remove all contaminated clothing, including footwear.<br>▸ Flush skin and hair with running water (and soap if available).<br>▸ Seek medical attention in event of irritation. |
| **Inhalation** | ▸ If fumes, aerosols or combustion products are inhaled remove from contaminated area.<br>▸ Other measures are usually unnecessary. |
| **Ingestion** | ▸ **IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY.**<br>▸ For advice, contact a Poisons Information Centre or a doctor.<br>▸ Urgent hospital treatment is likely to be needed.<br>▸ In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition. |

**Continued...**

| | |
|---|---|
| | ▸ If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the SDS should be provided. Further action will be the responsibility of the medical specialist.<br>▸ If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the SDS.<br><br>**Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:**<br>▸ **INDUCE** vomiting with fingers down the back of the throat, **ONLY IF CONSCIOUS**. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.<br>**NOTE:** Wear a protective glove when inducing vomiting by mechanical means. |

### Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

## SECTION 5 Firefighting measures

### Extinguishing media

The product contains a substantial proportion of water, therefore there are no restrictions on the type of extinguishing media which may be used. Choice of extinguishing media should take into account surrounding areas.
Though the material is non-combustible, evaporation of water from the mixture, caused by the heat of nearby fire, may produce floating layers of combustible substances.
In such an event consider:

- foam.
- dry chemical powder.
- carbon dioxide.

### Special hazards arising from the substrate or mixture

| | |
|---|---|
| **Fire Incompatibility** | None known. |

### Advice for firefighters

| | |
|---|---|
| **Fire Fighting** | ▸ Alert Fire Brigade and tell them location and nature of hazard.<br>▸ Wear breathing apparatus plus protective gloves in the event of a fire.<br>▸ Prevent, by any means available, spillage from entering drains or water courses.<br>▸ Use fire fighting procedures suitable for surrounding area.<br>▸ **DO NOT** approach containers suspected to be hot.<br>▸ Cool fire exposed containers with water spray from a protected location.<br>▸ If safe to do so, remove containers from path of fire.<br>▸ Equipment should be thoroughly decontaminated after use. |
| **Fire/Explosion Hazard** | ▸ The material is not readily combustible under normal conditions.<br>▸ However, it will break down under fire conditions and the organic component may burn.<br>▸ Not considered to be a significant fire risk.<br>▸ Heat may cause expansion or decomposition with violent rupture of containers.<br>▸ Decomposes on heating and may produce toxic fumes of carbon monoxide (CO).<br>▸ May emit acrid smoke.<br><br>Decomposes on heating and produces toxic fumes of:<br>carbon dioxide ($CO_2$)<br>sulfur oxides (SOx)<br>other pyrolysis products typical of burning organic material.<br>May emit poisonous fumes.<br>May emit corrosive fumes. |
| **HAZCHEM** | Not Applicable |

## SECTION 6 Accidental release measures

### Personal precautions, protective equipment and emergency procedures

See section 8

### Environmental precautions

See section 12

### Methods and material for containment and cleaning up

| | |
|---|---|
| **Minor Spills** | ▸ Clean up all spills immediately.<br>▸ Avoid breathing vapours and contact with skin and eyes.<br>▸ Control personal contact with the substance, by using protective equipment.<br>▸ Contain and absorb spill with sand, earth, inert material or vermiculite.<br>▸ Wipe up.<br>▸ Place in a suitable, labelled container for waste disposal. |
| **Major Spills** | Moderate hazard.<br>▸ Clear area of personnel and move upwind.<br>▸ Alert Fire Brigade and tell them location and nature of hazard.<br>▸ Wear breathing apparatus plus protective gloves.<br>▸ Prevent, by any means available, spillage from entering drains or water course.<br>▸ Stop leak if safe to do so.<br>▸ Contain spill with sand, earth or vermiculite.<br>▸ Collect recoverable product into labelled containers for recycling. |

Personal Protective Equipment advice is contained in Section 8 of the SDS.

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## SECTION 7 Handling and storage

### Precautions for safe handling

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|---|---|
| **Safe handling** | ▸ **DO NOT** allow clothing wet with material to stay in contact with skin<br>▸ Avoid all personal contact, including inhalation.<br>▸ Wear protective clothing when risk of exposure occurs.<br>▸ Use in a well-ventilated area.<br>▸ Prevent concentration in hollows and sumps.<br>▸ **DO NOT** enter confined spaces until atmosphere has been checked.<br>▸ **DO NOT** allow material to contact humans, exposed food or food utensils.<br>▸ Avoid contact with incompatible materials.<br>▸ When handling, **DO NOT** eat, drink or smoke. |
| **Other information** | ▸ Store in original containers.<br>▸ Keep containers securely sealed.<br>▸ Store in a cool, dry, well-ventilated area.<br>▸ Store away from incompatible materials and foodstuff containers.<br>▸ Protect containers against physical damage and check regularly for leaks.<br>▸ Observe manufacturer's storage and handling recommendations contained within this SDS. |

### Conditions for safe storage, including any incompatibilities

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|---|---|
| **Suitable container** | ▸ Polyethylene or polypropylene container.<br>▸ Packing as recommended by manufacturer.<br>▸ Check all containers are clearly labelled and free from leaks. |
| **Storage incompatibility** | Metaraminol is incompatible with fibrinogen, thiopentone sodium, warfarin sodium, hylprednisolone sodium succinate, hydrocortisone sodium succinate, prednisolone sodium phosphate and dexamethasone sodium phosphate in sodium chloride injection and glucose injection.<br>There is loss of clarity when intravenous solutions are mixed with those of benzylpenicillin, hydrocortisone, sodium succinate, methicillin sodium or phenytoin sodium or glucose solutions of thiopentone or warfarin sodium.<br>Nitrofurantoin sodium in glucose injection is incompatible; the pH falls to 7.2 and a brown precipitate is formed. |

## SECTION 8 Exposure controls / personal protection

### Control parameters

**Occupational Exposure Limits (OEL)**

**INGREDIENT DATA**

| Source | Ingredient | Material name | TWA | STEL | Peak | Notes |
|---|---|---|---|---|---|---|
| Australia Exposure Standards | sodium metabisulfite | Sodium metabisulphite | 5 mg/m3 | Not Available | Not Available | Not Available |
| Australia Exposure Standards | sodium hydroxide | Sodium hydroxide | Not Available | Not Available | 2 mg/m3 | Not Available |

**Emergency Limits**

| Ingredient | TEEL-1 | TEEL-2 | TEEL-3 |
|---|---|---|---|
| sodium metabisulfite | 15 mg/m3 | 64 mg/m3 | 390 mg/m3 |
| sodium chloride | 0.5 ppm | 2 ppm | 20 ppm |
| tartaric acid | 1.6 mg/m3 | 17 mg/m3 | 100 mg/m3 |
| sodium hydroxide | Not Available | Not Available | Not Available |

| Ingredient | Original IDLH | Revised IDLH |
|---|---|---|
| metaraminol bitartrate | Not Available | Not Available |
| sodium metabisulfite | Not Available | Not Available |
| sodium chloride | Not Available | Not Available |
| tartaric acid | Not Available | Not Available |
| sodium hydroxide | 10 mg/m3 | Not Available |
| water | Not Available | Not Available |

**Occupational Exposure Banding**

| Ingredient | Occupational Exposure Band Rating | Occupational Exposure Band Limit |
|---|---|---|
| metaraminol bitartrate | E | ≤ 0.01 mg/m³ |
| sodium chloride | E | ≤ 0.01 mg/m³ |
| tartaric acid | E | ≤ 0.01 mg/m³ |
| ***Notes:*** | *Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.* | |

### Exposure controls

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|---|---|
| **Appropriate engineering controls** | **For potent pharmacological agents:**<br>**Solutions Handling:**<br>▸ Solutions can be handled outside a containment system or without local exhaust ventilation during procedures with no potential for aerosolisation. If the procedures have a potential for aerosolisation, an air-purifying respirator is to be worn by all personnel in the immediate area.<br>▸ Solutions used for procedures where aerosolisation may occur (e.g., vortexing, pumping) are to be handled within a containment system or with local exhaust ventilation.<br>▸ In situations where this is not feasible (may include animal dosing), an air-purifying respirator is to be worn by all personnel in the immediate |

**Continued...**

| | |
|---|---|
| | area. If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use.<br>▸ Ensure gloves are protective against solvents in use.<br>**Unless written procedures, specific to the workplace are available, the following is intended as a guide:**<br>▸ **For Laboratory-scale handling of Substances assessed to be toxic by inhalation. *Quantities of up to 25 grams*** may be handled in Class II biological safety cabinets *; ***Quantities of 25 grams to 1 kilogram*** may be handled in Class II biological safety cabinets* or equivalent containment systems; ***Quantities exceeding 1 kg*** may be handled either using specific containment, a hood or Class II biological safety cabinet*,<br>▸ HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours.<br>▸ The need for respiratory protection should also be assessed where incidental or accidental exposure is anticipated. Dependent on levels of contamination, PAPR, full face air purifying devices with P2 or P3 filters or air supplied respirators should be evaluated. When handling: ***Quantities of up to 25 grams***, an approved respirator with HEPA filters or cartridges should be considered; ***Quantities of 25 grams to 1 kilogram,*** a half-face negative pressure, full negative pressure, or powered helmet-type air purifying respirator should be considered. ***Quantities in excess of 1 kilogram*****,** a full face negative pressure, helmet-type air purifying, or supplied air respirator should be considered.<br>Written procedures, specific to a particular work-place, may replace these recommendations<br>* For Class II Biological Safety Cabinets, Types B2 or B3 should be considered. Where only Class I, open fronted Cabinets are available, glove panels may be added, Laminar flow cabinets do not provide sufficient protection when handling these materials unless especially designed to do so. |
| **Personal protection** |  |
| **Eye and face protection** | ▸ Safety glasses with side shields.<br>▸ Chemical goggles.<br>▸ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. |
| **Skin protection** | See Hand protection below |
| **Hands/feet protection** | ▸ Wear chemical protective gloves, e.g. PVC.<br>▸ Wear safety footwear or safety gumboots, e.g. Rubber<br>**NOTE:**<br>▸ The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.<br>▸ Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed.<br>The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.<br>The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.<br>Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.<br>Suitability and durability of glove type is dependent on usage. |
| **Body protection** | See Other protection below |
| **Other protection** | ▸ Overalls.<br>▸ P.V.C apron.<br>▸ Barrier cream.<br>▸ Skin cleansing cream.<br>▸ Eye wash unit. |

### Recommended material(s)

**GLOVE SELECTION INDEX**

Glove selection is based on a modified presentation of the:
***"Forsberg Clothing Performance Index".***
The effect(s) of the following substance(s) are taken into account in the ***computer-generated*** selection:
Metaraminol 10mg/ml Solution for Injection / Infusion

| Material | CPI |
|---|---|
| BUTYL | C |
| NAT+NEOPR+NITRILE | C |
| NATURAL RUBBER | C |
| NATURAL+NEOPRENE | C |
| NEOPRENE | C |
| NEOPRENE/NATURAL | C |
| NITRILE | C |
| NITRILE+PVC | C |
| PE | C |
| PE/EVAL/PE | C |
| PVA | C |
| PVC | C |
| SARANEX-23 | C |
| SARANEX-23 2-PLY | C |

### Respiratory protection

Type A Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Where the concentration of gas/particulates in the breathing zone, approaches or exceeds the "Exposure Standard" (or ES), respiratory protection is required. Degree of protection varies with both face-piece and Class of filter; the nature of protection varies with Type of filter.

| Required Minimum Protection Factor | Half-Face Respirator | Full-Face Respirator | Powered Air Respirator |
|---|---|---|---|
| up to 10 x ES | A-AUS | - | A-PAPR-AUS / Class 1 |
| up to 50 x ES | - | A-AUS / Class 1 | - |
| up to 100 x ES | - | A-2 | A-PAPR-2 ^ |

^ - Full-face
A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

▸ Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content.
▸ The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.

**Continued...**

| | |
|---|---|
| TEFLON | C |
| VITON | C |
| VITON/CHLOROBUTYL | C |

* CPI - Chemwatch Performance Index
A: Best Selection
B: Satisfactory; may degrade after 4 hours continuous immersion
C: Poor to Dangerous Choice for other than short term immersion
**NOTE**: As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -
* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

- Cartridge performance is affected by humidity. Cartridges should be changed after 2 hr of continuous use unless it is determined that the humidity is less than 75%, in which case, cartridges can be used for 4 hr. Used cartridges should be discarded daily, regardless of the length of time used

## SECTION 9 Physical and chemical properties

### Information on basic physical and chemical properties

| | |
|---|---|
| **Appearance** | Clear colourless to slightly pink / yellow liquid; mixes with water. |

| | | | |
|---|---|---|---|
| **Physical state** | Liquid | **Relative density (Water = 1)** | 1.014 |
| **Odour** | Not Available | **Partition coefficient n-octanol / water** | Not Available |
| **Odour threshold** | Not Available | **Auto-ignition temperature (°C)** | Not Applicable |
| **pH (as supplied)** | 3.2-4.5 | **Decomposition temperature** | Not Available |
| **Melting point / freezing point (°C)** | Not Applicable | **Viscosity (cSt)** | Not Available |
| **Initial boiling point and boiling range (°C)** | Not Available | **Molecular weight (g/mol)** | Not Applicable |
| **Flash point (°C)** | Not Applicable | **Taste** | Not Available |
| **Evaporation rate** | Not Available | **Explosive properties** | Not Available |
| **Flammability** | Not Applicable | **Oxidising properties** | Not Available |
| **Upper Explosive Limit (%)** | Not Applicable | **Surface Tension (dyn/cm or mN/m)** | Not Available |
| **Lower Explosive Limit (%)** | Not Applicable | **Volatile Component (%vol)** | Not Available |
| **Vapour pressure (kPa)** | Not Available | **Gas group** | Not Available |
| **Solubility in water** | Miscible | **pH as a solution (Not Available%)** | Not Available |
| **Vapour density (Air = 1)** | Not Available | **VOC g/L** | Not Available |

## SECTION 10 Stability and reactivity

| | |
|---|---|
| **Reactivity** | See section 7 |
| **Chemical stability** | - Unstable in the presence of incompatible materials.<br>- Product is considered stable.<br>- Hazardous polymerisation will not occur. |
| **Possibility of hazardous reactions** | See section 7 |
| **Conditions to avoid** | See section 7 |
| **Incompatible materials** | See section 7 |
| **Hazardous decomposition products** | See section 5 |

## SECTION 11 Toxicological information

### Information on toxicological effects

| | |
|---|---|
| **Inhaled** | The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.<br>Not normally a hazard due to non-volatile nature of product |
| **Ingestion** | Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.<br>Metaraminol overdose may result in hypertension accompanied by headache, nausea, vomiting, diaphoresis (sweating), constricting sensation in the chest, cerebral haemorrhage, cardiac arrhythmias, cardiac arrest, myocardial infarction, or convulsions. Fatally poisoned rats and mice showed clonic convulsions, dyspnea, and loss of righting before death. Surviving animals exhibited tachypnea, mild excitement with subsequent lethargy and frequent piloerection. In clinical use acute pulmonary oedema, arrhythmias, cerebral haemorrhage or cardiac arrest has been reported when the hypertensive response is too rapidly induced. Due to its vasoconstricting effects, exposure by individuals with diabetes, cardiac or thyroid disease or hypertension should be avoided. |
| **Skin Contact** | This material can cause inflammation of the skin on contact in some persons.<br>The material may accentuate any pre-existing dermatitis condition<br>Skin contact with the material may damage the health of the individual; systemic effects may result following absorption. |

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| | |
|---|---|
| | Open cuts, abraded or irritated skin should not be exposed to this material<br>Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected. |
| **Eye** | This material can cause eye irritation and damage in some persons. |
| **Chronic** | Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.<br>Animal testing shows that metaraminol may cause vomiting, salivation, decreased weight, increased urine output, and increase in white cell count. No studies have been performed regarding potential to cause cancer, mutations or effects on fertility. It is not known whether metaraminol can harm the foetus or reproductive ability or whether it is secreted in human milk.<br>There is some evidence that inhaling this product is more likely to cause a sensitisation reaction in some persons compared to the general population.<br>There is limited evidence that, skin contact with this product is more likely to cause a sensitisation reaction in some persons compared to the general population. |

| **Metaraminol 10mg/ml Solution for Injection / Infusion** | **TOXICITY** | **IRRITATION** |
|---|---|---|
| | Not Available | Not Available |

| **metaraminol bitartrate** | **TOXICITY** | **IRRITATION** |
|---|---|---|
| | Oral (Mouse) LD50; 99 mg/kg[2] | Not Available |

| **sodium metabisulfite** | **TOXICITY** | **IRRITATION** |
|---|---|---|
| | dermal (rat) LD50: >2000 mg/kg[1] | Eye (rabbit): IRRITANT * |
| | Oral (Rat) LD50; 500 mg/kg[2] | |

| **sodium chloride** | **TOXICITY** | **IRRITATION** |
|---|---|---|
| | Dermal (rabbit) LD50: >10000 mg/kg[1] | Eye (rabbit): 10 mg - moderate |
| | Inhalation(Rat) LC50; >10.5 mg/l4h[1] | Eye (rabbit):100 mg/24h - moderate |
| | Oral (Rat) LD50; 3000 mg/kg[2] | Skin (rabbit): 500 mg/24h - mild |

| **tartaric acid** | **TOXICITY** | **IRRITATION** |
|---|---|---|
| | dermal (rat) LD50: >2000 mg/kg[1] | Not Available |
| | Oral (Rat) LD50; >=2000<=5000 mg/kg[1] | |

| **sodium hydroxide** | **TOXICITY** | **IRRITATION** |
|---|---|---|
| | Dermal (rabbit) LD50: 1350 mg/kg[2] | Eye (rabbit): 0.05 mg/24h SEVERE |
| | Oral (Rabbit) LD50; 325 mg/kg[1] | Eye (rabbit):1 mg/24h SEVERE |
| | | Eye (rabbit):1 mg/30s rinsed-SEVERE |
| | | Eye: adverse effect observed (irritating)[1] |
| | | Skin (rabbit): 500 mg/24h SEVERE |
| | | Skin: adverse effect observed (corrosive)[1] |

| **water** | **TOXICITY** | **IRRITATION** |
|---|---|---|
| | Oral (Rat) LD50; >90000 mg/kg[2] | Not Available |

| | |
|---|---|
| ***Legend:*** | *1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances* |

| | |
|---|---|
| **METARAMINOL BITARTRATE** | ADI: 0.01 mg/day * function/structure of salivary glands recorded. * Mercke, Sharp and Dohme<br>alpha-Adrenergic receptors have actions in common, but also individual effects. Common (or still receptor unspecified) actions include:<br>· vasoconstriction<br>· decreased motility of smooth muscle in gastrointestinal tract<br>Subtype unspecific alpha agonists can be used to treat rhinitis (they decrease mucus secretion). Subtype unspecific alpha antagonists can be used to treat pheochromocytoma (they decrease vasoconstriction caused by norepinephrine).<br>Alpha-agonist toxicity may occur accidentally or intentionally. Toxicity is often due to intentional overdose and accidental pediatric ingestion. Overdoses can occur after ingestion of pills, skin patches, or via self-administered medication pumps that may be misused or malfunctioning. Chronic and accidental overdose can occur in situations involving chronic pain, with use of oral extended-release and transdermal formularies. Pharmacy dosing and compounding errors have also occurred, which is of particular concern for pediatric toxicity. In addition, drug-drug interactions may occur.<br>Alpha-adrenergic agonist toxicity is due to a broad group of pharmaceutical agents known as alpha agonists, which can be further broken down into central alpha-2 agonists and peripheral alpha-1 agonists.<br>The substance exhibits effects on the adrenergic receptors<br>The adverse effects seen with adrenergic drugs are broad. The most common side effects are changes in heart rate and blood pressure. Non-selective binding to the adrenergic receptors can cause different side effects that vary based on the specific agent as well as the dosage. The common non-selective agonists are norepinephrine, epinephrine, and isoproterenol (isoprenaline). Common side effects are tachycardia, hypertension, arrhythmias, palpitations, and anxiety. Norepinephrine is less likely to cause arrhythmias than some of the other pressor medications, probably because it is more alpha-1 receptor-selective as compared with the beta-1 receptor. [<br>Adrenergic receptors all have drug antagonists. Alpha-blockers are not generally indicated for the treatment of alpha-agonist overdoses.<br>During exercise, alpha1-adrenergic receptors in active muscles are attenuated in an exercise intensity-dependent manner, allowing the beta2-adrenergic receptors which mediate vasodilation to dominate. In contrast to alpha2-adrenergic receptors, alpha1-adrenergic-receptors in the arterial vasculature of skeletal muscle are more resistant to inhibition, and attenuation of alpha1-adrenergic-receptor-mediated vasoconstriction only occurs during heavy exercise.<br>Note that only active muscle alpha1-adrenergic receptors will be blocked. Resting muscle will not have its alpha1-adrenergic receptors blocked, and hence the overall effect will be alpha1-adrenergic-mediated vasoconstriction |

**Continued...**

| | |
|---|---|
| | The alpha1-adrenergic receptor has several general functions in common with the alpha2-adrenergic receptor, but also has specific effects of its own. alpha1-Receptors primarily mediate smooth muscle contraction, but have important functions elsewhere as well<br>In smooth muscle cells of blood vessels the principal effect of activation of these receptors is vasoconstriction. Blood vessels with alpha1-adrenergic receptors are present in the skin, the sphincters[3] of gastrointestinal system, kidney (renal artery) and brain. During the fight-or-flight response vasoconstriction results in decreased blood flow to these organs. This accounts for the pale appearance of the skin of an individual when frightened.<br>It also induces contraction of the urinary bladder, although this effect is minor compared to the relaxing effect of beta2-adrenergic receptors. In other words, the overall effect of sympathetic stimuli on the bladder is relaxation, in order to inhibit micturition upon anticipation of a stressful event.<br>Adverse reactions to adrenaline include palpitations, tachycardia, arrhythmia, anxiety, panic attack, headache, tremor, hypertension, and acute pulmonary edema. The use of adrenaline (epinephrine)- based eye-drops, commonly used to treat glaucoma, may also lead to buildup of adrenochrome pigments in the conjunctiva, iris, lens, and retina.<br>Rarely, exposure to medically administered epinephrine may cause Takotsubo cardiomyopathy.<br>Use is contraindicated in people on nonselective beta-blockers, because severe hypertension and even cerebral hemorrhage may result.<br>For beta adrenoreceptor agonists<br>A major side effect of beta-agonists is cardiac arrhythmia. Because these drugs increase myocardial oxygen demand, they can precipitate angina in patients with coronary artery disease. Headache and tremor are also common.<br>Beta-adrenoceptor agonists (beta-agonists) bind to beta-receptors on cardiac and smooth muscle tissues. They also have important actions in other tissues, especially bronchial smooth muscle (relaxation), the liver (stimulate glycogenolysis) and kidneys (stimulate renin release).<br>Beta-adrenoceptors normally bind to norepinephrine released by sympathetic adrenergic nerves, and to circulating epinephrine. Therefore, beta-agonists mimic the actions of sympathetic adrenergic stimulation acting through ß-adrenoceptors. Overall, the effect of beta-agonists is cardiac stimulation (increased heart rate, contractility, conduction velocity, relaxation) and systemic vasodilation. Arterial pressure may increase, but not necessarily because the fall in systemic vascular resistance offsets the increase in cardiac output.<br>For G-protein inhibitors:/ antagonists/ modulators.<br>G protein-coupled receptors (GPCRs) are essential cell membrane signaling molecules and represent the most important class of drug targets. Some signaling pathways downstream of a GPCR may be responsible for drug adverse effects, while others mediate therapeutic efficacy. Biased ligands preferentially activate only a subset of all GPCR signaling pathways. They hold great potential to become next-generation GPCR drugs with less side effects due to their potential to exclusively activate desired signaling pathways.<br>GPCR ligands include odorants, tastants, and neurotransmitters, and vary in size and properties. Dramatic chemical diversity may occur even among ligands of the same receptor. Chemical variability of antagonists significantly correlates with the binding site hydrophobicity and anti-correlates with the number of hydrogen bond donors in the binding site. The number of disulfide bridges in the extracellular region of a receptor anti-correlates with the range of molecular weights of its antagonists, highlighting the role of the entrance pathway in determining the size selectivity for GPCR antagonists. |
| **SODIUM METABISULFITE** | The substance is classified by IARC as Group 3:<br>**NOT** classifiable as to its carcinogenicity to humans.<br>Evidence of carcinogenicity may be inadequate or limited in animal testing. |
| **SODIUM CHLORIDE** | The material may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.<br>The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin. |
| **TARTARIC ACID** | For simple alpha-hydroxy carbolic acids and their salts:<br>Experimental data available for members of this group shows that they have low acute, repeat-dose, reproductive and developmental toxicity. They are eye and skin irritants, but are not expected to be skin sensitisers. Testing shows they have little or no potential to cause mutations or cancer.<br>Convulsions, haemorrhage recorded. |
| **SODIUM HYDROXIDE** | The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis. |
| **WATER** | No significant acute toxicological data identified in literature search. |
| **METARAMINOL BITARTRATE & SODIUM METABISULFITE & SODIUM CHLORIDE & TARTARIC ACID & SODIUM HYDROXIDE** | Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production. |
| **METARAMINOL BITARTRATE & SODIUM HYDROXIDE** | The material may cause severe skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin. Repeated exposures may produce severe ulceration. |

| | | | |
|---|---|---|---|
| **Acute Toxicity** | ✔ | **Carcinogenicity** | ✘ |
| **Skin Irritation/Corrosion** | ✔ | **Reproductivity** | ✘ |
| **Serious Eye Damage/Irritation** | ✔ | **STOT - Single Exposure** | ✘ |
| **Respiratory or Skin sensitisation** | ✘ | **STOT - Repeated Exposure** | ✘ |
| **Mutagenicity** | ✘ | **Aspiration Hazard** | ✘ |

***Legend:*** ✘ *– Data either not available or does not fill the criteria for classification*
✔ *– Data available to make classification*

## SECTION 12 Ecological information

### Toxicity

**Metaraminol 10mg/ml Solution for Injection / Infusion**

| Endpoint | Test Duration (hr) | Species | Value | Source |
|---|---|---|---|---|
| Not Available | Not Available | Not Available | Not Available | Not Available |

**metaraminol bitartrate**

| Endpoint | Test Duration (hr) | Species | Value | Source |
|---|---|---|---|---|

**Continued...**

| | | | | | |
|---|---|---|---|---|---|
| | Not Available | Not Available | Not Available | Not Available | Not Available |

| **sodium metabisulfite** | | | | |
|---|---|---|---|---|
| **Endpoint** | **Test Duration (hr)** | **Species** | **Value** | **Source** |
| NOEC(ECx) | 504h | Crustacea | >10mg/l | 1 |
| LC50 | 96h | Fish | 21mg/l | 1 |
| EC50 | 72h | Algae or other aquatic plants | 43.8mg/l | 2 |
| EC50 | 48h | Crustacea | 89mg/l | 2 |
| EC50 | 96h | Algae or other aquatic plants | 40mg/l | 1 |

| **sodium chloride** | | | | |
|---|---|---|---|---|
| **Endpoint** | **Test Duration (hr)** | **Species** | **Value** | **Source** |
| NOEC(ECx) | 168h | Crustacea | 0.63mg/l | 4 |
| LC50 | 96h | Fish | 3644-4565mg/l | 4 |
| EC50 | 72h | Algae or other aquatic plants | 20.76-36.17mg/L | 4 |
| EC50 | 48h | Crustacea | 340.7-469.2mg/l | 4 |
| EC50 | 96h | Algae or other aquatic plants | 1110.36mg/L | 4 |

| **tartaric acid** | | | | |
|---|---|---|---|---|
| **Endpoint** | **Test Duration (hr)** | **Species** | **Value** | **Source** |
| NOEC(ECx) | 72h | Algae or other aquatic plants | 3.125mg/l | 2 |
| LC50 | 96h | Fish | >100mg/l | 2 |
| EC50 | 72h | Algae or other aquatic plants | 51.404mg/l | 2 |
| EC50 | 48h | Crustacea | 93.313mg/l | 2 |
| EC50 | 96h | Algae or other aquatic plants | 23616mg/L | 2 |

| **sodium hydroxide** | | | | |
|---|---|---|---|---|
| **Endpoint** | **Test Duration (hr)** | **Species** | **Value** | **Source** |
| EC50(ECx) | 48h | Crustacea | 34.59-47.13mg/l | 4 |
| LC50 | 96h | Fish | 144-267mg/l | 4 |
| EC50 | 48h | Crustacea | 34.59-47.13mg/l | 4 |

| **water** | | | | |
|---|---|---|---|---|
| **Endpoint** | **Test Duration (hr)** | **Species** | **Value** | **Source** |
| Not Available | Not Available | Not Available | Not Available | Not Available |

| | |
|---|---|
| ***Legend:*** | *Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data* |

**DO NOT** discharge into sewer or waterways.

### Persistence and degradability

| Ingredient | Persistence: Water/Soil | Persistence: Air |
|---|---|---|
| sodium chloride | LOW | LOW |
| tartaric acid | LOW | LOW |
| sodium hydroxide | LOW | LOW |
| water | LOW | LOW |

### Bioaccumulative potential

| Ingredient | Bioaccumulation |
|---|---|
| sodium chloride | LOW (LogKOW = 0.5392) |
| tartaric acid | LOW (LogKOW = -1.0017) |
| sodium hydroxide | LOW (LogKOW = -3.8796) |

### Mobility in soil

| Ingredient | Mobility |
|---|---|
| sodium chloride | LOW (KOC = 14.3) |
| tartaric acid | HIGH (KOC = 1) |
| sodium hydroxide | LOW (KOC = 14.3) |

## SECTION 13 Disposal considerations

### Waste treatment methods

| | |
|---|---|
| **Product / Packaging disposal** | ▸ Containers may still present a chemical hazard/ danger when empty.<br>▸ Return to supplier for reuse/ recycling if possible.<br>Otherwise: |

**Continued...**

| | |
|---|---|
| | ▸ If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill.<br>▸ Where possible retain label warnings and SDS and observe all notices pertaining to the product.<br>▸ **DO NOT** allow wash water from cleaning or process equipment to enter drains.<br>▸ It may be necessary to collect all wash water for treatment before disposal.<br>▸ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.<br>▸ Where in doubt contact the responsible authority.<br>▸ Recycle wherever possible.<br>▸ Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.<br>▸ Dispose of by: burial in a land-fill specifically licensed to accept chemical and / or pharmaceutical wastes or incineration in a licensed apparatus (after admixture with suitable combustible material).<br>▸ Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed. |

## SECTION 14 Transport information

### Labels Required

| | |
|---|---|
| **Marine Pollutant** | NO |
| **HAZCHEM** | Not Applicable |

### Land transport (ADG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

### Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

### Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

### Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

### Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

| Product name | Group |
|---|---|
| metaraminol bitartrate | Not Available |
| sodium metabisulfite | Not Available |
| sodium chloride | Not Available |
| tartaric acid | Not Available |
| sodium hydroxide | Not Available |
| water | Not Available |

### Transport in bulk in accordance with the ICG Code

| Product name | Ship Type |
|---|---|
| metaraminol bitartrate | Not Available |
| sodium metabisulfite | Not Available |
| sodium chloride | Not Available |
| tartaric acid | Not Available |
| sodium hydroxide | Not Available |
| water | Not Available |

## SECTION 15 Regulatory information

### Safety, health and environmental regulations / legislation specific for the substance or mixture

**metaraminol bitartrate is found on the following regulatory lists**

Australia Chemicals with non-industrial uses removed from the Australian Inventory of Chemical Substances (old Inventory)

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 4

**sodium metabisulfite is found on the following regulatory lists**

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals

Australian Inventory of Industrial Chemicals (AIIC)

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 5

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

**sodium chloride is found on the following regulatory lists**

Australian Inventory of Industrial Chemicals (AIIC)

**tartaric acid is found on the following regulatory lists**

Australian Inventory of Industrial Chemicals (AIIC)

**sodium hydroxide is found on the following regulatory lists**

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 5

Australian Inventory of Industrial Chemicals (AIIC)

**water is found on the following regulatory lists**

Australian Inventory of Industrial Chemicals (AIIC)

### National Inventory Status

**Continued...**

| National Inventory | Status |
|---|---|
| Australia - AIIC / Australia Non-Industrial Use | Yes |
| Canada - DSL | No (metaraminol bitartrate) |
| Canada - NDSL | No (metaraminol bitartrate; sodium metabisulfite; sodium chloride; tartaric acid; sodium hydroxide; water) |
| China - IECSC | No (metaraminol bitartrate) |
| Europe - EINEC / ELINCS / NLP | Yes |
| Japan - ENCS | No (metaraminol bitartrate) |
| Korea - KECI | No (metaraminol bitartrate) |
| New Zealand - NZIoC | No (metaraminol bitartrate) |
| Philippines - PICCS | No (metaraminol bitartrate) |
| USA - TSCA | No (metaraminol bitartrate) |
| Taiwan - TCSI | Yes |
| Mexico - INSQ | Yes |
| Vietnam - NCI | No (metaraminol bitartrate) |
| Russia - FBEPH | No (metaraminol bitartrate) |
| ***Legend:*** | *Yes = All CAS declared ingredients are on the inventory*<br>*No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.* |

## SECTION 16 Other information

| | |
|---|---|
| **Revision Date** | 28/04/2021 |
| **Initial Date** | 28/04/2021 |

### Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

### Definitions and abbreviations

PC—TWA: Permissible Concentration-Time Weighted Average
PC—STEL: Permissible Concentration-Short Term Exposure Limit
IARC: International Agency for Research on Cancer
ACGIH: American Conference of Governmental Industrial Hygienists
STEL: Short Term Exposure Limit
TEEL: Temporary Emergency Exposure Limit。
IDLH: Immediately Dangerous to Life or Health Concentrations
ES: Exposure Standard
OSF: Odour Safety Factor
NOAEL :No Observed Adverse Effect Level
LOAEL: Lowest Observed Adverse Effect Level
TLV: Threshold Limit Value
LOD: Limit Of Detection
OTV: Odour Threshold Value
BCF: BioConcentration Factors
BEI: Biological Exposure Index
AIIC: Australian Inventory of Industrial Chemicals
DSL: Domestic Substances List
NDSL: Non-Domestic Substances List
IECSC: Inventory of Existing Chemical Substance in China
EINECS: European INventory of Existing Commercial chemical Substances
ELINCS: European List of Notified Chemical Substances
NLP: No-Longer Polymers
ENCS: Existing and New Chemical Substances Inventory
KECI: Korea Existing Chemicals Inventory
NZIoC: New Zealand Inventory of Chemicals
PICCS: Philippine Inventory of Chemicals and Chemical Substances
TSCA: Toxic Substances Control Act
TCSI: Taiwan Chemical Substance Inventory
INSQ: Inventario Nacional de Sustancias Químicas
NCI: National Chemical Inventory
FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances