

## Histamil Antihistamine Injection



### Histamil Antihistamine Injection

Troy Laboratories Pty Ltd

Chemwatch Hazard Alert Code: 2

Chemwatch: 5401-51  
Version No: 2.1.1.1  
Safety Data Sheet according to WHS and ADG requirements

Issue Date: 15/05/2020  
Print Date: 20/05/2020  
L.GHS.AUS.EN

#### SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

##### Product Identifier

|                               |                                  |
|-------------------------------|----------------------------------|
| Product name                  | Histamil Antihistamine Injection |
| Synonyms                      | APVMA number: 50805              |
| Other means of identification | Not Available                    |

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

|                          |   |
|--------------------------|---|
| Relevant identified uses | Treatment of conditions responsive to antihistamine in cats, dogs, cattle, horses and sheep. To be used as directed on product label. |
|--------------------------|---|

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

|                         |  |
|-------------------------|--|
| Registered company name | Troy Laboratories Pty Ltd                          |
| Address                 | 37 Glendenning Road Glendenning NSW 2761 Australia |
| Telephone               | 02 8808 3600                                       |
| Fax                     | 02 9677 9300                                       |
| Website                 | www.Troylab.com.au                                 |
| Email                   | admin@troylab.com.au                               |

##### Emergency telephone number

|                                   |   |
|-----------------------------------|---|
| Association / Organisation        | Troy Laboratories Pty Ltd                                 |
| Emergency telephone numbers       | 02 8808 3600 (Office hours (8am – 4pm, Monday to Friday)) |
| Other emergency telephone numbers | Not Available   |

#### SECTION 2 HAZARDS IDENTIFICATION

##### Classification of the substance or mixture

|                    |   |
|--------------------|---|
| Poisons Schedule   | S4  |
| Classification [1] | Skin Sensitizer Category 1, Chronic Aquatic Hazard Category 3   |
| Legend:            | 1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI |

##### Label elements

|                     |  |
|---------------------|--|
| Hazard pictogram(s) |  |
|---------------------|--|

|             |                |
|-------------|----------------|
| SIGNAL WORD | <b>WARNING</b> |
|-------------|----------------|

##### Hazard statement(s)

|      |  |
|------|--|
| H317 | May cause an allergic skin reaction.               |
| H412 | Harmful to aquatic life with long lasting effects. |

##### Precautionary statement(s) Prevention

|      |  |
|------|--|
| P280 | Wear protective gloves/protective clothing/eye protection/face protection. |
| P261 | Avoid breathing mist/vapours/spray.  |
| P273 | Avoid release to the environment.  |
| P272 | Contaminated work clothing should not be allowed out of the workplace.     |

##### Precautionary statement(s) Response

|      |  |
|------|--|
| P321 | Specific treatment (see advice on this label). |
|------|--|

## Histamil Antihistamine Injection

|           |  |
|-----------|--|
| P363      | Wash contaminated clothing before reuse.                         |
| P302+P352 | IF ON SKIN: Wash with plenty of water.                           |
| P333+P313 | If skin irritation or rash occurs: Get medical advice/attention. |

### 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                                       |
|---------------|-----------|--|
| 100-51-6      | 1-10      | <u>benzyl alcohol</u>                      |
| 113-92-8      | 1-10      | <u>chlorpheniramine maleate</u>            |
| Not Available | balance   | Ingredients determined not to be hazardous |

## SECTION 4 FIRST AID MEASURES

### Description of first aid measures

|                     |  |
|---------------------|--|
| <b>Eye Contact</b>  | <p>If this product comes in contact with eyes:</p> <ul style="list-style-type: none"> <li>▶ Wash out immediately with water.</li> <li>▶ If irritation continues, seek medical attention.</li> <li>▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</li> </ul>   |
| <b>Skin Contact</b> | <p>If skin contact occurs:</p> <ul style="list-style-type: none"> <li>▶ Immediately remove all contaminated clothing, including footwear.</li> <li>▶ Flush skin and hair with running water (and soap if available).</li> <li>▶ Seek medical attention in event of irritation.</li> </ul>  |
| <b>Inhalation</b>   | <ul style="list-style-type: none"> <li>▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area.</li> <li>▶ Other measures are usually unnecessary.</li> </ul>  |
| <b>Ingestion</b>    | <ul style="list-style-type: none"> <li>▶ For advice, contact a Poisons Information Centre or a doctor at once.</li> <li>▶ Urgent hospital treatment is likely to be needed.</li> <li>▶ <b>If swallowed do NOT induce vomiting.</b></li> <li>▶ If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.</li> <li>▶ Observe the patient carefully.</li> <li>▶ Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.</li> <li>▶ Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.</li> <li>▶ Transport to hospital or doctor without delay.</li> </ul> |

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

Treat symptomatically.

## SECTION 5 FIREFIGHTING MEASURES

### Extinguishing media

- ▶ There is no restriction on the type of extinguisher which may be used.
- ▶ Use extinguishing media suitable for surrounding area.

### Special hazards arising from the substrate or mixture

|                             |             |
|-----------------------------|-------------|
| <b>Fire Incompatibility</b> | None known. |
|-----------------------------|-------------|

### Advice for firefighters

|                              |   |
|------------------------------|---|
| <b>Fire Fighting</b>         | <ul style="list-style-type: none"> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Wear breathing apparatus plus protective gloves in the event of a fire.</li> <li>▶ Prevent, by any means available, spillage from entering drains or water courses.</li> <li>▶ Use fire fighting procedures suitable for surrounding area.</li> <li>▶ <b>DO NOT</b> approach containers suspected to be hot.</li> <li>▶ Cool fire exposed containers with water spray from a protected location.</li> <li>▶ If safe to do so, remove containers from path of fire.</li> <li>▶ Equipment should be thoroughly decontaminated after use.</li> </ul> |
| <b>Fire/Explosion Hazard</b> | <ul style="list-style-type: none"> <li>▶ Non combustible.</li> <li>▶ Not considered a significant fire risk, however containers may burn.</li> </ul> <p>May emit poisonous fumes.<br/>May emit corrosive fumes.</p>   |
| <b>HAZCHEM</b>               | Not Applicable  |

## SECTION 6 ACCIDENTAL RELEASE MEASURES

## Histamil Antihistamine Injection

### Personal precautions, protective equipment and emergency procedures

See section 8

### Environmental precautions

See section 12

### Methods and material for containment and cleaning up

|                     |  |
|---------------------|--|
| <b>Minor Spills</b> | <ul style="list-style-type: none"> <li>▶ Clean up all spills immediately.</li> <li>▶ Avoid breathing vapours and contact with skin and eyes.</li> <li>▶ Control personal contact with the substance, by using protective equipment.</li> <li>▶ Contain and absorb spill with sand, earth, inert material or vermiculite.</li> <li>▶ Wipe up.</li> <li>▶ Place in a suitable, labelled container for waste disposal.</li> </ul>   |
| <b>Major Spills</b> | <p>Moderate hazard.</p> <ul style="list-style-type: none"> <li>▶ Clear area of personnel and move upwind.</li> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Wear breathing apparatus plus protective gloves.</li> <li>▶ Prevent, by any means available, spillage from entering drains or water course.</li> <li>▶ Stop leak if safe to do so.</li> <li>▶ Contain spill with sand, earth or vermiculite.</li> <li>▶ Collect recoverable product into labelled containers for recycling.</li> <li>▶ Neutralise/decontaminate residue (see Section 13 for specific agent).</li> <li>▶ Collect solid residues and seal in labelled drums for disposal.</li> <li>▶ Wash area and prevent runoff into drains.</li> <li>▶ After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using.</li> <li>▶ If contamination of drains or waterways occurs, advise emergency services.</li> </ul> |

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

## SECTION 7 HANDLING AND STORAGE

### Precautions for safe handling

|                          |  |
|--------------------------|--|
| <b>Safe handling</b>     | <ul style="list-style-type: none"> <li>▶ Avoid all personal contact, including inhalation.</li> <li>▶ Wear protective clothing when risk of exposure occurs.</li> <li>▶ Use in a well-ventilated area.</li> <li>▶ Prevent concentration in hollows and sumps.</li> <li>▶ <b>DO NOT enter confined spaces until atmosphere has been checked.</b></li> <li>▶ <b>DO NOT allow material to contact humans, exposed food or food utensils.</b></li> <li>▶ Avoid contact with incompatible materials.</li> <li>▶ <b>When handling, DO NOT eat, drink or smoke.</b></li> <li>▶ Keep containers securely sealed when not in use.</li> <li>▶ Avoid physical damage to containers.</li> <li>▶ Always wash hands with soap and water after handling.</li> <li>▶ Work clothes should be laundered separately. Launder contaminated clothing before re-use.</li> <li>▶ Use good occupational work practice.</li> <li>▶ Observe manufacturer's storage and handling recommendations contained within this SDS.</li> <li>▶ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.</li> </ul> |
| <b>Other information</b> | <ul style="list-style-type: none"> <li>▶ Store in original containers.</li> <li>▶ Keep containers securely sealed.</li> <li>▶ Store in a cool, dry, well-ventilated area.</li> <li>▶ Store away from incompatible materials and foodstuff containers.</li> <li>▶ Protect containers against physical damage and check regularly for leaks.</li> <li>▶ Observe manufacturer's storage and handling recommendations contained within this SDS.</li> </ul>  |

### Conditions for safe storage, including any incompatibilities

|                                |   |
|--------------------------------|---|
| <b>Suitable container</b>      | <ul style="list-style-type: none"> <li>▶ Polyethylene or polypropylene container.</li> <li>▶ Packing as recommended by manufacturer.</li> <li>▶ Check all containers are clearly labelled and free from leaks.</li> </ul> |
| <b>Storage incompatibility</b> | None known  |

## SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

### Control parameters

#### OCCUPATIONAL EXPOSURE LIMITS (OEL)

#### INGREDIENT DATA

Not Available

#### EMERGENCY LIMITS

| Ingredient               | Material name  | TEEL-1        | TEEL-2 | TEEL-3  |
|--------------------------|----------------|---------------|--------|---------|
| benzyl alcohol           | Benzyl alcohol | 30 ppm        | 52 ppm | 740 ppm |
| Ingredient               | Original IDLH  | Revised IDLH  |        |         |
| benzyl alcohol           | Not Available  | Not Available |        |         |
| chlorpheniramine maleate | Not Available  | Not Available |        |         |

#### OCCUPATIONAL EXPOSURE BANDING


## Histamil Antihistamine Injection

| Ingredient               | Occupational Exposure Band Rating | Occupational Exposure Band Limit |
|--------------------------|-----------------------------------|----------------------------------|
| benzyl alcohol           | E                                 | ≤ 0.1 ppm                        |
| chlorpheniramine maleate | E                                 | ≤ 0.01 mg/m <sup>3</sup>         |

**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.

## MATERIAL DATA

## Exposure controls

| Appropriate engineering controls  | <p>Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The basic types of engineering controls are:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use.</p> <p>Employers may need to use multiple types of controls to prevent employee overexposure.</p> <p>General exhaust is adequate under normal operating conditions. If risk of overexposure exists, wear SAA approved respirator. Correct fit is essential to obtain adequate protection. Provide adequate ventilation in warehouse or closed storage areas. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.</p>   |                      |            |   |                                |   |                            |  |                           |  |                                 |                        |                        |   |                                 |   |                                  |                                  |                               |   |
|---|---|----------------------|------------|---|--------------------------------|---|----------------------------|--|---------------------------|--|---------------------------------|------------------------|------------------------|---|---------------------------------|---|----------------------------------|----------------------------------|-------------------------------|---|
|   | <table border="1"> <thead> <tr> <th>Type of Contaminant:</th> <th>Air Speed:</th> </tr> </thead> <tbody> <tr> <td>solvent, vapours, degreasing etc., evaporating from tank (in still air)</td> <td>0.25-0.5 m/s<br/>(50-100 f/min)</td> </tr> <tr> <td>aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)</td> <td>0.5-1 m/s (100-200 f/min.)</td> </tr> <tr> <td>direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)</td> <td>1-2.5 m/s (200-500 f/min)</td> </tr> <tr> <td>grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).</td> <td>2.5-10 m/s<br/>(500-2000 f/min.)</td> </tr> </tbody> </table> <p>Within each range the appropriate value depends on:</p> <table border="1"> <thead> <tr> <th>Lower end of the range</th> <th>Upper end of the range</th> </tr> </thead> <tbody> <tr> <td>1: Room air currents minimal or favourable to capture</td> <td>1: Disturbing room air currents</td> </tr> <tr> <td>2: Contaminants of low toxicity or of nuisance value only</td> <td>2: Contaminants of high toxicity</td> </tr> <tr> <td>3: Intermittent, low production.</td> <td>3: High production, heavy use</td> </tr> <tr> <td>4: Large hood or large air mass in motion</td> <td>4: Small hood - local control only</td> </tr> </tbody> </table> <p>Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2 m/s (200-400 f/min.) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.</p> | Type of Contaminant: | Air Speed: | solvent, vapours, degreasing etc., evaporating from tank (in still air) | 0.25-0.5 m/s<br>(50-100 f/min) | aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation) | 0.5-1 m/s (100-200 f/min.) | direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion) | 1-2.5 m/s (200-500 f/min) | grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion). | 2.5-10 m/s<br>(500-2000 f/min.) | Lower end of the range | Upper end of the range | 1: Room air currents minimal or favourable to capture | 1: Disturbing room air currents | 2: Contaminants of low toxicity or of nuisance value only | 2: Contaminants of high toxicity | 3: Intermittent, low production. | 3: High production, heavy use | 4: Large hood or large air mass in motion |
| Type of Contaminant:  | Air Speed:  |                      |            |   |                                |   |                            |  |                           |  |                                 |                        |                        |   |                                 |   |                                  |                                  |                               |   |
| solvent, vapours, degreasing etc., evaporating from tank (in still air)   | 0.25-0.5 m/s<br>(50-100 f/min)  |                      |            |   |                                |   |                            |  |                           |  |                                 |                        |                        |   |                                 |   |                                  |                                  |                               |   |
| aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation) | 0.5-1 m/s (100-200 f/min.)  |                      |            |   |                                |   |                            |  |                           |  |                                 |                        |                        |   |                                 |   |                                  |                                  |                               |   |
| direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)  | 1-2.5 m/s (200-500 f/min)   |                      |            |   |                                |   |                            |  |                           |  |                                 |                        |                        |   |                                 |   |                                  |                                  |                               |   |
| grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).  | 2.5-10 m/s<br>(500-2000 f/min.)   |                      |            |   |                                |   |                            |  |                           |  |                                 |                        |                        |   |                                 |   |                                  |                                  |                               |   |
| Lower end of the range  | Upper end of the range  |                      |            |   |                                |   |                            |  |                           |  |                                 |                        |                        |   |                                 |   |                                  |                                  |                               |   |
| 1: Room air currents minimal or favourable to capture   | 1: Disturbing room air currents   |                      |            |   |                                |   |                            |  |                           |  |                                 |                        |                        |   |                                 |   |                                  |                                  |                               |   |
| 2: Contaminants of low toxicity or of nuisance value only   | 2: Contaminants of high toxicity  |                      |            |   |                                |   |                            |  |                           |  |                                 |                        |                        |   |                                 |   |                                  |                                  |                               |   |
| 3: Intermittent, low production.  | 3: High production, heavy use   |                      |            |   |                                |   |                            |  |                           |  |                                 |                        |                        |   |                                 |   |                                  |                                  |                               |   |
| 4: Large hood or large air mass in motion   | 4: Small hood - local control only  |                      |            |   |                                |   |                            |  |                           |  |                                 |                        |                        |   |                                 |   |                                  |                                  |                               |   |
| Personal protection   |    |                      |            |   |                                |   |                            |  |                           |  |                                 |                        |                        |   |                                 |   |                                  |                                  |                               |   |
| Eye and face protection   | <ul style="list-style-type: none"> <li>▶ Safety glasses with side shields.</li> <li>▶ Chemical goggles.</li> <li>▶ 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. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent]</li> </ul>   |                      |            |   |                                |   |                            |  |                           |  |                                 |                        |                        |   |                                 |   |                                  |                                  |                               |   |
| Skin protection   | See Hand protection below   |                      |            |   |                                |   |                            |  |                           |  |                                 |                        |                        |   |                                 |   |                                  |                                  |                               |   |
| Hands/feet protection   | <ul style="list-style-type: none"> <li>▶ Wear chemical protective gloves, e.g. PVC.</li> <li>▶ Wear safety footwear or safety gumboots, e.g. Rubber</li> </ul>  |                      |            |   |                                |   |                            |  |                           |  |                                 |                        |                        |   |                                 |   |                                  |                                  |                               |   |
| Body protection   | See Other protection below  |                      |            |   |                                |   |                            |  |                           |  |                                 |                        |                        |   |                                 |   |                                  |                                  |                               |   |
| Other protection  | <ul style="list-style-type: none"> <li>▶ Overalls.</li> <li>▶ P.V.C. apron.</li> <li>▶ Barrier cream.</li> <li>▶ Skin cleansing cream.</li> <li>▶ Eye wash unit.</li> </ul>   |                      |            |   |                                |   |                            |  |                           |  |                                 |                        |                        |   |                                 |   |                                  |                                  |                               |   |

## 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-**

## Respiratory protection

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

Selection of the Class and Type of respirator will depend upon the level of breathing zone contaminant and the chemical nature of the contaminant. Protection Factors

Continued...

## Histamil Antihistamine Injection

**generated** selection:

Histamil Antihistamine Injection

| Material       | CPI |
|----------------|-----|
| BUTYL          | A   |
| VITON          | A   |
| NATURAL RUBBER | C   |
| NEOPRENE       | C   |
| PVA            | 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.

(defined as the ratio of contaminant outside and inside the mask) may also be important.

| Required minimum protection factor | Maximum gas/vapour concentration present in air p.p.m. (by volume) | Half-face Respirator | Full-Face Respirator |
|------------------------------------|--|----------------------|----------------------|
| up to 10                           | 1000   | A-AUS / Class1 P2    | -                    |
| up to 50                           | 1000   | -                    | A-AUS / Class 1 P2   |
| up to 50                           | 5000   | Airline *            | -                    |
| up to 100                          | 5000   | -                    | A-2 P2               |
| up to 100                          | 10000  | -                    | A-3 P2               |
| 100+                               |  |                      | Airline**            |

\* - Continuous Flow \*\* - Continuous-flow or positive pressure demand  
 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(SO<sub>2</sub>), G = Agricultural chemicals, K = Ammonia(NH<sub>3</sub>), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

## SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

## Information on basic physical and chemical properties

|   |  |  |                |
|---|--|--|----------------|
| <b>Appearance</b>                                   | Clear colourless liquid with mild odour; mixes with water. |  |                |
| <b>Physical state</b>                               | Liquid   | <b>Relative density (Water = 1)</b>            | 1.005          |
| <b>Odour</b>  | Not Available  | <b>Partition coefficient n-octanol / water</b> | Not Available  |
| <b>Odour threshold</b>                              | Not Available  | <b>Auto-ignition temperature (°C)</b>          | Not Applicable |
| <b>pH (as supplied)</b>                             | 4.2-5.5  | <b>Decomposition temperature</b>               | Not Available  |
| <b>Melting point / freezing point (°C)</b>          | ~0   | <b>Viscosity (cSt)</b>                         | Not Available  |
| <b>Initial boiling point and boiling range (°C)</b> | ~100   | <b>Molecular weight (g/mol)</b>                | Not Applicable |
| <b>Flash point (°C)</b>                             | Not Applicable   | <b>Taste</b>                                   | Not Available  |
| <b>Evaporation rate</b>                             | Not Available  | <b>Explosive properties</b>                    | Not Available  |
| <b>Flammability</b>                                 | Not Applicable   | <b>Oxidising properties</b>                    | Not Available  |
| <b>Upper Explosive Limit (%)</b>                    | Not Applicable   | <b>Surface Tension (dyn/cm or mN/m)</b>        | Not Available  |
| <b>Lower Explosive Limit (%)</b>                    | Not Applicable   | <b>Volatile Component (%vol)</b>               | Not Available  |
| <b>Vapour pressure (kPa)</b>                        | 2.37 @20C  | <b>Gas group</b>                               | Not Available  |
| <b>Solubility in water</b>                          | Miscible   | <b>pH as a solution (1%)</b>                   | Not Available  |
| <b>Vapour density (Air = 1)</b>                     | Not Available  | <b>VOC g/L</b>                                 | Not Available  |

## SECTION 10 STABILITY AND REACTIVITY

|   |  |
|---|--|
| <b>Reactivity</b>                         | See section 7  |
| <b>Chemical stability</b>                 | <ul style="list-style-type: none"> <li>▶ Unstable in the presence of incompatible materials.</li> <li>▶ Product is considered stable.</li> <li>▶ Hazardous polymerisation will not occur.</li> </ul> |
| <b>Possibility of hazardous reactions</b> | See section 7  |
| <b>Conditions to avoid</b>                | See section 7  |
| <b>Incompatible materials</b>             | See section 7  |
| <b>Hazardous decomposition products</b>   | See section 5  |

## SECTION 11 TOXICOLOGICAL INFORMATION

## Information on toxicological effects

|                  |  |
|------------------|--|
| <b>Inhaled</b>   | The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, 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   |
| <b>Ingestion</b> | The material has <b>NOT</b> been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern. |

## Histamil Antihistamine Injection

|   |  |  |
|---|--|--|
| <b>Skin Contact</b>                     | The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.  |  |
| <b>Eye</b>                              | Although the liquid is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).   |  |
| <b>Chronic</b>                          | Practical experience shows that skin contact with the material is capable either of inducing a sensitisation reaction in a substantial number of individuals, and/or of producing a positive response in experimental animals. Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems. |  |
| <b>Histamil Antihistamine Injection</b> | <b>TOXICITY</b>  | <b>IRRITATION</b>  |
|   | Not Available  | Not Available  |
| <b>benzyl alcohol</b>                   | <b>TOXICITY</b>  | <b>IRRITATION</b>  |
|   | Dermal (rabbit) LD50: 2000 mg/kg <sup>[2]</sup>  | Eye (rabbit): 0.75 mg open SEVERE                        |
|   | Inhalation (rat) LC50: >4.178 mg/l/4h <sup>[2]</sup>   | Eye: adverse effect observed (irritating) <sup>[1]</sup> |
|   | Oral (rat) LD50: 1230 mg/kg <sup>[2]</sup>   | Skin (man): 16 mg/48h-mild                               |
|   |  | Skin (rabbit): 10 mg/24h open-mild                       |
|   | Skin: no adverse effect observed (not irritating) <sup>[1]</sup>   |  |
| <b>chlorpheniramine maleate</b>         | <b>TOXICITY</b>  | <b>IRRITATION</b>  |
|   | Oral (rat) LD50: 118 mg/kg <sup>[2]</sup>  | Not Available  |
| <b>Legend:</b>                          | 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  |  |

|                       |  |
|-----------------------|--|
| <b>BENZYL ALCOHOL</b> | <p>For benzyl alkyl alcohols:</p> <p>Unlike benzylic alcohols, the beta-hydroxyl group of the members of this cluster is unlikely to undergo phase II metabolic activation. Instead, the beta-hydroxyl group is expected to contribute to detoxification via oxidation to hydrophilic acid. Despite structural similarity to carcinogenic ethyl benzene, only a marginal concern has been assigned to phenethyl alcohol due to limited mechanistic analogy.</p> <p>For benzoates:</p> <p><b>Acute toxicity:</b> Benzyl alcohol, benzoic acid and its sodium and potassium salt can be considered as a single category regarding human health, as they are all rapidly metabolised and excreted via a common pathway within 24 hrs. Systemic toxic effects of similar nature (e.g. liver, kidney) were observed. However with benzoic acid and its salts toxic effects are seen at higher doses than with benzyl alcohol.</p> <p>The compounds exhibit low acute toxicity as for the oral and dermal route. The LD50 values are &gt; 2000 mg/kg bw except for benzyl alcohol which needs to be considered as harmful by the oral route in view of an oral LD50 of 1610 mg/kg bw. The 4 hrs inhalation exposure of benzyl alcohol or benzoic acid at 4 and 12 mg/l as aerosol/dust respectively gave no mortality, showing low acute toxicity by inhalation for these compounds.</p> <p>Benzoic acid and benzyl alcohol are slightly irritating to the skin, while sodium benzoate was not skin irritating. No data are available for potassium benzoate but it is also expected not to be skin irritating. Benzoic acid and benzyl alcohol are irritating to the eye and sodium benzoate was only slightly irritating to the eye. No data are available for potassium benzoate but it is expected also to be only slightly irritating to the eye.</p> <p><b>Sensitisation:</b> The available studies for benzoic acid gave no indication for a sensitising effect in animals, however occasionally very low positive reactions were recorded with humans (dermatological patients) in patch tests. The same occurs for sodium benzoate. It has been suggested that the very low positive reactions are non-immunologic contact urticaria. Benzyl alcohol gave positive and negative results in animals. Benzyl alcohol also demonstrated a maximum incidence of sensitization of only 1% in human patch testing. Over several decades no sensitization with these compounds has been seen among workers.</p> <p><b>Repeat dose toxicity:</b> For benzoic acid repeated dose oral toxicity studies give a NOAEL of 800 mg/kg/day. For the salts values &gt; 1000 mg/kg/day are obtained. At higher doses increased mortality, reduced weight gain, liver and kidney effects were observed.</p> <p>For benzyl alcohol the long-term studies indicate a NOAEL &gt; 400 mg/kg bw/d for rats and &gt; 200 mg/kg bw/d for mice. At higher doses effects on bodyweights, lesions in the brains, thymus, skeletal muscle and kidney were observed. It should be taken into account that administration in these studies was by gavage route, at which saturation of metabolic pathways is likely to occur.</p> <p><b>Mutagenicity:</b> All chemicals showed no mutagenic activity in <i>in vitro</i> Ames tests. Various results were obtained with other <i>in vitro</i> genotoxicity assays. Sodium benzoate and benzyl alcohol showed no genotoxicity <i>in vivo</i>. While some mixed and/or equivocal <i>in vitro</i> chromosomal/chromatid responses have been observed, no genotoxicity was observed in the <i>in vivo</i> cytogenetic, micronucleus, or other assays. The weight of the evidence of the <i>in vitro</i> and <i>in vivo</i> genotoxicity data indicates that these chemicals are not mutagenic or clastogenic. They also are not carcinogenic in long-term carcinogenicity studies.</p> <p>In a 4-generation study with benzoic acid no effects on reproduction were seen (NOAEL: 750 mg/kg). No compound related effects on reproductive organs (gross and histopathology examination) could be found in the (sub) chronic studies in rats and mice with benzyl acetate, benzyl alcohol, benzaldehyde, sodium benzoate and supports a non-reprotoxic potential of these compounds. In addition, data from reprotoxicity studies on benzyl acetate (NOAEL &gt;2000 mg/kg bw/d; rats and mice) and benzaldehyde (tested only up to 5 mg/kg bw; rats) support the non-reprotoxicity of benzyl alcohol and benzoic acid and its salts.</p> <p><b>Developmental toxicity:</b> In rats for sodium benzoate dosed via food during the entire gestation developmental effects occurred only in the presence of marked maternal toxicity (reduced food intake and decreased body weight) (NOAEL = 1400 mg/kg bw). For hamster (NOEL: 300 mg/kg bw), rabbit (NOEL: 250 mg/kg bw) and mice (CD-1 mice, NOEL: 175 mg/kg bw) no higher doses (all by gavage) were tested and no maternal toxicity was observed. For benzyl alcohol: NOAEL= 550 mg/kg bw (gavage; CD-1 mice). LOAEL = 750 mg/kg bw (gavage mice). In this study maternal toxicity was observed e.g. increased mortality, reduced body weight and clinical toxicology. Benzyl acetate: NOEL = 500 mg/kg bw (gavage rats). No maternal toxicity was observed.</p> <p>Adverse reactions to fragrances in perfumes and in fragranced cosmetic products include allergic contact dermatitis, irritant contact dermatitis, photosensitivity, immediate contact reactions (contact urticaria), and pigmented contact dermatitis. Airborne and connubial contact dermatitis occur.</p> <p>Intolerance to perfumes, by inhalation, may occur if the perfume contains a sensitising principal. Symptoms may vary from general illness, coughing, phlegm, wheezing, chest-tightness, headache, exertional dyspnoea, acute respiratory illness, hayfever, and other respiratory diseases (including asthma). Perfumes can induce hyper-reactivity of the respiratory tract without producing an IgE-mediated allergy or demonstrable respiratory obstruction. This was shown by placebo-controlled challenges of nine patients to "perfume mix". The same patients were also subject to perfume provocation, with or without a carbon filter mask, to ascertain whether breathing through a filter with active carbon would prevent symptoms. The patients breathed through the mouth, during the provocations, as a nose clamp was used to prevent nasal inhalation. The patient's earlier symptoms were verified; breathing through the carbon filter had no protective effect. The symptoms were not transmitted via the olfactory nerve but they may have been induced by trigeminal reflex via the respiratory tract or by the eyes.</p> <p>Cases of occupational asthma induced by perfume substances such as isoamyl acetate, limonene, cinnamaldehyde and benzaldehyde, tend to</p> |
|-----------------------|--|

## Histamin Antihistamine Injection

give persistent symptoms even though the exposure is below occupational exposure limits.

Inhalation intolerance has also been produced in animals. The emissions of five fragrance products, for one hour, produced various combinations of sensory irritation, pulmonary irritation, decreases in expiratory airflow velocity as well as alterations of the functional observational battery indicative of neurotoxicity in mice. Neurotoxicity was found to be more severe after mice were repeatedly exposed to the fragrance products, being four brands of cologne and one brand of toilet water.

Contact allergy to fragrances is relatively common, affecting 1 to 3% of the general population, based on limited testing with eight common fragrance allergens and about 16 % of patients patch tested for suspected allergic contact dermatitis.

Contact allergy to fragrance ingredients occurs when an individual has been exposed, on the skin, to a sufficient degree of fragrance contact allergens. Contact allergy is a life-long, specifically altered reactivity in the immune system. This means that once contact allergy is developed, cells in the immune system will be present which can recognise and react towards the allergen. As a consequence, symptoms, i.e. allergic contact dermatitis, may occur upon re-exposure to the fragrance allergen(s) in question. Allergic contact dermatitis is an inflammatory skin disease characterised by erythema, swelling and vesicles in the acute phase. If exposure continues it may develop into a chronic condition with scaling and painful fissures of the skin. Allergic contact dermatitis to fragrance ingredients is most often caused by cosmetic products and usually involves the face and/or hands. It may affect fitness for work and the quality of life of the individual. Fragrance contact allergy has long been recognised as a frequent and potentially disabling problem. Prevention is possible as it is an environmental disease and if the environment is modified (e.g. by reduced use concentrations of allergens), the disease frequency and severity will decrease. Fragrance contact allergy is mostly non-occupational and related to the personal use of cosmetic products. Allergic contact dermatitis can be severe and widespread, with a significant impairment of quality of life and potential consequences for fitness for work. Thus, prevention of contact sensitisation to fragrances, both in terms of primary prevention (avoiding sensitisation) and secondary prevention (avoiding relapses of allergic contact dermatitis in those already sensitised), is an important objective of public health risk management measure.

**Hands:** Contact sensitisation may be the primary cause of hand eczema, or may be a complication of irritant or atopic hand eczema. The number of positive patch tests has been reported to correlate with the duration of hand eczema, indicating that long-standing hand eczema may often be complicated by sensitisation. Fragrance allergy may be a relevant problem in patients with hand eczema; perfumes are present in consumer products to which their hands are exposed. A significant relationship between hand eczema and fragrance contact allergy has been found in some studies based on patients investigated for contact allergy. However, hand eczema is a multi-factorial disease and the clinical significance of fragrance contact allergy in (severe) chronic hand eczema may not be clear.

**Axillae Bilateral axillary** (underarm) dermatitis may be caused by perfume in deodorants and, if the reaction is severe, it may spread down the arms and to other areas of the body. In individuals who consulted a dermatologist, a history of such first-time symptoms was significantly related to the later diagnosis of perfume allergy.

**Face** Facial eczema is an important manifestation of fragrance allergy from the use of cosmetic products (16). In men, after-shave products can cause an eczematous eruption of the beard area and the adjacent part of the neck and men using wet shaving as opposed to dry have been shown to have an increased risk of being fragrance allergic.

**Irritant reactions (including contact urticaria):** Irritant effects of some individual fragrance ingredients, e.g. citral are known. Irritant contact dermatitis from perfumes is believed to be common, but there are no existing investigations to substantiate this. Many more people complain about intolerance or rashes to perfumes/perfumed products than are shown to be allergic by testing. This may be due to irritant effects or inadequate diagnostic procedures. Fragrances may cause a dose-related contact urticaria of the non-immunological type (irritant contact urticaria). Cinnamal, cinnamic alcohol, and Myroxylon pereirae are well recognised causes of contact urticaria, but others, including menthol, vanillin and benzaldehyde have also been reported. The reactions to Myroxylon pereirae may be due to cinnamates. A relationship to delayed contact hypersensitivity was suggested, but no significant difference was found between a fragrance-allergic group and a control group in the frequency of immediate reactions to fragrance ingredients in keeping with a nonimmunological basis for the reactions seen.

**Pigmentary anomalies:** The term "pigmented cosmetic dermatitis" was introduced in 1973 for what had previously been known as melanosis faciei feminae when the mechanism (type IV allergy) and causative allergens were clarified. It refers to increased pigmentation, usually on the face/neck, often following sub-clinical contact dermatitis. Many cosmetic ingredients were patch tested at non-irritant concentrations and statistical evaluation showed that a number of fragrance ingredients were associated: jasmine absolute, ylang-ylang oil, cananga oil, benzyl salicylate, hydroxycitronellal, sandalwood oil, geraniol, geranium oil.

**Photo-reactions** Musk ambrette produced a considerable number of allergic photocontact reactions (in which UV-light is required) in the 1970s and was later banned from use in the EU. Nowadays, photoallergic contact dermatitis is uncommon. Furocoumarins (psoralens) in some plant-derived fragrance ingredients caused phototoxic reactions with erythema followed by hyperpigmentation resulting in Berloque dermatitis. There are now limits for the amount of furocoumarins in fragrance products. Phototoxic reactions still occur but are rare.

**General/respiratory:** Fragrances are volatile and therefore, in addition to skin exposure, a perfume also exposes the eyes and naso-respiratory tract. It is estimated that 2-4% of the adult population is affected by respiratory or eye symptoms by such an exposure. It is known that exposure to fragrances may exacerbate pre-existing asthma. Asthma-like symptoms can be provoked by sensory mechanisms. In an epidemiological investigation, a significant association was found between respiratory complaints related to fragrances and contact allergy to fragrance ingredients, in addition to hand eczema, which were independent risk factors in a multivariate analysis.

Fragrance allergens act as haptens, i.e. low molecular weight chemicals that are immunogenic only when attached to a carrier protein. However, not all sensitising fragrance chemicals are directly reactive, but require previous activation. A prohaptens is a chemical that itself is non- or low-sensitising, but that is transformed into a hapten outside the skin by simple chemical transformation (air oxidation, photoactivation) and without the requirement of specific enzymatic systems. A prohaptens is a chemical that itself is non- or low-sensitising but that is transformed into a hapten in the skin (bioactivation) usually via enzyme catalysis. It is not always possible to know whether a particular allergen that is not directly reactive acts as a prohaptens or as a prohaptens, or both, because air oxidation and bioactivation can often give the same product (geraniol is an example). Some chemicals might act by all three pathways.

### Prohaptens

Compounds that are bioactivated in the skin and thereby form haptens are referred to as prohaptens.

In the case of prohaptens, the possibility to become activated is inherent to the molecule and activation cannot be avoided by extrinsic measures. Activation processes increase the risk for cross-reactivity between fragrance substances. Crossreactivity has been shown for certain alcohols and their corresponding aldehydes, i.e. between geraniol and geranial (citral) and between cinnamyl alcohol and cinnamal.

The human skin expresses enzyme systems that are able to metabolise xenobiotics, modifying their chemical structure to increase hydrophilicity and allow elimination from the body. Xenobiotic metabolism can be divided into two phases: phase I and phase II. Phase I transformations are known as activation or functionalisation reactions, which normally introduce or unmask hydrophilic functional groups. If the metabolites are sufficiently polar at this point they will be eliminated. However, many phase I products have to undergo subsequent phase II transformations, i.e. conjugation to make them sufficiently water soluble to be eliminated. Although the purpose of xenobiotic metabolism is detoxification, it can also convert relatively harmless compounds into reactive species. Cutaneous enzymes that catalyse phase I transformations include the cytochrome P450 mixed-function oxidase system, alcohol and aldehyde dehydrogenases, monoamine oxidases, flavin-containing monooxygenases and hydrolytic enzymes. Acyltransferases, glutathione S-transferases, UDP-glucuronosyltransferases and sulfotransferases are examples of phase II enzymes that have been shown to be present in human skin. These enzymes are known to catalyse both activating and deactivating biotransformations, but the influence of the reactions on the allergenic activity of skin sensitisers has not been studied in detail. Skin sensitising prohaptens can be recognised and grouped into chemical classes based on knowledge of xenobiotic bioactivation reactions, clinical observations and/or in vivo and in vitro studies of sensitisation potential and chemical reactivity.

**QSAR prediction:** The relationships between molecular structure and reactivity that form the basis for structural alerts are based on well established principles of mechanistic organic chemistry. Examples of structural alerts are aliphatic aldehydes (alerting to the possibility of sensitisation via a Schiff base reaction with protein amino groups), and alpha,beta-unsaturated carbonyl groups, C=C-CO- (alerting to the possibility of sensitisation via Michael addition of protein thiol groups). Prediction of the sensitisation potential of compounds that can act via abiotic or metabolic activation (pre- or prohaptens) is more complex compared to that of compounds that act as direct haptens without any activation. The autoxidation patterns can differ due to differences in the stability of the intermediates formed, e.g. it has been shown that autoxidation of the structural isomers linalool and geraniol results in different major haptens/allergens. Moreover, the complexity of the prediction increases further for those compounds that can act both as pre- and prohaptens. In such cases, the impact on the sensitisation potency depends on the degree of abiotic activation (e.g. autoxidation) in relation to the metabolic activation.

The material may cause skin irritation after prolonged or repeated exposure and may produce a contact dermatitis (nonallergic). This form of

## Histamil Antihistamine Injection

dermatitis is often characterised by skin redness (erythema) and swelling the epidermis. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis.

A member or analogue of a group of benzyl derivatives generally regarded as safe (GRAS) based in part on their self-limiting properties as flavouring substances in food; their rapid absorption, metabolic detoxification, and excretion in humans and other animals, their low level of flavour use, the wide margin of safety between the conservative estimates of intake and the no-observed-adverse effect levels determined from chronic and subchronic studies and the lack of significant genotoxic and mutagenic potential. This evidence of safety is supported by the fact that the intake of benzyl derivatives as natural components of traditional foods is greater than the intake as intentionally added flavouring substances. All members of this group are aromatic primary alcohols, aldehydes, carboxylic acids or their corresponding esters or acetals. The substances in this group:

- contain a benzene ring substituted with a reactive primary oxygenated functional group or can be hydrolysed to such a functional group
- the major pathway of metabolic detoxification involves hydrolysis and oxidation to yield the corresponding benzoic acid derivate which is excreted either as the free acid or the glycine conjugate
- they show a consistent pattern of toxicity in both short- and long- term studies and
- they exhibit no evidence of genotoxicity in standardised batteries of in vitro and in vivo assays.

The benzyl derivatives are rapidly absorbed through the gut, metabolised primarily in the liver, and excreted in the urine as glycine conjugates of benzoic acid derivatives.

In general, aromatic esters are hydrolysed in vivo through the catalytic activity of carboxylesterases, the most important of which are the A-esterases. Hydrolysis of benzyl and benzoate esters to yield corresponding alcohols and carboxylic acids and hydrolysis of acetals to yield benzaldehyde and simple alcohols have been reported in several experiments.

The alcohols and aldehydes are rapidly oxidised to benzoic acid while benzoate esters are hydrolysed to benzoic acid.

Flavor and Extract Manufacturers Association (FEMA)

The aryl alkyl alcohol (AAA) fragrance ingredients are a diverse group of chemical structures with similar metabolic and toxicity profiles.

The AAA fragrances demonstrate low acute and subchronic dermal and oral toxicity.

At concentrations likely to be encountered by consumers, AAA fragrance ingredients are non-irritating to the skin.

The potential for eye irritation is minimal.

With the exception of benzyl alcohol and to a lesser extent phenethyl and 2-phenoxyethyl AAA alcohols, human sensitization studies, diagnostic patch tests and human induction studies, indicate that AAA fragrance ingredients generally have no or low sensitization potential. Available data indicate that the potential for photosensitization is low.

NOAELs for maternal and developmental toxicity are far in excess of current human exposure levels.

No carcinogenicity in rats or mice was observed in 2-year chronic testing of benzyl alcohol or a-methylbenzyl alcohol; the latter did induce species and gender-specific renal adenomas in male rats at the high dose. There was no to little genotoxicity, mutagenicity, or clastogenicity in the mutagenicity in vitro bacterial assays, and in vitro mammalian cell assays. All in vivo micronucleus assays were negative.

It is concluded that these materials would not present a safety concern at current levels of use as fragrance ingredients

The Research Institute for Fragrance Materials (RIFM) Expert Panel

**CHLORPHENIRAMINE  
MALEATE**

Hamster ovary cell mutagen in vitro Reproductive effector in mice A large study linked the development of Alzheimers disease and other forms of dementia to the use of chlorpheniramine and other first-generation antihistamines, due to their anticholinergic properties

**BENZYL ALCOHOL &  
CHLORPHENIRAMINE  
MALEATE**

The following information refers to contact allergens as a group and may not be specific to this product.

Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitisation potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitising substance which is widely distributed can be a more important allergen than one with stronger sensitising potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested.

|                                   |   |                          |   |
|-----------------------------------|---|--------------------------|---|
| 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

| Histamil Antihistamine Injection | ENDPOINT      | TEST DURATION (HR) | SPECIES       | VALUE         | SOURCE        |
|----------------------------------|---------------|--------------------|---------------|---------------|---------------|
|                                  | Not Available | Not Available      | Not Available | Not Available | Not Available |

| benzyl alcohol | ENDPOINT | TEST DURATION (HR) | SPECIES                       | VALUE      | SOURCE |
|----------------|----------|--------------------|-------------------------------|------------|--------|
|                | LC50     | 96                 | Fish                          | 10mg/L     | 2      |
|                | EC50     | 48                 | Crustacea                     | 230mg/L    | 2      |
|                | EC50     | 96                 | Algae or other aquatic plants | 76.828mg/L | 2      |
|                | NOEC     | 336                | Fish                          | 5.1mg/L    | 2      |

| chlorpheniramine maleate | ENDPOINT      | TEST DURATION (HR) | SPECIES       | VALUE         | SOURCE        |
|--------------------------|---------------|--------------------|---------------|---------------|---------------|
|                          | Not Available | Not Available      | Not Available | Not Available | Not Available |

Legend: 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 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

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

Continued...



## Histamil Antihistamine Injection

### Persistence and degradability

| Ingredient     | Persistence: Water/Soil | Persistence: Air |
|----------------|-------------------------|------------------|
| benzyl alcohol | LOW                     | LOW              |

### Bioaccumulative potential

| Ingredient     | Bioaccumulation    |
|----------------|--------------------|
| benzyl alcohol | LOW (LogKOW = 1.1) |

### Mobility in soil

| Ingredient     | Mobility          |
|----------------|-------------------|
| benzyl alcohol | LOW (KOC = 15.66) |

## SECTION 13 DISPOSAL CONSIDERATIONS

### Waste treatment methods

|                                     |  |
|-------------------------------------|--|
| <b>Product / Packaging disposal</b> | <ul style="list-style-type: none"> <li>▶ Containers may still present a chemical hazard/ danger when empty.</li> <li>▶ Return to supplier for reuse/ recycling if possible.</li> </ul> <p>Otherwise:</p> <ul style="list-style-type: none"> <li>▶ 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.</li> <li>▶ Where possible retain label warnings and SDS and observe all notices pertaining to the product.</li> <li>▶ Recycle wherever possible or consult manufacturer for recycling options.</li> <li>▶ Consult State Land Waste Authority for disposal.</li> <li>▶ Bury or incinerate residue at an approved site.</li> <li>▶ Recycle containers if possible, or dispose of in an authorised landfill.</li> </ul> |
|-------------------------------------|--|

## SECTION 14 TRANSPORT INFORMATION

### Labels Required

|                         |                |
|-------------------------|----------------|
| <b>Marine Pollutant</b> | NO             |
| <b>HAZCHEM</b>          | 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

## SECTION 15 REGULATORY INFORMATION

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

#### BENZYL ALCOHOL IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals

Australia Inventory of Chemical Substances (AICS)

#### CHLORPHENIRAMINE MALEATE IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 2

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 3

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

### National Inventory Status

| National Inventory            | Status  |
|-------------------------------|---|
| Australia - AICS              | Yes   |
| Canada - DSL                  | Yes   |
| Canada - NDSL                 | No (benzyl alcohol; chlorpheniramine maleate) |
| China - IECSC                 | No (chlorpheniramine maleate)                 |
| Europe - EINEC / ELINCS / NLP | Yes   |
| Japan - ENCS                  | No (chlorpheniramine maleate)                 |
| Korea - KECI                  | Yes   |
| New Zealand - NZIoC           | Yes   |
| Philippines - PICCS           | Yes   |
| USA - TSCA                    | Yes   |
| Taiwan - TCSI                 | Yes   |

|                |  |
|----------------|--|
| Mexico - INSQ  | Yes  |
| Vietnam - NCI  | Yes  |
| Russia - ARIPS | No (chlorpheniramine maleate)  |
| <b>Legend:</b> | Yes = All CAS declared ingredients are on the inventory<br>No = One or more of the CAS listed ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets) |

## SECTION 16 OTHER INFORMATION

|                      |            |
|----------------------|------------|
| <b>Revision Date</b> | 15/05/2020 |
| <b>Initial Date</b>  | 15/05/2020 |

### SDS Version Summary

| Version | Issue Date | Sections Updated            |
|---------|------------|-----------------------------|
| 2.1.1.1 | 15/05/2020 | Classification, Ingredients |

### 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  
 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

This document is copyright.

Apart from any fair dealing for the purposes of private study, research, review or criticism, as permitted under the Copyright Act, no part may be reproduced by any process without written permission from CHEMWATCH.

TEL (+61 3) 9572 4700.