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### **1 Identification**

- · Product identifier
- · Trade name: dimenhydrinate
- · Article number: 100400
- · CAS Number:
- 523-87-5
- EC number: 208-350-8
- Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Pharma Active ingredients
- · Details of the supplier of the safety data sheet

• Manufacturer/Supplier: Fagron Services B.V. Molenwerk 13, UITGEEST, 1911DB Netherlands Phone: +31251361400

Supplier Azelis Australia Suite 217 117 Old Pittwater Road Brookvale NSW 2100 Australia Phone: +61 0299392188 Fax: +61 0299392799 e-mail: info@azelis.com.au

· Further information obtainable from: info@fagron.com.au

• Emergency telephone number: In case of emergency, please call your local poisons: Emergency Australia: 13 11 26 Emergency NZ: 0800 764 766 (0800 POISON)

1800 127 406 (24 h, Australia) | +64 4 917 9888 (24 h, Worldwide) CareChem 24x7 : EUROPE: +44 1235 239670 | USA: +1 202 464 2554 | CANADA - +1 800 579 7421 (Toll Free)| ASIA - +65 3158 1074 | MOROCCO - +44 1235 239671 | REST OF THE WORLD - +44 1865 407333 (English only )

## 2 Hazard(s) Identification

#### $\cdot$ Classification of the substance or mixture

Acute Tox. 4 H302 Harmful if swallowed.Acute Tox. 4 H312 Harmful in contact with skin.Skin Irrit. 2 H315 Causes skin irritation.Eye Irrit. 2A H319 Causes serious eye irritation.

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- · Label elements
- · GHS label elements

The substance is classified and labelled according to the Globally Harmonised System (GHS). • Hazard pictograms



- · Signal word Warning
- Hazard statements Harmful if swallowed. Harmful in contact with skin.
- Causes skin irritation.
- Causes serious eye irritation.
- Precautionary statements
- Wear protective gloves/protective clothing/eye protection/face protection.
- IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
- Rinse mouth.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If skin irritation occurs: Get medical advice/attention.

Dispose of contents/container in accordance with local/regional/national/international regulations.

- Other hazards
- · Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

## **3 Composition and Information on Ingredients**

- · Chemical characterisation: Substances
- · CAS No. Description
- 523-87-5 dimenhydrinate
- Identification number(s)
- EC number: 208-350-8

## **4 First Aid Measures**

- · Description of first aid measures
- General information:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

- · After inhalation: In case of unconsciousness place patient stably in side position for transportation.
- After skin contact: If skin irritation continues, consult a doctor.
- Immediately wash with water and soap and rinse thoroughly.
- · After eye contact:
- Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- · After swallowing: Call for a doctor immediately.

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- Information for doctor:
- Most important symptoms and effects, both acute and delayed No further relevant information available.
- Indication of any immediate medical attention and special treatment needed
   No further relevant information available.

## **5 Fire Fighting Measures**

- · Extinguishing media
- Suitable extinguishing agents: Water haze
- Alcohol resistant foam
- Fire-extinguishing powder
- Carbon dioxide
- Use fire extinguishing methods suitable to surrounding conditions.
- $\cdot$  Special hazards arising from the substance or mixture
- In case of fire, the following can be released:
- Carbon monoxide (CO) Nitrogen oxides (NOx)
- Hydrogen chloride (HCl)
- Advice for firefighters
- Advice for firefighters
- Protective equipment: No special measures required.

## 6 Accidental Release Measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- · Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up: Pick up mechanically.
- · Reference to other sections
- See Section 7 for information on safe handling.
- See Section 8 for information on personal protection equipment.
- See Section 13 for disposal information.

## 7 Handling and Storage

- · Handling:
- · Precautions for safe handling No special precautions are necessary if used correctly.
- · Information about fire and explosion protection: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- Further information about storage conditions: Keep container tightly sealed.
- Specific end use(s) No further relevant information available.

## 8 Exposure controls and personal protection

· Additional information about design of technical facilities: No further data; see item 7.

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- Control parameters
- Ingredients with limit values that require monitoring at the workplace: Not required.
- Additional information: The lists valid during the making were used as basis.
- Exposure controls
- Personal protective equipment:
- General protective and hygienic measures: Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing Wash hands before breaks and at the end of work. Avoid contact with the eves and skin.
- Respiratory protection:

Suitable respiratory protective device recommended. Filter P1

Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

• Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

#### Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

• Eye protection:



Tightly sealed goggles

· Body protection: Protective work clothing

## 9 Physical and Chemical Properties

- · Information on basic physical and chemical properties
- General Information
- · Appearance:
- Form:
- Colour:
- Odour:
   Odour threshold:

Crystalline powder White Odourless Not determined.

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pH-value:	6.5–7.5
Change in condition	
Melting point/freezing point:	102–107°C
Initial boiling point and boiling range	: Undetermined.
Flash point:	Not applicable.
Flammability (solid, gas):	Product is not flammable.
Decomposition temperature:	Not determined.
Auto-ignition temperature:	Not determined.
Explosive properties:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapour pressure:	Not applicable.
Density:	Not determined.
Bulk density:	400–600 kg/m <sup>3</sup>
Relative density	Not determined.
Vapour density	Not applicable.
Evaporation rate	Not applicable.
Solubility in / Miscibility with	
water at 20°C:	3 g/l
Partition coefficient: n-octanol/water:	Not determined.
Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
Other information	No further relevant information available.

## **10 Stability and Reactivity**

- · Reactivity No further relevant information available.
- · Chemical stability
- Thermal decomposition / conditions to be avoided:
- No decomposition if used according to specifications.
- Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- Hazardous decomposition products:
- Carbon monoxide and carbon dioxide
- Nitrogen oxides (NOx)
- Hydrogen chloride (HCl)

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## **11 Toxicological Information**

- · Information on toxicological effects
- · Acute toxicity
- · LD/LC50 values relevant for classification:
- Oral LD50 1320 mg/kg (rat)
- · Primary irritant effect:
- · Skin corrosion/irritation Irritant to skin and mucous membranes.
- · Serious eye damage/irritation Irritating effect.
- Respiratory or skin sensitisation No sensitising effects known.

## **12 Ecological Information**

- · Toxicity
- Aquatic toxicity: No further relevant information available.
- Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · **vPvB:** Not applicable.
- · Other adverse effects No further relevant information available.

## **13 Disposal considerations**

- · Waste treatment methods
- Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

UN-Number		
ADG, IMDG, IATA	not regulated	
UN proper shipping name		
ADĠ, IMDG, IATA	not regulated	



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	(Co	ntd. of page 6)
· Transport hazard class(es)		
· ADG, ADN, IMDG, IATA · Class	not regulated	
· Packing group · ADG, IMDG, IATA	not regulated	
· Environmental hazards:	Not applicable.	
· Special precautions for user	Not applicable.	
<ul> <li>Transport in bulk according to Anno Marpol and the IBC Code</li> </ul>	ex II of Not applicable.	
· UN "Model Regulation":	not regulated	

## **15 Regulatory information**

• Safety, health and environmental regulations/legislation specific for the substance or mixture • Australian Inventory of Industrial Chemicals Substance is not listed.

- · Standard for the Uniform Scheduling of Medicines and Poisons S2, S3, S4
- · Australia: Priority Existing Chemicals Substance is not listed.
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I Substance is not listed.
- · National regulations:

• Other regulations, limitations and prohibitive regulations Therapeutic goods are listed on the Australian Register of Therapeutic Goods(ARTG)

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

## **16 Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- · Department issuing SDS: Product Safety Department
- Contact:
- Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation - Category 2A

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