MATERIAL SAFETY DATA SHEET ACCORDING TO 1907/2006/EC, ARTICLE 31

(CYCLOPENTOLATE HYDROCHLORIDE)

1. IDENTIFICATION OF THE SUBSTANCE:

Chemical Name: 2-(Dimethylamino) ethyl (2RS)-(1-hydroxycyclopentyl)-(phenyl) acetate hydrochloride

Name: Cyclopentolate Hydrochloride

Article number: CP010204

Application of the substance / the preparation

Pharma Active ingredients

Pharmaceutical active substance

Manufacturing / Supplier:

PIONEER AGRO INDUSTRIES SANVIN LABORATORIES PRIVATE LIMITED

Plot No 6, 7,8,20 & 24, M.I.D.C. Industrial area, Post Kulgaon, Badlapur, Dist. Thane-421 503.

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Further information obtainable from:

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2. HAZARDS IDENTIFICATION

Hazard Description:

Non hazardous

Information concerning to particular hazards to man and environment :

R 20 Harmful by inhalation.

R 22 Harmful if swallowed.

R 38 Irritating to skin

GHS label elements:

Harmful if swallowed, Irritating to skin

Warning

H332 - Harmful if inhaled.

Prevention:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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Response:

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

P321 Specific treatment (see on this label).

P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Additional information:

Myderiatic

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization:

CAS No. Description:

5870-29-1 Cyclopentolate Hydrochloride

Identification number(s):

Not available

EINECS Number:

227-521-8

4. FIRST AID MEASURES:

General informations:

Immediately remove any clothing soiled by the product.

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

In case of irregular breathing or respiratory arrest provide artificial respiration.



Seek medical advice

After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor.

In case of unconsciousness place patient stably in side position for transportation.

After skin contact:

Immediately wash with water and soap and rinse thoroughly.

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After eye contact:

Rinse opened eye for several minutes under running water. Then consult a doctor.

After swallowing:

Seek immediate medical advice.

Do not induce vomiting if unconscious, call for medical helps immediately.

Rinse out mouth and drink plenty of water, provided person is conscious and induce vomiting. Seek medical help.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media:

Carbon dioxide,

Foam,

Dry chemical powder

Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases:

In case of fire, the following can be released:

Nitrogen oxides (NOx) Hydrogen chloride (HCl), Carbon Monoxide, Carbondioxide

Formation of poisonous gases during heating or in fires. Nitrogen oxides (NOx)

Hydrogen chloride (HCI), Carbon Monoxide, Carbondioxide

Protective equipment:

Wear self-contained respiratory protective device.

Wear fully protective suit.

Mount respiratory protective device.

Additional information:

Dispose off fire debris and contaminated fire fighting water in accordance with official regulations.

6. ACCIDENTAL RELEASE MEASURES

Person-related safety precautions:

Wear protective equipment. Keep unprotected persons away.

Avoid raising dust.

Keep away from ignition sources.

Measures for environmental protection:

Do not allow product to reach sewage system or any water course.

Damp down dust with water spray jet.

Keep dirty washing water for appropriate disposal.

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Measures for cleaning/collecting:

Ensure adequate ventilation.

Dispose of the material collected according to regulations.

Collect mechanically.

Dispose contaminated material as waste according to item 13.

7. HANDLING AND STORAGE:

Handling

Information for safe handling:

Thorough dedusting.

Ensure good ventilation/exhaustion at the workplace. Open and handle receptacle with care.

Prevent formation of dust.

Ensure good ventilation/exhaustion at the workplace.

Information about fire - and explosion protection:

Keep ignition sources away - do not smoke.

Protect against electrostatic charges.

Dust can combine with air to form an explosive mixture.

Storage:

Requirements to be met by storerooms and receptacles:

No special requirements

Information about storage in one common storage facility:

Store away from foodstuffs.

Store in a cool location.

Store away from oxidizing agents and incompactible material

Further information about storage conditions:

Keep receptacle tightly sealed.

Store in a well-closed container

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Additional information about design of technical facilities:

No further data; see item 7.

Ingredients with limit values that require monitoring at the workplace:

Not required.

Additional information:

The lists valid during the making were used as basis.

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.

* Respiratory protection:

Filter P3.

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use airline respiratory protective device.

Recommended filter for short term use: Filter P3

*Protection of hands:



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:

For the mixture of chemicals mentioned below the penetration time has to be at least 480 minutes (Permeation according to EN 374 Part 3: Level 6).

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

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Eye protection:

Use safety goggles.

Body protection:

Use protective suit.

Wear light weight protective clothing.

PHYSICAL AND CHEMICAL PROPERTIES

General Information

Form :Crystalline powder

Colour :White Odour :Odourless

Change in condition

Melting point/Melting range : About 138°C

Boiling point/Boiling range : N/A

Decomposition temperature: N/A

Danger of explosion : Product does not present an explosion hazard.

The product is not explosive.

Density : Not determined

Solubility in / Miscibility with: Very soluble in water.

Water at 20°C:

10. STABILITY AND REACTIVITY:

Thermal decomposition / conditions to be avoided:

To avoid thermal decomposition do not overheat.

Materials to be avoided:

Oxidizing agents.

Dangerous reactions:

Risk of dust explosion may be expected

Dangerous decomposition products:

Hydrogen chloride (HCI), Carbon Monoxide, Carbon dioxide

Oxides of N

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11. **TOXICOLOGICAL INFORMATION:**

Acute toxicity:

Oral LD50: 960 mg/kg (Mouse)

LD/LC50 values relevant for classification: LD50: orl-mouse: 960 mg/kg

Primary irritant effect:

On the skin may cause irritation.

Sensitization: No sensitizing effect known.

12. ECOLOGICAL INFORMATION

Information about elimination (persistence and degradability): No relevant data available

DISPOSAL CONSIDERATIONS 13.

Product:

Recommendation

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

After prior treatment the product has to be disposed in an incinerator for hazardous waste under adherence to the regulations pertaining to the disposal of particularly hazardous waste.

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

14. TRANSPORT INFORMATION

Land transport ADR/RID (cross-border)

ADR/RID class : Not available Danger code (Kemler) : Not applicable **UN-Number** : Not applicable Packaging group : Not available Hazard label : Not applicable

Description of goods: Non hazardous, organic solid (Cyclopentolate hydrochloride)

Tunnel restriction code: Not available

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Maritime transport IMDG:

IMDG Class : Not available
UN Number : Not applicable
Label : Not available
Packaging group : Not available
EMS Number : Not available

Marine pollutant : No

Proper shipping name: Non hazardous, organic solid (Cyclopentolate hydrochloride)

Air transport ICAO-TI and IATA-DGR:

ICAO/IATA Class
 UN/ID Number
 Label
 Not available
 Not available
 Packaging group
 Not available

Proper shipping name : Non hazardous, organic solid (Cyclopentolate hydrochloride)

UN "Model Regulation": Non hazardous, organic solid (Cyclopentolate hydrochloride)

15. REGULATORY INFORMATION

Code letter and hazard designation of product:

Not applicable

Risk phrases:

R -20 Harmful by inhalation.

R-22 harmful if swallowed.

R 38 Irritating to skin

Safety phrases:

S-22 Do not breathe dust.

S-26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S-36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

S-45 In case of accident or if you feel unwell, seek medical advice immediately (show the label

where possible).

National regulations

Technical instructions (air): Not available

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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 MSDS: Documentation

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Abbreviations and acronyms:

ADR: Accord European sur le transport des merchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organization

ICAO-TI: Technical Instructions by the "International Civil Aviation Organization"

(ICAO) GHS: Globally Harmonized System of Classification and Labelling of Chemicals

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

Data compared to the previous version altered.

Disclaimer: Pioneer provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must experience their independent judgment in determining its appropriateness for a particular purpose. Pioneer makes no presentations or warranties of merchantability, fitness for a particular purpose with respect to the information set forth herein or the product to which the information refers. Accordingly Pioneer will not be responsible for damages resulting from use of or reliance upon this information.

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