SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Cyproheptadine Formulation

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

1.1 Product identifier
   Trade name : Cyproheptadine Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company : MSD
   Shotton Lane
   NE23 3JU Cramlington NU - Great Britain
   Telephone : 44 1 670 59 30 00
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Eye irritation, Category 2        H319: Causes serious eye irritation.
   Long-term (chronic) aquatic hazard, Category 2 H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms :
   !
   Signal word : Warning
   Hazard statements :
   H319 Causes serious eye irritation.
   H411 Toxic to aquatic life with long lasting effects.
   Precautionary statements :
   Prevention:
   P264 Wash skin thoroughly after handling.
   P273 Avoid release to the environment.
P280  Wear eye protection/ face protection.

Response:
P337 + P313  If eye irritation persists: Get medical advice/ attention.
P391  Collect spillage.

2.3 Other hazards
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyproheptadine</td>
<td>41354-29-4</td>
<td>Acute Tox.3; H301 Eye Dam.1; H318 Repr.2; H361d STOT SE3; H336 Aquatic Acute1; H400 Aquatic Chronic1; H410</td>
<td>&gt;= 1 - &lt; 2,5</td>
</tr>
</tbody>
</table>

M-Factor (Acute aquatic toxicity): 10
M-Factor (Chronic aquatic toxicity): 10

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled : If inhaled, remove to fresh air. Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.

If swallowed: If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed
Risks: Causes serious eye irritation.
Contact with dust can cause mechanical irritation or drying of the skin.

4.3 Indication of any immediate medical attention and special treatment needed
Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Metal oxides
Oxides of phosphorus

5.3 Advice for firefighters
Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

Environmental precautions: Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling: Do not breathe dust. Do not swallow. Do not get in eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-
Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

### Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyproheptadine</td>
<td>41354-29-4</td>
<td>TWA</td>
<td>15 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>150 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

**Engineering measures**

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

**Personal protective equipment**

Eye protection: Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Hand protection**

**Material** : Chemical-resistant gloves

**Remarks** : Consider double gloving.

**Skin and body protection**

Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially contaminated clothing.

**Respiratory protection**

If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Equipment should conform to NS EN 143

**Filter type** : Particulates type (P)

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**SECTION 9: Physical and chemical properties**

**9.1 Information on basic physical and chemical properties**

- **Appearance** : solid
- **Colour** : white
- **Odour** : odourless
- **Odour Threshold** : No data available
- **pH** : No data available
- **Melting point/freezing point** : No data available
- **Initial boiling point and boiling range** : No data available
- **Flash point** : Not applicable
- **Evaporation rate** : Not applicable
- **Flammability (solid, gas)** : May form explosive dust-air mixture during processing, handling or other means.
- **Upper explosion limit / Upper flammability limit** : No data available
- **Lower explosion limit / Lower flammability limit** : No data available
- **Vapour pressure** : Not applicable
- **Relative vapour density** : Not applicable
- **Relative density** : No data available
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Density : No data available

Solubility(ies)
- Water solubility : No data available
- Partition coefficient: n-octanol/water : Not applicable
- Auto-ignition temperature : No data available
- Decomposition temperature : No data available

Viscosity
- Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information
- Flammability (liquids) : No data available
- Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : Heat, flames and sparks. Avoid dust formation.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Information on likely routes of exposure
- Inhalation
- Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

**Product:**

**Acute oral toxicity**

Acute toxicity estimate: > 2.000 mg/kg

**Method:** Calculation method

**Components:**

**Cyproheptadine:**

Acute oral toxicity: LD50 (Rat): 295 mg/kg
LD50 (Mouse): 123 mg/kg
LD50 (Dog): 69 mg/kg

Skin corrosion/irritation
Not classified based on available information.

**Components:**

**Cyproheptadine:**

Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.

**Components:**

**Cyproheptadine:**

Species: Rabbit
Result: Severe irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

**Components:**

**Cyproheptadine:**

Remarks: No data available

Germ cell mutagenicity
Not classified based on available information.
Components:

Cyproheptadine:

Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: Chromosomal aberration
  Test system: Human lymphocytes
  Result: negative
- Test Type: Chromosomal aberration
  Test system: Human diploid fibroblasts
  Result: negative

Carcinogenicity
Not classified based on available information.

Reproductive toxicity
Not classified based on available information.

Components:

Cyproheptadine:

Effects on fertility:
- Test Type: Multi-generation study
  Species: Rat
  Application Route: Oral
  Fertility: NOAEL: 5 mg/kg body weight
  Result: No effects on fertility
- Test Type: Multi-generation study
  Species: Mouse
  Application Route: Oral
  Fertility: NOAEL: 5 mg/kg body weight
  Result: No effects on fertility

Effects on foetal development:
- Test Type: Development
  Species: Rat
  Application Route: Subcutaneous
  Developmental Toxicity: NOAEL: 5 mg/kg body weight
  Result: No teratogenic effects
- Test Type: Development
  Species: Rat
  Application Route: Intraperitoneal
  Developmental Toxicity: LOAEL: 2 mg/kg body weight
  Result: Foetal mortality, Skeletal and visceral variations
- Test Type: Development
  Species: Rat
  Application Route: Oral
  Developmental Toxicity: LOAEL: 5 mg/kg body weight
  Target Organs: Pancreas
  Result: Fetal effects
Reproductive toxicity - Assessment
May damage the unborn child.

STOT - single exposure
Not classified based on available information.

Components:
Cyproheptadine:
Assessment : May cause drowsiness or dizziness.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:
Cyproheptadine:
Species : Rat
LOAEL : 10 mg/kg
Application Route : Oral
Target Organs : Pancreas
Remarks : The mechanism or mode of action may not be relevant in humans.

Species : Dog
Application Route : Oral
Exposure time : 12 Months
Remarks : No significant adverse effects were reported

Aspiration toxicity
Not classified based on available information.

Components:
Cyproheptadine:
Not applicable

Experience with human exposure

Components:
Cyproheptadine:
Inhalation : Symptoms: Drowsiness, decrease in appetite
Ingestion : Symptoms: central nervous system effects, Drowsiness

SECTION 12: Ecological information

12.1 Toxicity

Components:
Cyproheptadine:
Toxicity to fish: LC50 (Cyprinodon variegatus (sheepshead minnow)): 0,71 mg/l 
Exposure time: 96 h 
LC50 (Fat head minnow): 0,10 mg/l 
Exposure time: 96 hrs

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 0,32 mg/l 
Exposure time: 48 h 
EC50 (Americamysis): 0,36 mg/l 
Exposure time: 96 h

M-Factor (Acute aquatic toxicity): 10
M-Factor (Chronic aquatic toxicity): 10

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential
Components:
Cyproheptadine: Partition coefficient: n-octanol/water 
log Pow: 5,4

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number
Cyproheptadine Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.10</td>
<td>23.03.2020</td>
<td>734688-00011</td>
<td>13.09.2019</td>
<td>01.06.2016</td>
</tr>
</tbody>
</table>

| ADN     | : UN 3077      |
| ADR     | : UN 3077      |
| RID     | : UN 3077      |
| IMDG    | : UN 3077      |
| IATA    | : UN 3077      |

14.2 UN proper shipping name

| ADN     | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Cyproheptadine) |
| ADR     | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Cyproheptadine) |
| RID     | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Cyproheptadine) |
| IMDG    | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Cyproheptadine) |
| IATA    | : Environmentally hazardous substance, solid, n.o.s. (Cyproheptadine) |

14.3 Transport hazard class(es)

| ADN     | : 9 |
| ADR     | : 9 |
| RID     | : 9 |
| IMDG    | : 9 |
| IATA    | : 9 |

14.4 Packing group

**ADN**
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9 (ENVIRONM.)

**ADR**
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9 (ENVIRONM.)
- Tunnel restriction code: (-)

**RID**
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
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Labels: 9 (ENVIRONM.)

IMDG
Packing group: III
Labels: 9 (ENVIRONM.)
EmS Code: F-A, S-F

IATA (Cargo)
Packing instruction (cargo aircraft): 956
Packing instruction (LQ): Y956
Packing group: III
Labels: Miscellaneous,

IATA (Passenger)
Packing instruction (passenger aircraft): 956
Packing instruction (LQ): Y956
Packing group: III
Labels: Miscellaneous,

14.5 Environmental hazards

ADN
Environmentally hazardous: yes

ADR
Environmentally hazardous: yes

RID
Environmentally hazardous: yes

IMDG
Marine pollutant: yes

IATA (Passenger)
Environmentally hazardous: yes

IATA (Cargo)
Environmentally hazardous: yes

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable
REACH - Candidate List of Substances of Very High: Not applicable
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Concern for Authorisation (Article 59).
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

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

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements
H301 : Toxic if swallowed.
H318 : Causes serious eye damage.
H336 : May cause drowsiness or dizziness.
H361d : Suspected of damaging the unborn child.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Dam. : Serious eye damage
Repr. : Reproductive toxicity
STOT SE : Specific target organ toxicity - single exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Cana-
SAFETY DATA SHEET
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Cyproheptadine Formulation

Version 1.10
Revision Date: 23.03.2020
SDS Number: 734688-00011
Date of last issue: 13.09.2019
Date of first issue: 01.06.2016

Further information
Sources of key data used to compile the Safety Data Sheet:

Classification of the mixture:
- Eye Irrit. 2: H319, Calculation method
- Aquatic Chronic 2: H411, Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.