1: Identification

1.1 Product identifier
- Trade name: Doxylamine Succinate
  Doxylaminii hydrogensuccinas
- Product Code: 102610
- CAS Number: 562-10-7
- EC number: 209-228-7

1.2 Relevant identified uses of the substance or mixture and uses advised against
No further relevant information available.

1.3 Application of the substance / the mixture
- Pharma Active ingredients

1.4 Details of the supplier of the safety data sheet
- Manufacturer/Supplier:
  Fagron Inc
  2400 Pilot Knob Road
  St. Paul, MN 55120
  www.fagron.us
  QA@fagron.us
- Information department:
  Tel.: 800-423-6967
  Fax: 800-339-1596

1.5 Emergency telephone number:
- Emergency Telephone:
  US: 1-800-535-5053
  International: 1-352-323-3500

2: Hazard(s) identification

2.1 Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008
  GHS07
  Acute Tox. 4  H302  Harmful if swallowed.
  Skin Irrit. 2  H315  Causes skin irritation.
  Eye Irrit. 2A  H319  Causes serious eye irritation.
  STOT SE 3  H335  May cause respiratory irritation.

2.2 Label elements
- Labelling according to Regulation (EC) No 1272/2008
  The substance is classified and labeled according to the CLP regulation.
  Hazard pictograms GHS07
  Signal word Warning
  Hazard statements
  H302 Harmful if swallowed.
  H315 Causes skin irritation.
  H319 Causes serious eye irritation.
  H335 May cause respiratory irritation.

(Contd. on page 2)
Trade name: Doxylamine Succinate
   Doxylamini hydrogensuccinas

- Precautionary statements
  P261 Avoid breathing dust/fume/gas/mist/vapors/spray
  P280 Wear protective gloves.
  P280 Wear eye protection / face protection.
  P321 Specific treatment (see on this label).
  P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  P405 Store locked up.

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

3: Composition/information on ingredients

- 3.1 Chemical characterization: Substances
  - CAS No. Description
    562-10-7 Doxylamine Succinate
    Doxylamini hydrogensuccinas
  - Identification number(s)
  - EC number: 209-228-7

4: First-aid measures

- 4.1 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:
    Seek medical treatment. 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:
    Seek medical treatment. Immediately call a doctor.
  - 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
  - 4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.

5: Fire-fighting measures

- 5.1 Extinguishing media
  - Suitable extinguishing agents:
    Water spray
    Alcohol resistant foam
Trade name: Doxylamine Succinate
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Carbon dioxide
Fire-extinguishing powder

5.2 Special hazards arising from the substance or mixture
Formation of toxic gases is possible during heating or in case of fire.
Carbon monoxide (CO)
Nitrogen oxides (NOx)

5.3 Advice for firefighters
Protective equipment: Wear self-contained respiratory protective device.

6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Wear protective equipment. Keep unprotected persons away.
Ensure adequate ventilation

6.2 Environmental precautions: Do not allow to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up:
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.

6.4 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

7.1 Precautions for safe handling No special precautions are necessary if used correctly.
Information about protection against explosions and fires: No special measures required.

7.2 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: Store in cool, dry conditions in well sealed receptacles.

7.3 Specific end use(s) No further relevant information available.

8: Exposure controls/personal protection

8.1 Control parameters
Components with limit values that require monitoring at the workplace: Not required.
Additional information: The lists that were valid during the creation were used as basis.

8.2 Exposure controls
Personal protective equipment:
General protective and hygienic measures:
Clean skin thoroughly immediately after handling the product.
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 eyes and skin.

- **Breathing equipment:**
  Filter P1
  In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

- **Protection of hands:**

  ![Protective gloves](image)

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

- **Eye protection:**

  ![Tightly sealed goggles](image)

  **Body protection:** Protective work clothing

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### 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
  **General Information**
  **Appearance:**
  - Form: Crystalline
  - Color: Whitish
  - Odor: Characteristic
  - Odour threshold: Not determined.
  **pH-value (10 g/l) at 20 °C (68 °F):** 4.9 - 5.1

  **Change in condition**
  - Melting point/Melting range: 103-108 °C (217-226 °F)
  - Boiling point/Boiling range: Undetermined.

  **Flash point:** Not applicable.

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### Safety Data Sheet
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**Trade name:** Doxylamine Succinate  
**Doxylamini hydrogensuccinas**

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<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Flammability (solid, gaseous):</td>
<td>Product is not flammable.</td>
</tr>
<tr>
<td>· Ignition temperature:</td>
<td></td>
</tr>
<tr>
<td>· Decomposition temperature:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>· Auto igniting:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>· Danger of explosion:</td>
<td>Product does not present an explosion hazard.</td>
</tr>
<tr>
<td>· Explosion limits:</td>
<td></td>
</tr>
<tr>
<td>· Lower:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>· Upper:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>· Vapor pressure:</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>· Density:</td>
<td></td>
</tr>
<tr>
<td>· Relative density</td>
<td>Not determined.</td>
</tr>
<tr>
<td>· Vapour density</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>· Evaporation rate</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>· Solubility in / Miscibility with Water at 20 °C (68 °F):</td>
<td>710 g/l</td>
</tr>
<tr>
<td>· Partition coefficient (n-octanol/water):</td>
<td>Not determined.</td>
</tr>
<tr>
<td>· Viscosity:</td>
<td></td>
</tr>
<tr>
<td>· Dynamic:</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>· Kinematic:</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>· 9.2 Other information</td>
<td>No further relevant information available.</td>
</tr>
</tbody>
</table>

### 10: Stability and reactivity

- **10.1 Reactivity**
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** To avoid thermal decomposition do not overheat.
- **10.3 Possibility of hazardous reactions**
- Reacts with strong oxidizing agents.
- Reacts with acids.
- Reacts with alkali (lyes).
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:**
- Nitrogen oxides (NOx)
- Carbon monoxide and carbon dioxide

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11: Toxicological information

11.1 Information on toxicological effects
Acute toxicity:

LD/LC50 values that are relevant for classification:

<table>
<thead>
<tr>
<th>Route</th>
<th>LD50/LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>470 mg/kg (mus)</td>
</tr>
</tbody>
</table>

Primary irritant effect:
- on the skin: Irritant to skin and mucous membranes.
- on the eye: Irritating effect.
- Sensitization: No sensitizing effects known.

Additional toxicological information:

Carcinogenic categories
- IARC (International Agency for Research on Cancer)
  562-10-7 Doxylamine Succinate
  Doxylamini hydrogensuccinas
  3
- NTP (National Toxicology Program) Substance is not listed.
- OSHA-Ca (Occupational Safety & Health Administration) Substance is not listed.

12: Ecological information

12.1 Toxicity
Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability No further relevant information available.

12.3 Bioaccumulative potential No further relevant information available.

12.4 Mobility in soil No further relevant information available.

Additional ecological information:

General notes:
- Water hazard class 2 (Assessment by list): hazardous for water
- Do not allow product to reach ground water, water course or sewage system.
- Danger to drinking water if even small quantities leak into the ground.

12.5 Results of PBT and vPvB assessment
- PBT: Not applicable.
- vPvB: Not applicable.

12.6 Other adverse effects No further relevant information available.

13: Disposal considerations

13.1 Waste treatment methods
Recommendation:
- Must be specially treated adhering to official regulations.
- Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
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Trade name: Doxylamine Succinate
Doxylamini hydrogensuccinas

(Contd. of page 6)

14: Transport information

- 14.1 UN-Number
  DOT, ADR, ADN, IMDG, IATA Void

- 14.2 UN proper shipping name
  DOT, ADR, ADN, IMDG, IATA Void

- 14.3 Transport hazard class(es)
  DOT, ADR, ADN, IMDG, IATA
  Class Void

- 14.4 Packing group
  DOT, ADR, IMDG, IATA Void

- 14.5 Environmental hazards:
  Not applicable.

- 14.6 Special precautions for user
  Not applicable.

- 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
  Not applicable.

- Transport/Additional information:
  Not dangerous according to the above specifications.

- UN "Model Regulation": -

15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
  No further relevant information available.

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

16: Other information

This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered to be dependable and is accurate to the best of the Company’s knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. The Company cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

- Department issuing SDS:
  Fagron US
  Quality Assurance

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Safety Data Sheet
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Trade name: Doxylamine Succinate
        Doxylamini hydrogensuccinas

· **Contact:** QA@fagron.us
· **Date of preparation / last revision** 10/21/2015 / 16
· **Abbreviations and acronyms:**
  RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
  ICAO: International Civil Aviation Organisation
  ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
  GHS: Globally Harmonised 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
  Acute Tox. 4: Acute toxicity, Hazard Category 4
  Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
  Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A
  STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3
· * Data compared to the previous version altered.*