1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier
Product Name
DELZICOL

Other means of identification
Product Code
FG00137
Synonyms
Mesalamine Delayed Release Capsules Finished Product

Recommended use of the chemical and restrictions on use
Recommended Use
aminosalicylate indicated for the treatment of mildly to moderately active ulcerative colitis and for the maintenance of remission of ulcerative colitis.

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Details of the supplier of the safety data sheet
Manufacturer
Allergan plc
5 Giralda Farms
Madison, NJ USA 07940
+1-800-272-5525
E-mail address
SDS@Allergan.com

Emergency telephone number
Emergency Telephone
Call CHEMTREC Day or Night
Within USA or Canada: 1-800-424-9300
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status
This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

<table>
<thead>
<tr>
<th>Carcinogenicity</th>
<th>Category 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on or via lactation</td>
<td>Yes</td>
</tr>
<tr>
<td>Specific target organ toxicity (single exposure)</td>
<td>Category 3 - (H335)</td>
</tr>
<tr>
<td>Specific target organ toxicity (repeated exposure)</td>
<td>Category 2</td>
</tr>
</tbody>
</table>

Label elements

Emergency Overview

Warning

Hazard statements
H351 - Suspected of causing cancer
H362 - May cause harm to breast-fed children
H373 - May cause damage to organs through prolonged or repeated exposure
H335 - May cause respiratory irritation
H336 - May cause drowsiness or dizziness
Precautionary statements
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P201 - Obtain special instructions before use
P263 - Avoid contact during pregnancy/while nursing
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P312 - Call a POISON CENTER or doctor if you feel unwell
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P271 - Use only outdoors or in a well-ventilated area
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P312 - Call a POISON CENTER or doctor if you feel unwell
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
P405 - Store locked up
P280 - Avoid breathing dust/fume/gas/mist/vapors/spray
P314 - Get medical advice/attention if you feel unwell
P501 - Dispose of contents/container to an approved waste disposal plant

Other Information
Unknown Acute Toxicity
30.63% of the mixture consists of ingredient(s) of unknown toxicity

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No.</th>
<th>EINECS</th>
<th>Weight-%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesalamine</td>
<td>89-57-6</td>
<td>201-919-1</td>
<td>15 - 40*</td>
</tr>
</tbody>
</table>
4. FIRST AID MEASURES

First aid measures

Eye contact  
Rinse immediately with plenty of water and seek medical advice.

Skin Contact  
Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Inhalation  
Remove to fresh air.

Ingestion  
Consult a physician if necessary.

Chemical Name  
Mesalamine  
Trospium Chloride

Note to physicians  
Treat symptomatically.  
Trospium chloride is contraindicated in patients with urinary retention, gastric retention, uncontrolled narrow-angle glaucoma, and known hypersensitivity to the drug or its ingredients.  
Angioedema, rash and anaphylactic reaction have been reported.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media  
None known.

Specific hazards arising from the chemical  
Fire may produce irritating, corrosive and/or toxic gases.

Explosion data  
Sensitivity to Mechanical Impact  
Not impact sensitive.  
Sensitivity to Static Discharge  
Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Protective equipment and precautions for firefighters  
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions  
Use personal protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions  
See Section 12 for additional ecological information.

Methods for containment  
Prevent further leakage or spillage if safe to do so.

Methods for cleaning up  
Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE
Advice on safe handling
Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not eat, drink or smoke when using this product.

Storage Conditions
Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.

Incompatible materials
None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH IDLH</th>
<th>Allergan OEL (ug/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesalamine</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>800 ug/m³</td>
</tr>
<tr>
<td>TALC USP(1656)</td>
<td>TWA: 2 mg/m³ particulate matter containing no asbestos and &lt;1% crystalline silica, respirable particulate matter</td>
<td>(vacated) TWA: 2 mg/m³ respirable dust &lt;1% Crystalline silica, containing no Asbestos TWA: 20 mppcf if 1% Quartz or more use Quartz limit</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>FERRIC OXIDE NF (RED 30)</td>
<td>TWA: 5 mg/m³ respirable particulate matter</td>
<td>TWA: 10 mg/m³ fume TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction (vacated) TWA: 10 mg/m³ fume and total dust Iron oxide (vacated) TWA: 5 mg/m³ respirable fraction regulated under Rouge</td>
<td>IDLH: 2500 mg/m³ Fe dust and fume TWA: 5 mg/m³ Fe dust and fume</td>
<td>N/A</td>
</tr>
<tr>
<td>Trospium Chloride</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>100 ug/m³</td>
</tr>
</tbody>
</table>

NIOSH IDLH Immediately Dangerous to Life or Health

Other Information
Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

Appropriate engineering controls

Engineering Controls
The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

Eye/face protection
No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.

Skin and body protection
During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).

Respiratory protection
Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.
9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Solid</td>
</tr>
<tr>
<td>Color</td>
<td>No information available</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No information available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Capsule</td>
</tr>
<tr>
<td>Odor</td>
<td>No information available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>No information available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No information available</td>
</tr>
<tr>
<td>Boiling point / boiling range</td>
<td>No information available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No information available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No information available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No information available</td>
</tr>
<tr>
<td>Flammability Limit in Air</td>
<td>No information available</td>
</tr>
<tr>
<td>Upper flammability limit:</td>
<td>No information available</td>
</tr>
<tr>
<td>Lower flammability limit:</td>
<td>No information available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No information available</td>
</tr>
<tr>
<td>Vapor density</td>
<td>No information available</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>No information available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>No information available</td>
</tr>
<tr>
<td>Solubility in other solvents</td>
<td>No information available</td>
</tr>
<tr>
<td>Partition coefficient</td>
<td>No information available</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No information available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No information available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No information available</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>No information available</td>
</tr>
</tbody>
</table>

Other Information

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular weight</td>
<td>No information available</td>
</tr>
<tr>
<td>VOC Content (%)</td>
<td>No information available</td>
</tr>
<tr>
<td>Density</td>
<td>No information available</td>
</tr>
<tr>
<td>Bulk density</td>
<td>No information available</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Reactivity
Not defined As Reactive substance

Chemical stability
Stable under normal conditions.

Possibility of Hazardous Reactions
None under normal processing.

Conditions to avoid
Aerosol formation.

Incompatible materials
None known based on information supplied.

Hazardous Decomposition Products
None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Acute toxicity

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Inhalation</th>
<th>Eye contact</th>
<th>Skin Contact</th>
<th>Ingestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesalamine</td>
<td>If dusts or particulates from this product are inhaled.</td>
<td>Conjunctivitis, eye pain, blurred vision, vision</td>
<td>Prolonged contact may cause redness and irritation.</td>
<td>If this compound is swallowed, CALL</td>
</tr>
</tbody>
</table>
remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect occurs after removal to fresh air.

abnormality. If particulates from this product enter the eyes, open victim's eyes while under gently running water. Use sufficient force to open eyelids. Have victim "roll" eyes. Minimum flushing is for 20 minutes. Do not interrupt flushing. Seek immediate medical attention after flushing if adverse effect occurs.

PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Rinse mouth with water immediately. Victim should drink large quantities of water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.

Trospium Chloride

If airborne dusts generated by this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect continues after removal to fresh air.

Contact with the eyes of airborne dusts generated by this compound may cause mild to moderate irritation, redness, and tearing (mechanical irritation).

In therapeutic use, this compound has caused swelling of the skin, rash and anaphylactic reactions. Angioedema of the face, lips, tongue and/or larynx has been reported with therapeutic use of Trospium. Angioedema associated with upper airway swelling may be life threatening. May cause irritation to skin. Prolonged or repeated skin contact may cause dermatitis (dry, red skin).

If this compound is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Rinse mouth with water immediately. Victim should drink large quantities of water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.

### Chemical Name

**Oral LD50** | **Dermal LD50** | **Inhalation LC50**
--- | --- | ---
Mesalamine | 2800 mg/kg (Rat) | > 5 g/kg (Rabbit) | N/A
POVIDONE USP/PLASDONE K-29-32 | 100 g/kg (Rat) | N/A | N/A
FERRIC OXIDE NF (RED 30) | > 10000 mg/kg (Rat) | N/A | N/A
Trospium Chloride | 1510 mg/kg (Rat) | N/A | N/A

### Delayed and immediate effects as well as chronic effects from short and long-term exposure

**Chemical Name** | **Germ cell mutagenicity** | **Carcinogenicity** | **Reproductive toxicity** | **Effects on or via lactation**
--- | --- | --- | --- | ---
Mesalamine | Not mutagenic in the standard battery of tests. | Animal studies in mice and rats have not shown carcinogenicity. | Mesalamine, at oral doses up to 480 mg/kg/day (about 0.8 times the recommended human treatment dose based on body surface area), was found to have no effect on fertility or reproductive performance of male and female rats. Studies in rats and rabbits have not shown teratogenicity or harm to the fetus. | Mesalamine and its N-acetyl metabolite are present in human milk. In published lactation studies, maternal Mesalamine doses from various oral and rectal formulations and products ranged from 500 mg to 3 g daily. The concentration of Mesalamine in milk ranged from non-detectable to 0.11 mg/L. The concentration of the N-acetyl-5-aminosalicylic acid metabolite ranged from 5 to 18.1 mg/L. Based on these concentrations, estimated infant daily doses for an exclusively breastfed infant are 0 to 0.017 mg/kg/day of Mesalamine and 0.75 to 2.72 mg/kg/day
of N-acetyl-5-aminosalicylic acid. Dibutyl phthalate (DBP), an inactive ingredient in the enteric coating of Asacol HD tablets, and its primary metabolite mono-butyl phthalate (MBP) are excreted into human milk. The clinical significance of this has not been determined. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>STOT - single exposure</th>
<th>STOT - repeated exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesalamine</td>
<td>Harmful if swallowed. Irritating to eyes, respiratory system and skin.</td>
<td>Repeated exposure may cause irritation to the eyes, skin and respiratory system.</td>
</tr>
</tbody>
</table>

**Target Organ Effects**

Central Vascular System (CVS), Eyes, Gastrointestinal tract (GI), Respiratory system, Skin.

**Numerical measures of toxicity - Product Information**

**Unknown Acute Toxicity**

30.63% of the mixture consists of ingredient(s) of unknown toxicity

The following values are calculated based on chapter 3.1 of the GHS document.

ATEmix (oral) 4634 mg/kg

ATEmix (dermal) 9920 mg/kg

### 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

85.94% of the mixture consists of components(s) of unknown hazards to the aquatic environment

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Algae/aquatic plants</th>
<th>Fish</th>
<th>Crustacea</th>
</tr>
</thead>
<tbody>
<tr>
<td>TALC USP(1656) 14807-96-6</td>
<td>N/A</td>
<td>100: 96 h Brachydanio rerio g/L LC50 semi-static</td>
<td>N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Persistence and degradability</th>
<th>Bioaccumulation</th>
<th>Mobility</th>
<th>Partition coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesalamine 89-57-6</td>
<td>This product has not been tested for persistence or biodegradability. It is expected that the components will slowly degrade in the environment and form a variety of organic and inorganic materials; however, no specific information is known.</td>
<td>No information available</td>
<td>Expected to have high mobility in soil</td>
<td>pKa1 (2.3); pKa2 (5.69)</td>
</tr>
<tr>
<td>Trospium Chloride 10405-02-4</td>
<td>No information available</td>
<td>No information available</td>
<td>No information available</td>
<td>Log P = 0.70</td>
</tr>
</tbody>
</table>
Other adverse effects

No information available

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes

Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging

Do not reuse container. Dispose of contents/containers in accordance with local regulations.

14. TRANSPORT INFORMATION

DOT
Not regulated

TDG
Not regulated

ICAO (air)
Not regulated

IATA
Not regulated

IMDG
Not regulated

ADR
Not regulated

ADN
Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA
Not Listed

DSL/NDSL
Not Listed

EINECS/ELINCS
Not Listed

Legend:
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

US Federal Regulations

Carcinogenicity

The table below indicates whether each agency has listed any ingredient as a carcinogen. This product contains one or more substances which are classified by IARC as carcinogenic to humans (Group I), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B).

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Povidone USP (PLASDONE K-29-32) 9003-39-8</td>
<td>-</td>
<td>Group 3</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Talc USP (1656) 14807-96-6</td>
<td>-</td>
<td>Group 3</td>
<td>-</td>
<td>X</td>
</tr>
<tr>
<td>Ferric Oxide NF (RED 80) 1309-37-1</td>
<td>-</td>
<td>Group 3</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

IARC (International Agency for Research on Cancer)
Group 1 - Carcinogenic to Humans
Not classifiable as a human carcinogen
NTP (National Toxicology Program)
Known - Known Carcinogen
OSHA (Occupational Safety and Health Administration of the US Department of Labor)
X - Present

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories
Acute health hazard  Yes
Chronic Health Hazard  No
Fire hazard  No
Sudden release of pressure hazard  No
Reactive Hazard  No

CWA (Clean Water Act)
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

US State Regulations
California Proposition 65
This product contains the following Proposition 65 chemicals

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>California Proposition 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>MICROCRYSTALLINE CELLULOSE (AVICEL PH102) - 9004-34-6</td>
<td>Carcinogen</td>
</tr>
</tbody>
</table>

U.S. State Right-to-Know Regulations

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>Pennsylvania</th>
</tr>
</thead>
<tbody>
<tr>
<td>TALC USP (1656) 14807-96-6</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>FERRIC OXIDE NF (RED 30) 1309-37-1</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>MICROCRYSTALLINE CELLULOSE (AVICEL PH102) 9004-34-6</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>CORN STARCH NF 9005-25-8</td>
<td>-</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>White Cresin Wax 8002-74-2</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Revision Date 29-Sep-2018
Revision Note No information available

Disclaimer
The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet