SECTION 1. IDENTIFICATION

Product name : Zantac®
Synonyms : Active ingredient: Ranitidine hydrochloride <= 60%
Zantac® tablets, Zantac® 150mg Cool Mint Tablets, Zantac®
Maximum Strength 150mg Tablets
Product code : 000000030874

Manufacturer or supplier’s details
Company name of supplier : Boehringer-Ingelheim Pharmaceuticals, Incorporated
Address : 900 Ridgebury Road
Ridgefield, Connecticut
06877-0368
Telephone :
Telefax :
Emergency telephone number : +1-800-424-9300 CHEMTREC Emergency Phone Number
CHEMTREC – 24 Hours
Routine Contact Number : (203) 778-7759

Recommended use of the chemical and restrictions on use
Recommended use : Mixture for production of finished medicinal products.
Prepared by : Corp. Div. EHS & Sustainability / Global EHS Services
EHS-service@boehringer-ingelheim.com

SECTION 2. HAZARDS IDENTIFICATION

Skin sensitisation : Category 1

Hazard pictograms :

Signal word : Warning
Hazard statements : H317 May cause an allergic skin reaction.
Precautionary statements : Prevention:
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray. 
P280 Wear protective gloves. 

Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water. 
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention. 

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant. 

Other hazards 
None known. 

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS 
Substance / Mixture : Mixture 

Hazardous components 
<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS-No.</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranitidine hydrochloride</td>
<td>66357-59-3</td>
<td>60</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES 
General advice : Remove from exposure, lie down. 
Take off immediately all contaminated clothing. 
Victim to lie down in the recovery position, cover and keep him warm. 
First Aid responders should pay attention to self-protection and use the recommended protective clothing. 

If inhaled : Keep patient calm, remove to fresh air, seek medical attention. 

In case of skin contact : Immediately wash thoroughly with plenty of water, apply sterile dressings, consult a skin specialist. 

In case of eye contact : Immediately wash affected eyes for at least 15 minutes under running water with eyelids held open, consult an eye specialist. 

If swallowed : Rinse mouth immediately and then drink plenty of water, seek medical attention. 

Most important symptoms and effects, both acute and delayed : Nausea 
Vomiting 
Diarrhea 
Headache 
May cause an allergic skin reaction. 

Notes to physician : Observe the summary of product characteristics of proprietary
medicinal products

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Water
Alcohol-resistant foam
Carbon dioxide (CO2)

Specific hazards during fire-fighting: In case of fire and/or explosion do not breathe fumes.
Can be released in case of fire:
Carbon oxides
Nitrogen oxides (NOx)
Hydrogen chloride gas
Sulphur oxides

Further information: Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Wear personal protective equipment.
Ensure adequate ventilation.
Never return spills in original containers for re-use.

Environmental precautions: Do not flush into surface water or sanitary sewer system.

Methods and materials for containment and cleaning up: Wear personal protective equipment.
Clean-up methods - large spillage
Dampen, pick up mechanically and dispose of.
Clean-up methods - small spillage
Use approved industrial vacuum cleaner for removal.
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion: No special protective measures against fire required.

Advice on safe handling: Provide sufficient air exchange and/or exhaust in work rooms.
Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces.
Minimize dust generation and accumulation.
Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Breathing must be protected when large quantities are decanted without local exhaust ventilation. Keep container closed when not in use.

Conditions for safe storage:
- Store in original container.
- Protect from heat and direct sunlight.
- Jointless smooth floor
- Keep container tightly closed.

Materials to avoid:
- Keep away from food, drink and animal feedingstuffs.
- Advice on Segregation

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>Basis</th>
<th>Factor</th>
<th>Category</th>
<th>Values</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-[2-[[5-[(Dimethylamino)methyl][fururyl]thio]ethyl]-n'-methyl-2-nitrovinylidenediamine hydrochloride 66357-59-3</td>
<td>ECL</td>
<td></td>
<td>2</td>
<td>279 µg/m3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BIPC</td>
<td></td>
<td>1a</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ECL (BIPI Exposure Control Limit)

Contains no substances with occupational exposure limit values.

**Engineering measures**
- Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Use only appropriately classified electrical equipment and powered industrial trucks.

**Personal protective equipment**

Respiratory protection
- Use breathing apparatus if exposed to vapours/dust/aerosol. half mask (EN 140) particle filter P1

Hand protection Material
- Chemical resistant gloves made of butyl rubber or nitrile rubber category III according to EN 374.

Directive
- Protective gloves against chemicals and micro-organisms

Eye protection
- Safety glasses with side-shields

Skin and body protection
- Laboratory: laboratory coat; factory: disposable Overall.

Protective measures
- Handle in accordance with good industrial hygiene and safety
practice. Do not breathe dust. Avoid contact with skin, eyes and clothing. Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.

Hygiene measures: General industrial hygiene practice. Wash hands and face before breaks and immediately after handling the product. Keep working clothes separately.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/range</td>
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</tr>
<tr>
<td>Boiling point/boiling range</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit</td>
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</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density</td>
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</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility</td>
</tr>
<tr>
<td></td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Auto-ignition temperature : No data available

Decomposition temperature : No decomposition if stored and handled as prescribed/indicated.

Viscosity
   Viscosity, dynamic : Not applicable

Explosive properties : No data available

Oxidizing properties : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : No decomposition if stored and applied as directed.

Possibility of hazardous reactions : No data available

Conditions to avoid : No data available

Incompatible materials : Strong oxidizing agents

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
   Method: Calculation method

Components:

Ranitidine hydrochloride:
   Acute oral toxicity : LD50 (Rat): = 4,190 mg/kg
                        LD50 (Mouse): = 1,100 mg/kg
   Acute inhalation toxicity : Remarks: No data available
   Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation
Not classified based on available information.

Components:

Ranitidine hydrochloride:
   Remarks: No data available
Serious eye damage/eye irritation
Not classified based on available information.

Components:
Ranitidine hydrochloride: Remarks: No data available

Respiratory or skin sensitisation
Skin sensitisation: May cause an allergic skin reaction.
Respiratory sensitisation: Not classified based on available information.

Components:
Ranitidine hydrochloride: Assessment: May cause sensitisation by skin contact. Result: Sensitising Remarks: May cause an allergic skin reaction.

Germ cell mutagenicity
Not classified based on available information.

Components:
Ranitidine hydrochloride: Genotoxicity in vitro: Test Type: Ames-test Result: negative

Genotoxicity in vivo: Remarks: No data available

Carcinogenicity
Not classified based on available information.

Components:
Ranitidine hydrochloride: Remarks: No data available

IARC No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
Not classified based on available information.

STOT - single exposure
Not classified based on available information.
SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity
Components:
Ranitidine hydrochloride:  
Toxicity to fish: Remarks: No data available
Toxicity to daphnia and other aquatic invertebrates: Remarks: No data available
Toxicity to algae: Remarks: No data available
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): Remarks: No data available

Persistence and degradability
No data available

Bioaccumulative potential
Components:
Ranitidine hydrochloride:  
Partition coefficient: n-octanol/water: Remarks: No data available

Mobility in soil
Product:
Distribution among environmental compartments: Remarks: No data available

Other adverse effects
Product:
Ozone-Depletion Potential:  
Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances  
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Components:
Ranitidine hydrochloride:  
Additional ecological infor-
SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents. Uncontaminated packaging can be recycled.

SECTION 14. TRANSPORT INFORMATION

International Regulation
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know Act

SARA 311/312 Hazards : Acute Health Hazard
SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.
SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act
This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B). This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61). This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F). This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCOMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act
This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A. This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3. This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307.

Massachusetts Right To Know
No components are subject to the Massachusetts Right to Know Act.

**Pennsylvania Right To Know**
- Non-hazardous galenic excipients: Not Assigned
- Ranitidine hydrochloride: 66357-59-3

**New Jersey Right To Know**
- Non-hazardous galenic excipients: Not Assigned
- Ranitidine hydrochloride: 66357-59-3

**California Prop 65**
- This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

### SECTION 16. OTHER INFORMATION

**Further information**

**NFPA:**
- Flammability: 1
- Health: 0
- Instability: 0

**HMIS III:**
- HEALTH: 0
- FLAMMABILITY: 1
- PHYSICAL HAZARD: 0

Vertical lines in the left hand margin indicate an amendment from the previous version.

Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

Sources of key data used to compile the Safety Data Sheet: The specifications are based on own tests and/or literature data.

Revision Date: 06/03/2015

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 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.