Section 1. Product Identification and Uses

<table>
<thead>
<tr>
<th>Common/Trade name</th>
<th>Chemical name</th>
<th>Chemical formula</th>
<th>Chemical family</th>
<th>Material uses</th>
<th>Supplier</th>
<th>Manufacturer</th>
<th>Emergency phone</th>
<th>DIN</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>CI#</th>
<th>DSL#</th>
<th>CAS#</th>
<th>Code</th>
<th>Molecular weight</th>
<th>Chemical structure</th>
<th>Covered by Food &amp; Drug Act and therefore not regulated under WHMIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not available.</td>
<td>Not on the DSL list.</td>
<td>Not applicable.</td>
<td>RANID0FAPO</td>
<td>Not applicable.</td>
<td>Not applicable.</td>
<td></td>
</tr>
</tbody>
</table>

Section 2. Hazards Identification

Potential Acute Health Effects
Not expected to be hazardous under normal handling conditions.

Potential Chronic Health Effects
Possible hypersensitization.

WHMIS
WHMIS CLASS D-2B: Material causing other toxic effects (TOXIC).

Remark
Covered by Food & Drug Act and therefore not regulated under WHMIS.

Continued on Next Page
**Section 3. First Aid Measures**

**Eye contact**
Flush with copious quantities of water. If irritation persists, obtain medical advice.

**Skin contact**
Not expected to result in hazardous effects.

**Hazardous skin contact**
Flush with copious amounts of water. Seek medical attention if irritation persist.

**Slight inhalation**
Not expected to result in hazardous effects.

**Hazardous inhalation**
Remove from exposure. Persons developing serious hypersensitivity reactions must receive immediate medical attention. If not breathing give artificial respiration (use protective mask with one-way valve). If breathing is difficult give oxygen.

**Slight ingestion**
Not expected to be hazardous. It is good practice to rinse mouth thoroughly with water and drink a cup of water to minimize discomfort.

**Hazardous ingestion**
Never give anything by mouth if victim is rapidly losing consciousness, or is unconscious or convulsing. Rinse mouth thoroughly with water. If breathing is difficult, give oxygen. If breathing has stopped, trained personnel should begin artificial respiration, or if the heart has stopped, cardiopulmonary resuscitation (CPR) immediately. Seek medical attention.

Treatment of histamine H2-receptor antagonist overdose is symptomatic and supportive and may include the following:
1. Administer activated charcoal as slurry.
2. Perform gastric lavage soon after ingestion (within one hour).
3. For seizures, treat with intravenous diazepam or lorazepam. Consider phenobarbital if seizures recur.
4. For bradycardia, treat with atropine.
5. For ventricular arrhythmias - Treat with lidocaine. (USP DI and Meditext 2006)

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**Section 4. Hazardous Ingredients**

<table>
<thead>
<tr>
<th>Name</th>
<th>CAS #</th>
<th>% (w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranitidine hydrochloride</td>
<td>66357-59-3</td>
<td>50-70</td>
</tr>
</tbody>
</table>

**Toxicity values of the hazardous ingredients**
Refer to Sec. 11.

**TLV**
Not established.

---

**Section 5. Fire Fighting Measures**

**The product is:**
Combustible.

**Autoignition temperature**
Not available.

**Fire degradation products**
These products are carbon oxides (CO, CO2), nitrogen oxides (NO, NO2...), sulfur oxides (SO2, SO3...).

**Flash points**
Not applicable.

**Flammable limits**
Not available.

**Fire extinguishing procedures**
Extinguisher media: water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials. Special fire fighting procedures: As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing.

**Flammability**
Emits toxic fumes under fire conditions.

**Remark**
No additional remark.

**Risks of explosion**
Risks of explosion of the product in presence of mechanical impact: No.
Risks of explosion of the product in presence of static discharge: No.

**Remark**
No additional remark.
Section 6. Accidental Release Measures

**Spill and leak**
Vacuum or sweep up spillage. Avoid dust. Place spillage into an appropriate labeled waste disposal container. Wash contaminated clothing before reuse. Ventilate area and wash spill site. Follow appropriate Safe Work Practices.

**Protective Clothing Pictograms in case of large spill and/or high exposure levels**

**Protective clothing in case of large spill**

Section 7. Handling and Storage

**Precautions**
In case of insufficient ventilation, wear suitable respiratory equipment. Avoid breathing dust. Wash thoroughly after handling.

**Storage**
Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F). Store in a dry place. Protect from light. Dispense in a tight, light-resistant container.

Section 8. Exposure Controls/Personal Protection

**Engineering Controls**
Exposure to this material can be controlled in many ways. The measures appropriate for a particular worksite depend on how this material is used and on the extent of exposure. This general information can be used to help develop specific control measures. Ensure that control systems are properly designed and maintained. Comply with occupational, environmental, fire, and other applicable regulations. Engineering methods to control hazardous conditions are preferred. Methods include mechanical (local exhaust) ventilation, process or personnel enclosure and control of process conditions. Administrative controls and personal protective equipment may also be required. Supply sufficient replacement air to make up for air removed by exhaust system.

**Personal Protection**
Covering uniform. Gloves.

**Protective Clothing (Pictograms)**

PERSONAL PROTECTIVE EQUIPMENT/RESPIRATORY PROTECTION GUIDELINES:
Under normal work conditions, the use of personal protective equipment is not expected to be required. However major spills should require the use of designated personal protective equipment. Have appropriate equipment available for use in emergencies such as spills or fire.

If the physical state of the finished product is altered by crushing, grinding or breakage, appropriate PPE may be required including half facepiece Air Purifying Respirator with combination particulate/organic vapour cartridges.

The respirator use limitations specified by the approving agency and the manufacturer must be observed.

EYE/FACE PROTECTION: Not required under normal working conditions.

SKIN PROTECTION: The use of nitrile gloves is required for Good Manufacturing Practices (GMP) compliance.

RESISTANCE OF MATERIALS FOR PROTECTIVE CLOTHING:
Resistance of specific materials can vary from product to product. Evaluate resistance under conditions of use and maintain clothing carefully.

EXPOSURE CONTROLS/PERSONAL PROTECTION COMMENTS:
Remove contaminated clothing promptly. Launder before rewear. Inform laundry personnel of contaminant's hazards. Do not eat, drink or smoke in work areas. Wash hands thoroughly after handling this material. Maintain good housekeeping.

Continued on Next Page
## Section 9. Physical and Chemical Properties

| Physical state and appearance | 150 mg: round, white to off-white, biconvex, film-coated, unscored tablets, engraved “APO” and “RAN” over “150” on the other side.  
|  | 300 mg: round, white to off-white capsule shaped biconvex, film-coated unscored tablets, engraved “APO” and “RAN 300” on the other side. |
| pH | Not available. |
| Odor threshold | Not available. |
| Taste | Not available. |
| Odor | Not available. |
| Volatility | Not applicable. |
| Melting point/Freezing point | Not available. |
| Boiling point | Not applicable. |
| Specific gravity | Not available. |
| Vapor density | Not applicable. |
| Vapor pressure | Not applicable. |
| Partition Coefficient | Not available. |
| Ionicity (surface active agent) | Not available. |
| Critical temperature | Not available. |
| Instability temperature | Not available. |
| Conditions of instability | No additional remark. |
| Dispersion properties | See solubility. |
| Evaporation rate | Not available. |
| Solubility | Soluble in water. |

## Section 10. Stability and Reactivity

| Stability | The product is stable. |
| Hazardous decomp. products | These products are halogenated compounds, hydrogen chloride. |
| Degradability | Not available. |
| Corrosivity | Not corrosive. |
| Remark | No additional remark. |
| Reactivity/Incompatibility | Avoid exposure to light and moisture. |
| Remark | No additional remark. |
## Section 11. Toxicological Information

<table>
<thead>
<tr>
<th>Routes of entry</th>
<th>As the product is a solid dosage form, the major route of entry is ingestion. Other routes of entry, including inhalation, skin and eye contact may occur only under certain circumstances.</th>
</tr>
</thead>
</table>
| **Toxicity data** | **Ranitidine:**  
RTECS#: KM6556500  
TDLo: 87 mg/kg/4D intermittent (oral-man)  
LD50: 4190 mg/kg (oral-rat)  
LD50: 1100 mg/kg (oral-mouse)  

**Remark**  
No additional remark. |
| **Long-term effects** | Possible hypersensitization.  
Target organs: Gastrointestinal system.  
Carcinogenicity: Not listed by IARC, NTP, ACGIH, or OSHA.  
There was no indication of tumorigenic or carcinogenic effects in life-span studies in mice and rats at dosages up to 2000 mg/kg per day.  
Reproductive Toxicity: In a dominant lethal assay, a single oral dose of 1000 mg/kg to male rats was without effect on the outcome of two matings per week for the next 9 weeks.  
Teratogenicity: Studies in rats and rabbits at doses of 800 and 400 mg/kg have not shown that ranitidine impairs fertility or causes adverse effects on the fetus. Pregnancy Category B.  
Mutagenicity: Ranitidine was not mutagenic in standard bacterial tests (Salmonella, Escherichia coli). Ranitidine was not mutagenic in a dominant lethal assay at a dose of 1000 mg/kg in male rats.  

**Remark**  
Medical conditions aggravated by exposure:  
Hypersensitivity to material, compromised immune system, history of acute porphyria, and impaired liver or kidney function.  
Cross sensitivity: Persons sensitive to one of the histamine H2-receptor antagonists may be sensitive to this material as well. |
| **Short-term effects and Signs & Symptoms of overexposure** | The usual oral adult dose of ranitidine hydrochloride is 150 mg two times a day or 300 mg at bedtime.  
Adverse effects may include: Headache, blurred vision, constipation or diarrhea, nausea or vomiting, abdominal or muscle pain, dizziness, drowsiness or tiredness, loss of appetite, trouble sleeping, yellow skin or eyes, blistering, peeling, or red skin rash, hair loss, decreased sexual desire or ability, unusual bleeding or bruising, swelling of breasts or breast soreness (both males and females), uneven heartbeat.  
Possible allergic reaction to material if inhaled, ingested or in contact with skin.  

**Remark**  
The above adverse effects are based on clinical studies. |

## Section 12. Ecological Information

**Ecological Information** Not available.

## Section 13. Disposal Considerations

**Waste Disposal** For internal Apotex waste disposal: Collect in sealed containers and place in appropriate labeled pharmaceutical solid waste class 261N.  
For external waste disposal: Follow all appropriate safe work procedures and federal, provincial and local regulations for disposal. Use only licensed disposal and waste hauling companies.

## Section 14. Transport Information TDG, IATA, IMDG

**Not controlled under TDG (Canada).**

**UN** Not applicable (PIN and PG).  
**Special Provisions for Transport** Not applicable.
Section 15. Other Regulatory Information and Pictograms

USA Classifications

**NATIONAL FIRE PROTECTION ASSOCIATION (NFPA) HAZARD INDEX**

- NFPA-HEALTH-blue: 1-Slightly hazardous to health.
- NFPA-FLAMMABILITY-red: 1-Materials that must be preheated before ignition can occur.
- NFPA-REACTIVITY-yellow: 0-Normally stable.

<table>
<thead>
<tr>
<th>National Fire Protection Association (U.S.A.)</th>
<th>Fire Hazard</th>
<th>Reactivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Hazard</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Specific Hazard

Hazardous Material Information System (U.S.A.)

HCS (Hazardous Communication System) (OHS, U.S.A.)

Not an HCS controlled material in USA.

DOT (Department of Transportation) (U.S.A) (Pictograms)

Not a DOT controlled material (United States).

European Classifications

DSCL (Dangerous Substances Classifications) (Europe) (Pictograms)

DSCL Risk (R) and Safety (S) Phrases

R33- Danger of cumulative effects.

ADR (European Agreement of Dangerous goods by Road) (Pictograms)

Not controlled under ADR (Europe).

Other Regulations

Not available.

Section 16. Other Information

References

The Merck Index, twelfth edition
PDR Electronic Library
HSBD & RTECS Database
MSDS:

Validation date:
(year.month)

United States Pharmacopeial Convention, Inc.
12601 Twinbrook Parkway
Rockville, MD 20852 USA
(301) 881-0666

Continued on Next Page
Other Special Considerations

**SAMPLING AND ANALYSIS:**
Use appropriate instrumentation and sampling strategy (location, timing, duration, frequency, and number of samples). Interpretation of the sampling results is related to these variables and the analytical method.

Validated on 03/13/2008.

Printed 03/13/2008.

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