SECTION 1 - CHEMICAL PRODUCT & COMPANY IDENTIFICATION

Pfizer Consumer Healthcare
Pfizer Inc
201 Tabor Road
Morris Plains, New Jersey 07950

Emergency telephone +1-973-385-2000
Hours of operation 24 hours

Product name Zantac® 75
Synonyms Ranitidine Tablets 75 mg
Therapeutic use Relief and prevention of heartburn
Description Pink tablets

SECTION 2 - COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranitidine Hydrochloride*</td>
<td>66357-59-3</td>
<td>84 mg/tablet</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(56%)**</td>
</tr>
<tr>
<td>Microcrystalline cellulose*</td>
<td>9004-34-6</td>
<td>Trade secret</td>
</tr>
<tr>
<td>Magnesium stearate*</td>
<td>557-04-0</td>
<td>Trade secret</td>
</tr>
<tr>
<td>Opadry Pink YS-1-1441-G</td>
<td>Not determined</td>
<td>Trade secret</td>
</tr>
<tr>
<td>Hydroxypropyl Methylcellulose</td>
<td>9004-65-3</td>
<td>Trade secret</td>
</tr>
<tr>
<td>Titanium dioxide*</td>
<td>13463-67-7</td>
<td>Trade secret</td>
</tr>
<tr>
<td>Triacetin</td>
<td>102-76-1</td>
<td>Trade secret</td>
</tr>
<tr>
<td>Synthetic red iron oxide</td>
<td>Not assigned</td>
<td>Trade secret</td>
</tr>
</tbody>
</table>

*Hazardous

Note: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

** 84 mg Ranitidine Hydrochloride is equivalent to 75 mg/tablet of Ranitidine HCl

SECTION 3 - HAZARDS IDENTIFICATION

Signal word WARNING!
Statements of hazard MAY CAUSE ALLERGIC SKIN REACTION
MAY CAUSE ALLERGIC RESPIRATORY REACTION
Eye effects Dust may cause irritation (based on components).
Skin effects May cause allergic skin reaction (Based on components). Dust may cause irritation.
SECTION 3 - HAZARDS IDENTIFICATION

Inhalation effects
Occupational exposure to dust may cause irritation and allergic respiratory reaction. However, inhalation is not an expected route of exposure except in the workplace. An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).

Ingestion effects
See 'Known clinical effects and 'Other potential health effects', below.

Known clinical effects
Adverse effects most commonly reported in clinical use include headache, tiredness, dizziness, mild GI disturbance, and transient changes in liver function tests. There have been rare reports of changes to heart rate, atrioventricular block, premature ventricular beats, blood count changes, skin rashes, and hypersensitivity reactions.

Other potential health effects
Occupational exposure has indicated that ranitidine is a skin sensitizer. Occupational exposure has resulted in rhinitis, conjunctivitis, dry irritable cough, nasal congestion, sneezing, and wheezing. Based on these findings it has been concluded that ranitidine is capable of causing occupational asthma.

Additional data
For a more detailed discussion of potential health hazards and toxicity see Section 11.

NOTE:
This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

SECTION 4 - FIRST AID MEASURES

Eyes
Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin
Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention.

Inhalation
Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

Ingestion
Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

SECTION 5 - FIRE FIGHTING MEASURES

Fire fighting instructions
Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Ranitidine HCl may decompose exothermically at temperatures in excess of 70°C.
SECTION 5 - FIRE FIGHTING MEASURES  ... continued

Extinguishing media  Water, dry powder or foam extinguishers are recommended.
Flash point  Not applicable
Hazardous combustion products  No data available

SECTION 6 - ACCIDENTAL RELEASE MEASURES

General  Review Sections 3, 8 and 12 before proceeding with clean up.
Small spill  Wipe up with a damp cloth and place in container for disposal. Avoid generating airborne dust. Clean spill area thoroughly.
Large spill  Contain the source of the spill or leak if it is safe to do so. Spills should be handled by vacuuming or wet mopping. Avoid brush sweeping and generation of airborne dust.

SECTION 7 - HANDLING AND STORAGE

General handling  If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.
Storage conditions  Store as directed by product packaging.
Temperature range for storage  36 - 86°F

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Compound</th>
<th>Issuer</th>
<th>Type</th>
<th>OEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td>OSHA</td>
<td>TWA-8 Hr</td>
<td>5 mg/m³ (respirable fraction)</td>
</tr>
<tr>
<td></td>
<td>OSHA</td>
<td>TWA-8 Hr</td>
<td>15 mg/m³ (total dust)</td>
</tr>
<tr>
<td></td>
<td>ACGIH</td>
<td>TWA-8 Hr</td>
<td>10 mg/m³ (total dust)</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>ACGIH</td>
<td>TWA-8 Hr</td>
<td>10 mg/m³ (stearates)</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>ACGIH</td>
<td>TWA-8 HR</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>OSHA</td>
<td>TWA-8 HR</td>
<td>15 mg/m³ (total dust)</td>
</tr>
</tbody>
</table>

Exposure information  The exposure limit(s) listed for solid components are only relevant if dust may be generated.
Ventilation  Engineering controls should be used as the primary means to control exposures. Local and general ventilation should be used as necessary, when handling this material in bulk. For laboratory use, handle in a lab hood.
Eye protection  Wear safety glasses or goggles.
SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Skin protection
Protective coveralls should be worn. The sleeves should either be taped or have gloves worn over them to prevent material from contacting the skin.

Hand protection
Wear rubber or other impervious gloves.

Respiratory protection
If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical form: Tablet
Color: Pink
pH: No data available
Melting point: No data available
Water solubility: No data available
Solvent solubility: No data available

SECTION 10 - STABILITY AND REACTIVITY

Reactivity
Stable under normal conditions of use.

Conditions to avoid
Avoid excessive heat. (Temperatures above 70°C may result in exothermic decomposition.)

Incompatibilities
None known

Hazardous polymerization
Will not occur

SECTION 11 - TOXICOLOGY INFORMATION

Acute toxicity

<table>
<thead>
<tr>
<th>Compound</th>
<th>Type</th>
<th>Route</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranitidine Hydrochloride</td>
<td>LD₅₀</td>
<td>Oral</td>
<td>Rat</td>
<td>&gt;1000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD₅₀</td>
<td>Oral</td>
<td>Mouse</td>
<td>&gt;1000 mg/kg</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>LD₅₀</td>
<td>Oral</td>
<td>Rat</td>
<td>&gt;5000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD₅₀</td>
<td>Dermal</td>
<td>Rabbit</td>
<td>&gt;2000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Irritation</td>
<td>Ocular</td>
<td>Rabbit</td>
<td>Non-irritating</td>
</tr>
<tr>
<td></td>
<td>Irritation</td>
<td>Dermal</td>
<td>Rabbit</td>
<td>Non-irritating</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>LC₅₀/₁H</td>
<td>Inhalation</td>
<td>Rat</td>
<td>&gt;2000 mg/m³</td>
</tr>
<tr>
<td></td>
<td>LD₅₀</td>
<td>Oral</td>
<td>Rat</td>
<td>&gt;2000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD₅₀</td>
<td>Oral</td>
<td>Rat</td>
<td>&gt;1000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LC₅₀</td>
<td>Inhalation</td>
<td>Rat</td>
<td>&gt;2000 mg/m³</td>
</tr>
</tbody>
</table>
SECTION 11 - TOXICOLOGY INFORMATION  ... continued

Eye  May cause eye irritation based on components.

Skin  May cause skin irritation based on components.

Inhalation  May cause respiratory tract irritation based on components.

Ingestion  See Acute toxicity table. In humans, acute ingestion of up to 18 g has been associated with only transient adverse effects.

Mutagenicity  Ranitidine was negative in vitro and in vivo.

Subchronic effects  Not determined for this product.

Chronic effects/ carcinogenicity  Repeated oral administration of ranitidine to rats has resulted in hyperplastic changes in the stomach, leading to adenoma and carcinoid formation, considered to be secondary to compensatory hypergastrinemia produced by extremely high doses of ranitidine. Ranitidine showed no evidence of carcinogenicity in life-span studies in mice and rats at doses up to 2000 mg/kg/day.

Carcinogen status  None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Reproductive effects  Ranitidine showed no effects on fertility in rats or rabbits.

Teratogenicity  Ranitidine showed no effects on fetal development in rats or rabbits.

Sensitization  Occupational exposure to ranitidine has resulted in skin sensitization and occupational asthma. It was negative topically when tested in guinea pigs but weakly positive in the guinea pig optimization test.

SECTION 12 - ECOLOGICAL INFORMATION

Environmental overview  The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided. See aquatic toxicity data, below:

Aquatic toxicity  The following compounds are evaluated:

<table>
<thead>
<tr>
<th>Compound</th>
<th>Type</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranitidine Hydrochloride</td>
<td>EC50/48h</td>
<td>Daphnia magna</td>
<td>730 mg/l</td>
</tr>
<tr>
<td></td>
<td>EC50/3hr</td>
<td>Activated sludge</td>
<td>&gt;1000 mg/l</td>
</tr>
<tr>
<td></td>
<td>EbC50</td>
<td>Algae</td>
<td>150 mg/l</td>
</tr>
<tr>
<td></td>
<td>ErC50</td>
<td>Algae</td>
<td>&gt;160 mg/l</td>
</tr>
<tr>
<td></td>
<td>EC50/14 day</td>
<td>Rainbow Trout</td>
<td>&gt;100 mg/l</td>
</tr>
</tbody>
</table>

Note: A greater than (>) symbol indicates that toxic effects were not observed at the maximum solubility.
SECTION 13 - DISPOSAL INFORMATION

Disposal procedure
Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this mixture.

SECTION 14 - TRANSPORTATION INFORMATION

General shipping instructions
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

SECTION 15 - REGULATORY INFORMATION

EU Classification
Harmful; Irritant

EU Labelling
Xn

EU Label Pictogram(s)

Risk phrases
R42/43 - May cause sensitization by inhalation and skin contact.

Safety phrases
S22 - Do not breathe dust.
S24 - Avoid contact with skin.
S36 - Wear suitable protective clothing.
S45 - In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).

Canadian WHMIS
Class D, Division 2, Subdivision A
Class D, Division 2, Subdivision B

SECTION 16 - OTHER

Disclaimer
Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate. While Pfizer provides this information in good faith, it does not expressly or impliedly warrant its accuracy.