1. Identification

Product identifier: ZANTAC TABLETS

Other means of identification:

Synonyms: ZANTAC 150 TABLETS * ZANTAC 300 TABLETS * ANTAK TABLETS * AZANTAC TABLETS * SOSTRIL TABLETS * ZANDINE TABLETS * ZANTIC TABLETS * ZINETAC TABLETS * RANITIDINE HYDROCHLORIDE, FORMULATED PRODUCT

Recommended use:

Medicinal Product.

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.

Recommended restrictions:

No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information:

Manufacturer: GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249
Email Address: msds@gsk.com
Website: www.gsk.com

EMERGENCY PHONE NUMBERS - TRANSPORT EMERGENCIES:

US / International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards:

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements:

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC):

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures:

<table>
<thead>
<tr>
<th>Material name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>RANITIDINE HYDROCHLORIDE</td>
<td>AH 19065AB * N,N-DIMETHYL-5-(2-(1-METHYLAMINO-2-NITROVINYLAMINO)ETHYLHYDOTHIOMETHYL)FURFURYL AMINE HYDROCHLORIDE * 54 (GW ACN)</td>
<td>66357-59-3</td>
<td>50 - &lt; 60</td>
</tr>
<tr>
<td>MICROCRYSTALLINE CELLULOSE</td>
<td>AVICEL PH MICROCRYSTALLINE CELLULOSE * ALPHA-CELLULOSE * AVICEL PH101 * AVICEL PH102 * AVICEL PH103 * AVICEL PH105 * AVICEL PH112 * AVICEL PH200 * CELLULOSE (8CI9CI) * CELLULOSE CRYSTALLINE * CELLULOSE, FOOD GRADE * CRYSTALLINE CELLULOSE</td>
<td>9004-34-6</td>
<td>15 - &lt; 45</td>
</tr>
</tbody>
</table>
4. First-aid measures

Inhalation
Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist.

Skin contact
Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.

Eye contact
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion
If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.

Most important symptoms/effects, acute and delayed
Accidental exposure or contact might produce: Irritation of eyes and mucous membranes. Sensitization. Skin irritation. May cause an allergic skin reaction. Dermatitis. Rash. The following adverse effects have been noted with therapeutic use of this material: decrease in heart rate; decrease in blood pressure; temporary decrease in white blood cell counts; coughing; increased mucous secretion.

Indication of immediate medical attention and special treatment needed
Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.

General information
In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions
Move containers from fire area if you can do so without risk.

Specific methods
Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards
No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear protective clothing and equipment consistent with the degree of hazard. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up
Collect and place it in a suitable, properly labelled container for recovery or disposal. Stop the flow of material, if this is without risk. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS. No specific decontamination or detoxification procedures have been identified for this product.

Environmental precautions
For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

7. Handling and storage

Precautions for safe handling
Avoid prolonged exposure. Avoid breaking or crushing tablets.
8. Exposure controls/personal protection

Occupational exposure limits

<table>
<thead>
<tr>
<th>GSK Components</th>
<th>Type</th>
<th>Value</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>RANITIDINE HYDROCHLORIDE (CAS 66357-59-3)</td>
<td>15 MIN STEL</td>
<td>50 mcg/m3</td>
<td>SKIN SENSITISER</td>
</tr>
<tr>
<td></td>
<td></td>
<td>50 mcg/m3</td>
<td>RESPIRATORY SENSITISER</td>
</tr>
<tr>
<td></td>
<td>OHC</td>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)</td>
<td>PEL</td>
<td>5 mg/m3</td>
<td>Respirable fraction.</td>
</tr>
<tr>
<td>TITANIUM DIOXIDE (CAS 13463-67-7)</td>
<td>PEL</td>
<td>15 mg/m3</td>
<td>Total dust.</td>
</tr>
<tr>
<td>TITANIUM DIOXIDE (CAS 13463-67-7)</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td></td>
</tr>
</tbody>
</table>

US. ACGIH Threshold Limit Values

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAGNESIUM STEARATE (CAS 557-04-0)</td>
<td>TWA</td>
<td>10 mg/m3</td>
</tr>
<tr>
<td>MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)</td>
<td>TWA</td>
<td>10 mg/m3</td>
</tr>
<tr>
<td>TITANIUM DIOXIDE (CAS 13463-67-7)</td>
<td>TWA</td>
<td>10 mg/m3</td>
</tr>
</tbody>
</table>

US. NIOSH: Pocket Guide to Chemical Hazards

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)</td>
<td>TWA</td>
<td>5 mg/m3</td>
<td>Respirable.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>10 mg/m3 Total</td>
</tr>
</tbody>
</table>

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

General ventilation normally adequate.

Appropriate engineering controls

Individual protection measures, such as personal protective equipment

Eye/face protection

If contact is likely, safety glasses with side shields are recommended. Eye wash fountain is recommended.

Skin protection

Hand protection

Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

Other

Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection

No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance
<table>
<thead>
<tr>
<th>Physical state</th>
<th>Solid.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form</td>
<td>Tablet.</td>
</tr>
<tr>
<td>Color</td>
<td>Not available.</td>
</tr>
<tr>
<td>Odor</td>
<td>Not available.</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>Not available.</td>
</tr>
<tr>
<td>pH</td>
<td>Not available.</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>Not available.</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not available.</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Upper/lower flammability or explosive limits</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flammability limit - lower (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flammability limit - upper (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Explosive limit - lower (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Explosive limit - upper (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>Not available.</td>
</tr>
<tr>
<td>Vapor density</td>
<td>Not available.</td>
</tr>
<tr>
<td>Relative density</td>
<td>Not available.</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Solubility (water)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Partition coefficient (n-octanol/water)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>Not available.</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>Not available.</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not available.</td>
</tr>
</tbody>
</table>

**10. Stability and reactivity**

**Reactivity**
The product is stable and non-reactive under normal conditions of use, storage and transport.

**Chemical stability**
This product is expected to be stable.

**Possibility of hazardous reactions**
No dangerous reaction known under conditions of normal use.

**Conditions to avoid**
Contact with incompatible materials.

**Incompatible materials**
Strong oxidizing agents. Fluorine.

**Hazardous decomposition products**
None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

**11. Toxicological information**

**Information on likely routes of exposure**

**Inhalation**
Under normal conditions of intended use, this material is not expected to be an inhalation hazard. Prolonged inhalation may be harmful.

**Skin contact**
Health injuries are not known or expected under normal use.

**Eye contact**
Health injuries are not known or expected under normal use.

**Ingestion**
Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.

**Symptoms related to the physical, chemical and toxicological characteristics**
Accidental exposure or contact might produce: Irritation of eyes and mucous membranes. Sensitization. Skin irritation. Dermatitis. May cause an allergic skin reaction. Rash. The following adverse effects have been noted with therapeutic use of this material: decrease in heart rate; decrease in blood pressure; temporary decrease in white blood cell counts; coughing; increased mucous secretion.

**Information on toxicological effects**
## Acute toxicity

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MAGNESIUM STEARATE (CAS 557-04-0)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Rat</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td><strong>MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td>Rabbit</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td>Oral</td>
<td>Rat</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td><strong>RANITIDINE HYDROCHLORIDE (CAS 66357-59-3)</strong></td>
<td></td>
<td></td>
</tr>
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<td><strong>Acute</strong></td>
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<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Rat</td>
<td>&gt; 1000 mg/kg</td>
</tr>
<tr>
<td><strong>TITANIUM DIOXIDE (CAS 13463-67-7)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhalation</td>
<td>Rat</td>
<td>6820 mcg/m3</td>
</tr>
<tr>
<td>Oral</td>
<td>Rat</td>
<td>&gt; 24 g/kg</td>
</tr>
<tr>
<td><strong>Chronic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhalation</td>
<td>LOEC</td>
<td>8.6 mg/m3, 1 years TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophages in lymphoid tissue.</td>
</tr>
<tr>
<td>NOAEC</td>
<td>Rat</td>
<td>250 mg/m3, 2 years Highest dose 5 mg/m3, 24 months</td>
</tr>
<tr>
<td><strong>Subacute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhalation</td>
<td>LOEL</td>
<td>0.1 - 35 mg/m3, 4 weeks Mild macrophage hyperplasia, no change in bronchio-alveolar lavage fluid.</td>
</tr>
<tr>
<td>NOAEC</td>
<td>Guinea pig</td>
<td>26 mg/m3, 3 weeks No evidence of significant inflammation in respiratory tract.</td>
</tr>
<tr>
<td>Oral</td>
<td>NOAEL</td>
<td>100000 ppm, 14 Day Dietary study, highest dose tested.</td>
</tr>
<tr>
<td><strong>Subchronic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhalation</td>
<td>LOEC</td>
<td>3.2 - 20 mg/m3, 8 min Accumulation of TiO2 in macrophages and evidence of pulmonary inflammation.</td>
</tr>
</tbody>
</table>

* Estimates for product may be based on additional component data not shown.

## Skin corrosion/irritation

Health injuries are not known or expected under normal use.

<table>
<thead>
<tr>
<th>Irritation Corrosion - Skin</th>
<th>Species</th>
<th>Result</th>
<th>Literature data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TITANIUM DIOXIDE</strong></td>
<td>Guinea pig</td>
<td>Non-irritant</td>
<td>0, Literature data</td>
</tr>
<tr>
<td>Human</td>
<td>Non-irritant</td>
<td>0, Literature data</td>
<td></td>
</tr>
<tr>
<td>Material Name</td>
<td>Summary</td>
<td>Notes</td>
<td></td>
</tr>
<tr>
<td>---------------</td>
<td>---------</td>
<td>-------</td>
<td></td>
</tr>
<tr>
<td>TITANIUM DIOXIDE</td>
<td>Acute dermal irritation; OECD 404, Literature data</td>
<td>Result: Non-irritant Species: Rabbit</td>
<td></td>
</tr>
<tr>
<td>RANITIDINE HYDROCHLORIDE</td>
<td>Acute dermal irritation; OECD 404, Primary dermal irritation index = 0 Result: Negative Species: Rabbit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAGNESIUM STEARATE</td>
<td></td>
<td>Serious eye damage/eye irritation: Direct contact with eyes may cause temporary irritation.</td>
<td></td>
</tr>
<tr>
<td>RANITIDINE HYDROCHLORIDE</td>
<td>Acute ocular irritation; OECD 405, Kay and Calandra score = 3 Result: Minimal Irritant Species: Rabbit IRE Assay Result: Negative; not likely to be a severe irritant Species: Rabbit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TITANIUM DIOXIDE</td>
<td>OECD 405, Literature data Result: Mild irritant Species: Rabbit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAGNESIUM STEARATE</td>
<td></td>
<td>Eye/Kay and Calandra class - Intact</td>
<td></td>
</tr>
<tr>
<td>RANITIDINE HYDROCHLORIDE</td>
<td>Acute ocular irritation; OECD 405, Kay and Calandra score = 3 Result: Minimal Irritant Species: Rabbit IRE Assay Result: Negative; not likely to be a severe irritant Species: Rabbit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TITANIUM DIOXIDE</td>
<td>OECD 405, Literature data Result: Mild irritant Species: Rabbit</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Respiratory or skin sensitization</td>
<td></td>
</tr>
<tr>
<td>RANITIDINE HYDROCHLORIDE</td>
<td>Occupational exposure Result: Positive Species: Human</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Skin sensitization May cause an allergic skin reaction.</td>
<td></td>
</tr>
<tr>
<td>TITANIUM DIOXIDE</td>
<td>5% Optimisation Test, Literature data - Vehicle: petrolatum Result: Negative Species: Guinea pig Test Duration: 48 hour exposure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RANITIDINE HYDROCHLORIDE</td>
<td>Occupational exposure Result: Positive Species: Human Optimisation Test Result: Weak sensitiser Species: Guinea pig</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TITANIUM DIOXIDE</td>
<td>Patch test, Literature data Result: Negative Species: Human</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.</td>
<td></td>
</tr>
<tr>
<td>RANITIDINE HYDROCHLORIDE</td>
<td>Ames Assay, GLP assay Result: Negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TITANIUM DIOXIDE</td>
<td>Ames, Literature data Result: Negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RANITIDINE HYDROCHLORIDE</td>
<td>Chromosomal Aberration Assay In Vitro, human lymphocytes, Ranitidine bismuth citrate tested Result: Positive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chromosomal Aberration Assay In Vivo; germ cells, Maximum dose = 1000 mg/kg Result: Negative Species: Mouse GreenScreen Assay Result: Negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TITANIUM DIOXIDE</td>
<td>Micronucleus Assay in vitro, CHO cells, Literature data Result: Negative</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Mutagenicity

**TITANIUM DIOXIDE**
- Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data
  - Result: Positive

**RANITIDINE HYDROCHLORIDE**
- Micronucleus Test
  - Result: Negative
  - Species: Rat

- Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay
  - Result: Negative

- SOS/umu Assay
  - Result: Negative

**TITANIUM DIOXIDE**
- Syrian Hamster Embryo (SHE) cell transformation assay
  - Result: Negative

**RANITIDINE HYDROCHLORIDE**
- Unscheduled DNA Synthesis in vivo, Maximum dose = 200 mg/kg
  - Result: Negative
  - Species: Rat

- Organ: Stomach

**TITANIUM DIOXIDE**
- Wil2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data
  - Result: Positive

**RANITIDINE HYDROCHLORIDE**
- Yeast Mutation Assay
  - Result: Negative

Carcinogenicity

Carcinogenic effects are not expected as a result of occupational exposure.

**TITANIUM DIOXIDE**
- 0.5 mg/m³, Literature data
  - Result: Negative
  - Species: Rat
  - Test Duration: 24 months

- 0.72 - 14.8 mg/m³, Literature data
  - Result: Negative
  - Species: Mouse

- 10 - 250 mg/m³, Dietary study - Literature data.
  - Result: Inflammation at all doses with alveolar/bronchiolar adenoma at the highest concentration.
  - Species: Rat
  - Test Duration: 24 months

**RANITIDINE HYDROCHLORIDE**
- 2 year bioassay, Maximum dose = 2000 mg/kg/day
  - Result: Negative
  - Species: Mouse

  - 2 year bioassay, Maximum dose = 2000 mg/kg/day
    - Result: Negative
    - Species: Rat

IARC Monographs. Overall Evaluation of Carcinogenicity

**TITANIUM DIOXIDE** (CAS 13463-67-7)
- 2B Possibly carcinogenic to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
- Not listed.

Reproductive toxicity

Contains no ingredient listed as toxic to reproduction

**Reproductivity**

**RANITIDINE HYDROCHLORIDE**
- Embryo-foetal development - Oral
  - Result: Foetal NOAEL = 100 mg/kg/day (maximum dose);
    Maternal NOAEL = 25 mg/kg/day (decreased weight gain at 50 and 100 mg/kg/day)
  - Species: Rat

- Embryo-foetal development - Oral
  - Result: NOAEL = 100 mg/kg/day (maximum dose)
  - Species: Rabbit
Reproductivity
RANITIDINE HYDROCHLORIDE

Fertility
Result: NOAEL / fertility = 100 mg/kg/day (male) and 200 mg/kg/day (female) (maximum doses)
Species: Rat

Specific target organ toxicity - single exposure
None known.

Specific target organ toxicity - repeated exposure
None known.

Aspiration hazard
Not available.

Chronic effects
Prolonged inhalation may be harmful. Prolonged exposure may cause chronic effects.

Further information
Occupational exposure to the substance or mixture may cause adverse effects.

12. Ecological information

Ecotoxicity
No information is available about the potential of this product to produce adverse environmental effects. The product contains a substance which may cause long-term adverse effects in the environment.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAGNESIUM STEARATE (CAS 557-04-0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fish</td>
<td>EC50</td>
<td>Orange-red killfish (Adult Oryzias latipes)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>130 mg/l, 96 hours</td>
</tr>
<tr>
<td>RANITIDINE HYDROCHLORIDE (CAS 66357-59-3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activated Sludge Respiration</td>
<td>IC50</td>
<td>Residential sludge</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; 1000 mg/l, 3 hours OECD 209</td>
</tr>
<tr>
<td>Algae</td>
<td>EC50</td>
<td>Green algae (Selenastrum capricornutum)</td>
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<tr>
<td></td>
<td></td>
<td>167 mg/l, 72 hours OECD 201</td>
</tr>
<tr>
<td>NOEC</td>
<td></td>
<td>Green algae (Selenastrum capricornutum)</td>
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<tr>
<td></td>
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<td>56 mg/l, 72 hours</td>
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<tr>
<td>Crustacea</td>
<td>EC50</td>
<td>Water flea (Daphnia magna)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>730 mg/l, 48 hours Static test, OECD 202</td>
</tr>
<tr>
<td>NOEC</td>
<td></td>
<td>Water flea (Daphnia magna)</td>
</tr>
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<td>347 mg/l, 48 hours Static test</td>
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<tr>
<td>Fish</td>
<td>EC50</td>
<td>Rainbow trout (Juvenile Oncorhyncus mykiss)</td>
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<tr>
<td></td>
<td></td>
<td>&gt; 112 mg/l, 14 days Flow-through test, OECD 203</td>
</tr>
<tr>
<td>NOEC</td>
<td></td>
<td>Rainbow trout (Juvenile Oncorhyncus mykiss)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>112 mg/l, 14 days Flow-through test</td>
</tr>
<tr>
<td><strong>Chronic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crustacea</td>
<td>LOEC</td>
<td>Water flea (Ceriodaphnia dubia)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100 mg/l, 8 days Static renewal test, EPA 1002</td>
</tr>
<tr>
<td>NOEC</td>
<td></td>
<td>Water flea (Ceriodaphnia dubia)</td>
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<tr>
<td></td>
<td></td>
<td>32 mg/l, 8 days</td>
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<tr>
<td>TITANIUM DIOXIDE (CAS 13463-67-7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crustacea</td>
<td>EC50</td>
<td>Water flea (Daphnia magna)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; 1000 mg/l, 48 hours Static test</td>
</tr>
</tbody>
</table>

* Estimates for product may be based on additional component data not shown.

Persistence and degradability

Photolysis

Half-life (Photolysis-aqueous)
RANITIDINE HYDROCHLORIDE 70 Minutes Measured, Lake water

Half-life (Photolysis-atmospheric)
MAGNESIUM STEARATE 17 Hours Estimated
**Photolysis**

UV/visible spectrum wavelength

- MAGNESIUM STEARATE: 210 nm
- RANITIDINE HYDROCHLORIDE: 313 nm Measured, pH 7

**Hydrolysis**

Half-life (Hydrolysis-neutral)

- RANITIDINE HYDROCHLORIDE: > 1 Years Measured

**Biodegradability**

Percent degradation (Aerobic biodegradation-inherent)

- MAGNESIUM STEARATE: 77 %, 28 days BOD
- RANITIDINE HYDROCHLORIDE: 2 %, 28 days Modified Zahn-Wellens, DOC removal,
  Activated sludge
  43 %, 28 days Modified Zahn-Wellens, primary biodegradation, loss of parent,
  Activated sludge

Percent degradation (Aerobic biodegradation-soil)

- MAGNESIUM STEARATE: 50 %, 13 days
- RANITIDINE HYDROCHLORIDE: 3 - 10 %, 67 days

Percent degradation (Anaerobic biodegradation)

- RANITIDINE HYDROCHLORIDE: 12 %, 35 days

**Bioaccumulative potential**

Partition coefficient n-octanol / water (log Kow)

- RANITIDINE HYDROCHLORIDE: 0.0815

Bioconcentration factor (BCF)

- MAGNESIUM STEARATE: > 9999 Estimated

**Mobility in soil**

Adsorption

- Soil/sediment sorption - log Koc
  - MAGNESIUM STEARATE: 5.86 Estimated
  - RANITIDINE HYDROCHLORIDE: 2.51 - 4.49, pH 5-7

**Mobility in general**

Volutility

- Henry’s law
  - RANITIDINE HYDROCHLORIDE: 0 atm m^3/mol, 24 C Estimated

Distribution

- Octanol/water distribution coefficient log DOW
  - RANITIDINE HYDROCHLORIDE: -1.09, pH 7
  - -2.5, pH 5
  - 0.14, pH 9

**Other adverse effects**

Not available.

13. Disposal considerations

**Disposal instructions**

Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

**Local disposal regulations**

Dispose in accordance with all applicable regulations.

**Hazardous waste code**

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

**Waste from residues / unused products**

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.

**Contaminated packaging**

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

**DOT**

Not regulated as a dangerous good.

**IATA**

Not regulated as dangerous goods.
IMDG
Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

15. Regulatory information

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)
Not listed.

SARA 304 Emergency release notification
Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance
Not listed.

SARA 311/312 Hazardous chemical
No

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
Not regulated.

Safe Drinking Water Act (SDWA)
Not regulated.

US state regulations

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)
Not listed.

US. Massachusetts RTK - Substance List
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)
TITANIUM DIOXIDE (CAS 13463-67-7)

US. New Jersey Worker and Community Right-to-Know Act
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)
TITANIUM DIOXIDE (CAS 13463-67-7)

US. Pennsylvania Worker and Community Right-to-Know Law
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)
TITANIUM DIOXIDE (CAS 13463-67-7)

US. Rhode Island RTK
Not regulated.

US. California Proposition 65
WARNING: This product contains a chemical known to the State of California to cause cancer.

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance
TITANIUM DIOXIDE (CAS 13463-67-7) Listed: September 2, 2011
International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
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<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
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<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
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<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
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<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
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<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
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<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
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<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
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<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s).
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 11-07-2014
Revision date 11-07-2014
Version # 12
Further information This material has not been assessed for HMIS or NFPA ratings.

HMIS® ratings
Health: 2*
Flammability: 1
Physical hazard: 0

NFPA ratings
Health: 2
Flammability: 1
Instability: 0

References GSK Hazard Determination

Disclaimer The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Revision Information This document has undergone significant changes and should be reviewed in its entirety.