SAFETY DATA SHEET

1. Identification

Product identifier VOLIBRIS TABLETS

Other means of identification

Synonyms VOLIBRIS 5 MG TABLETS * VOLIBRIS 10 MG TABLETS * AMBRISENTAN, 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>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<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 (6CI9CI) * CELLULOSE CRYSTALLINE * CELLULOSE, FOOD GRADE * CRYSTALLINE CELLULOSE</td>
<td>9004-34-6</td>
<td>&lt; 25</td>
</tr>
<tr>
<td>AMBRISENTAN</td>
<td>(S)-2-(4,6-DIMETHYL-PYRIMIDIN-2-YLOXY)-3-METHOXY-3,3-DIPHENYLPROPAANOIC ACID * BSF 208075 * GSK1325760</td>
<td>177036-94-1</td>
<td>3.4 - &lt; 7</td>
</tr>
<tr>
<td>MAGNESIUM STEARATE</td>
<td>STEARIC ACID, MAGNESIUM SALT * MAGNESIUM DISTEARATE * DIBASIC MAGNESIUM STEARATE * MAGNESIUM DISTEARATE, PURE</td>
<td>557-04-0</td>
<td>&lt; 1</td>
</tr>
<tr>
<td>TALC</td>
<td>TALCUM, NON-ASBESTOS FORM * TALC * HYDROUS MAGNESIUM SILICATE</td>
<td>14807-96-6</td>
<td>&lt; 1</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. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

**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**
None known. The following adverse effects have been noted with therapeutic use of this material: headache; flushing; dizziness.

**Indication of immediate medical attention and special treatment needed**
No specific antidotes are recommended. 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.

**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. 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**
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.

**Environmental precautions**
Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

**Precautions for safe handling**
Avoid prolonged exposure. Observe good industrial hygiene practices.

**Conditions for safe storage, including any incompatibilities**
Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).
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>AMBRISENTAN (CAS 177036-94-1)</td>
<td>8 HR TWA</td>
<td>20 mcg/m3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OHC</td>
<td>3</td>
<td>REPRODUCTIVE HAZARD</td>
</tr>
<tr>
<td>MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)</td>
<td>OHC</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) 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>
</tbody>
</table>

US. OSHA Table Z-3 (29 CFR 1910.1000)

<table>
<thead>
<tr>
<th>US. OSHA Table Z-3 (29 CFR 1910.1000) Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>TALC (CAS 14807-96-6)</td>
<td>TWA</td>
<td>0.3 mg/m3</td>
<td>Total dust.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.1 mg/m3</td>
<td>Respirable.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>20 mppcf</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.4 mppcf</td>
<td></td>
</tr>
</tbody>
</table>

US. ACGIH Threshold Limit Values

<table>
<thead>
<tr>
<th>US. ACGIH Threshold Limit Values Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAGNESIUM STEARATE (CAS 557-04-0)</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td></td>
</tr>
<tr>
<td>MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td></td>
</tr>
<tr>
<td>TALC (CAS 14807-96-6)</td>
<td>TWA</td>
<td>2 mg/m3</td>
<td>Respirable fraction.</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. NIOSH: Pocket Guide to Chemical Hazards

<table>
<thead>
<tr>
<th>US. NIOSH: Pocket Guide to Chemical Hazards 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>TALC (CAS 14807-96-6)</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td>Total</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 mg/m3</td>
<td>Respirable.</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.

Skin protection

Hand protection

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. 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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. New or expectant mothers might be at greater risk from overexposure. Risk assessments must take this into consideration. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager. This will act as the trigger for individual re-assessment of the employee’s work practices.

9. Physical and chemical properties

Appearance

- **Physical state**: Solid.
- **Form**: Tablet.
- **Color**: Not available.
- **Odor**: Not available.
- **Odor threshold**: Not available.
- **pH**: Not available.
- **Melting point/freezing point**: Not available.
- **Initial boiling point and boiling range**: Not available.
- **Flash point**: Not available.
- **Evaporation rate**: Not available.
- **Flammability (solid, gas)**: Not available.

**Upper/lower flammability or explosive limits**

- **Flammability limit - lower (%)**: Not available.
- **Flammability limit - upper (%)**: Not available.
- **Explosive limit - lower (%)**: Not available.
- **Explosive limit - upper (%)**: Not available.

**Vapor pressure**: Not available.

**Vapor density**: Not available.

**Relative density**: Not available.

**Solubility(ies)**

- **Solubility (water)**: Not available.

**Partition coefficient**

- **(n-octanol/water)**: Not available.

**Auto-ignition temperature**: Not available.

**Decomposition temperature**: Not available.

**Viscosity**: Not available.

10. Stability and reactivity

**Reactivity**

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

**Chemical stability**

Material is stable under normal conditions.

**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.

**Skin contact**

Health injuries are not known or expected under normal use. Dust or powder may irritate the skin.
Eye contact

Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.

Ingestion

Health injuries are not known or expected under normal use. May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics

None known.

The following adverse effects have been noted with therapeutic use of this material: headache; flushing; dizziness.

Information on toxicological effects

Acute toxicity

Health injuries are not known or expected under normal use. May be harmful if swallowed.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMBRISSENTAN (CAS 177036-94-1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute Oral</td>
<td>Rat</td>
<td>&gt;= 3160 mg/kg</td>
</tr>
<tr>
<td>LD50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAGNESIUM STEARATE (CAS 557-04-0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute Oral</td>
<td>Rat</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td>LD50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute Dermal</td>
<td>Rabbit</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td>LD50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Rat</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td>LD50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TITANIUM DIOXIDE (CAS 13463-67-7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute Inhalation LC50</td>
<td>Rat</td>
<td>6820 mcg/m3</td>
</tr>
<tr>
<td>Oral LD50</td>
<td>Rat</td>
<td>&gt; 24 g/kg</td>
</tr>
<tr>
<td>Chronic Inhalation LOEC</td>
<td>Rat</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>Subacute Inhalation LOEL</td>
<td>Rat</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 NOAEL</td>
<td>Rat</td>
<td>100000 ppm, 14 Day Dietary study, highest dose tested.</td>
</tr>
<tr>
<td>Subchronic Inhalation LOEC</td>
<td>Rat</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. Prolonged skin contact may cause temporary irritation.

**Irritation Corrosion - Skin**

TITANIUM DIOXIDE

0, Literature data

Result: Non-irritant

Species: Guinea pig

0, Literature data

Result: Non-irritant

Species: Human

Acute dermal irritation; OECD 404, Literature data

Result: Non-irritant

Species: Rabbit

**AMBRISENTAN**

Reconstituted Human Epidermis (RHE)

Result: Negative - Not likely to be a significant irritant.

**Irritation Corrosion - Skin: P.I.I. value**

MAGNESIUM STEARATE

0

**Serious eye damage/eye irritation**

Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.

**Eye**

TITANIUM DIOXIDE

OECD 405, Literature data

Result: Mild irritant

Species: Rabbit

AMBRISENTAN

Reconstituted Human Corneal Epithelium (HCE)

Result: Negative; not likely to be a severe irritant

**Eye / Kay and Calandra class - Intact**

MAGNESIUM STEARATE

4

Recovery Period: 2 days

**Respiratory or skin sensitization**

**Respiratory sensitization**

Not available.

**Skin sensitization**

Health injuries are not known or expected under normal use.

**Sensitization**

TITANIUM DIOXIDE

5 % Optimisation Test, Literature data - Vehicle: petrolatum

Result: Negative

Species: Guinea pig

Test Duration: 48 hour exposure

AMBRISENTAN

OECD 429 / Local Lymph Node Assay, Maximum concentration = 50%; vehicle = DMF

Result: Negative

Species: Mouse

TITANIUM DIOXIDE

Patch test, Literature data

Result: Negative

Species: Human

**Germ cell mutagenicity**

Health injuries are not known or expected under normal use. No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

**Mutagenicity**

AMBRISENTAN

Ames Assay, GLP assay

Result: Negative

TITANIUM DIOXIDE

Ames, Literature data

Result: Negative

AMBRISENTAN

Chromosomal Aberration Assay In Vitro

Result: Positive

TITANIUM DIOXIDE

Micronucleus Assay in vitro, CHO cells, Literature data

Result: Negative

Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data

Result: Positive

AMBRISENTAN

Micronucleus Assay, GLP assay

Result: Negative

Species: Rat

TITANIUM DIOXIDE

Syrian Hamster Embryo (SHE) cell transformation assay

Result: Negative

AMBRISENTAN

Unscheduled DNA Synthesis in vivo

Result: Negative

Species: Rat
Mutagenicity

TITANIUM DIOXIDE

WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data
Result: Positive

Carcinogenicity

Health injuries are not known or expected under normal use. Contains a material (titanium dioxide) classified as a carcinogen by external agencies. Carcinogenic activity was seen in inhalation studies using laboratory animals. High concentrations or doses administered over an extended period of time were required to produce adverse effects.

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

25000 - 50000 ppm, Dietary study
Result: Negative
Species: Mouse

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

Suspected of damaging fertility or the unborn child.

Reproductivity

AMBRISIENTAN

Embryo-foetal development
Result: Foetal toxicity, malformations in multiple species; endothelin receptor antagonist class effect
Fertility, Male
Result: Testicular toxicity, reduced fertility in mice and rats

Specific target organ toxicity - single exposure
None known.

Specific target organ toxicity - repeated exposure
None known.

Aspiration hazard
Not available.

Chronic effects
Prolonged exposure may cause chronic effects.

Further information
Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

12. Ecological information

Ecotoxicity

Not expected to be harmful to aquatic organisms.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMBRISIENTAN (CAS 177036-94-1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aquatic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Algae</td>
<td>EC50</td>
<td>Algae</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 - 100 mg/l, 96 hours QSAR Estimate</td>
</tr>
<tr>
<td>Crustacea</td>
<td>EC50</td>
<td>Daphnia</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 - 100 mg/l, 48 hours QSAR Estimate</td>
</tr>
<tr>
<td>Fish</td>
<td>EC50</td>
<td>Fish</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 - 100 mg/l, 96 hours QSAR Estimate</td>
</tr>
</tbody>
</table>
Components Test Results

Species

<table>
<thead>
<tr>
<th>Component</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAGNESIUM STEARATE (CAS 557-04-0)</td>
<td>Orange-red killfish (Adult Oryzias latipes) 130 mg/l, 96 hours</td>
</tr>
<tr>
<td>TALC (CAS 14807-96-6)</td>
<td>Zebra fish (Adult Brachydanio rerio) &gt; 100 g/l, 24 hours Static renewal test</td>
</tr>
<tr>
<td>TITANIUM DIOXIDE (CAS 13463-67-7)</td>
<td>Water flea (Daphnia magna) &gt; 1000 mg/l, 48 hours Static test</td>
</tr>
</tbody>
</table>

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

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

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)
TALC (CAS 14807-96-6)
TITANIUM DIOXIDE (CAS 13463-67-7)

US. New Jersey Worker and Community Right-to-Know Act
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)
TALC (CAS 14807-96-6)
TITANIUM DIOXIDE (CAS 13463-67-7)

US. Pennsylvania Worker and Community Right-to-Know Law
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)
TALC (CAS 14807-96-6)
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 (NDSSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
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</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
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</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: 11-05-2014
Revision date: 11-05-2014
Version #: 02

Further information
HMIS® is a registered trade and service mark of the NPCA.

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

NFPA ratings
Health: 2
Flammability: 0
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
Product and Company Identification: Business Units
Composition / Information on Ingredients: Ingredients
Exposure Controls / Personal Protection: Physical & Chemical Properties:
Regulatory Information: United States
GHS: Classification