SAFETY DATA SHEET

XOFLUZA(TM) (Baloxavir Marboxil) Tablets 40mg

SECTION 1. IDENTIFICATION

Product name : XOFLUZA(TM) (Baloxavir Marboxil) Tablets 40mg

Product code : RO719-1686/F13

Common name(s), synonym(s) of the substance : XOFLUZA Film Coated Tablets 40 mg
XOFLUZA F.C. Tablets 40 mg
BS11564, BS11395

Manufacturer or supplier’s details
Company name of supplier : Genentech, Inc.

Address : DNA Way 1
94080 South San Francisco
CA
USA

Telephone : 001-(650) 225-1000
E-mail address : info.sds@roche.com

Emergency telephone : US Chemtrec phone (800)-424-9300

Recommended use of the chemical and restrictions on use
Recommended use : Formulated pharmaceutical active substance
Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Carcinogenicity : Category 1A

GHS label elements
Hazard pictograms :

Signal Word : Danger
Hazard Statements : H350 May cause cancer.
Precautionary Statements : Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
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Response:
P308 + P313 IF exposed or concerned: Get medical advice/attention.

Storage:
P405 Store locked up.

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

<table>
<thead>
<tr>
<th>Substance / Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baloxavir Marboxil</td>
<td>1985606-14-1</td>
<td>15.9</td>
</tr>
<tr>
<td>Lactose-1-Hydrate</td>
<td>64044-51-5</td>
<td>61.9</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>9.0</td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
<td>4.4</td>
</tr>
<tr>
<td>2-Pyrrolidinone, 1-ethenyl-, homopolymer</td>
<td>9003-39-8</td>
<td>4.4</td>
</tr>
<tr>
<td>sodium octadecyl fumarate</td>
<td>4070-80-8</td>
<td>1.3</td>
</tr>
<tr>
<td>Titanium oxide (TiO2)</td>
<td>13463-67-7</td>
<td>&lt; 0.9</td>
</tr>
<tr>
<td>Talc (Mg3H2(SiO3)4)</td>
<td>14807-96-6</td>
<td>0.1</td>
</tr>
<tr>
<td>non hazardous compounds</td>
<td>Not Assigned</td>
<td>2.1</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

General advice: Do not leave the victim unattended.

If inhaled: Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.

In case of skin contact: If on skin, rinse well with water.

In case of eye contact: Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
If eye irritation persists, consult a specialist.

If swallowed: Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Rinse mouth with water.

Most important symptoms and effects, both acute and delayed:
May cause cancer.

Notes to physician:
The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media:
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards during fire fighting:
Do not allow run-off from fire fighting to enter drains or water courses.

Hazardous combustion products:
In case of fire hazardous decomposition products may be produced such as:
- Hydrogen fluoride
- Sulfur oxides
- Nitrogen oxides (NOx)
- Carbon 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.

Special protective equipment for fire-fighters:
Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
Avoid dust formation.

Environmental precautions:
Prevent product from entering drains.

Methods and materials for containment and cleaning up:
Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion:
Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling:
For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area.

Conditions for safe storage:
Containers which are opened must be carefully resealed and
kept upright to prevent leakage. Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions: See label, package insert or internal guidelines

Materials to avoid: No materials to be especially mentioned.

Storage temperature: Protected from heat and light

Further information on storage stability: No decomposition if stored and applied as directed.

Packaging material: Suitable material: Blister packages, Stainless steel, glass bottles

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baloxavir Marboxil</td>
<td>1985606-14-1</td>
<td>IOEL</td>
<td>0.0025 mg/m3</td>
<td>Roche Industrial Hygiene Committee (RIHC)</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m3</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m3</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>15 mg/m3</td>
<td>OSHA P0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>5 mg/m3</td>
<td>OSHA P0</td>
</tr>
<tr>
<td>Titanium oxide (TiO2)</td>
<td>13463-67-7</td>
<td>TWA (total dust)</td>
<td>15 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m3</td>
<td>OSHA P0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m3 (Titanium dioxide)</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Talc (Mg3H2(SiO3)4)</td>
<td>14807-96-6</td>
<td>TWA (Dust)</td>
<td>20 Million particles per cubic foot</td>
<td>OSHA Z-3</td>
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<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>2 mg/m3</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
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Engineering measures: No data available

Personal protective equipment
Respiratory protection: No personal respiratory protective equipment normally required.

Hand protection
Material: Protective gloves

Remarks: Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.

Eye protection: Safety glasses

Skin and body protection: Protective suit

Hygiene measures: Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: tablet
Color: white, light yellow
Odor: Not applicable
Odor Threshold: Not applicable
pH: Not applicable
Melting point/range: No data available
Boiling point/boiling range: No data available
Evaporation rate: No data available
Self-ignition: No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapor pressure: No data available
Relative vapor density: Not applicable
### Relative Density
Relative density: No data available

### Solubility
- **Water solubility**: No data available
- **Solubility in other solvents**: No data available

### Partition Coefficient
- **n-octanol/water**: No data available

### Autoignition Temperature
Autoignition temperature: No data available

### Decomposition Temperature
Decomposition temperature: No data available

### Viscosity
- **Viscosity, dynamic**: Not applicable
- **Viscosity, kinematic**: Not applicable

### Explosive Properties
Explosive properties: No data available

### Oxidizing Properties
Oxidizing properties: No data available

### SECTION 10. STABILITY AND REACTIVITY

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

**Chemical Stability**: Stable under normal conditions.

**Possibility of Hazardous Reactions**
Stable under recommended storage conditions.
No hazards to be specially mentioned.

**Incompatible Materials**: No data available

**Hazardous Decomposition Products**: No data available

### 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

**Acute Inhalation Toxicity**
Acute toxicity estimate: 95.26 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute toxicity estimate: 118.18 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

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

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

Components:

**Baloxavir Marboxil:**
Acute oral toxicity: LD50 Oral (Rat): > 2,000 mg/kg

**Cellulose:**
Acute oral toxicity: LD50 Oral (Rat): > 5,000 mg/kg
Acute dermal toxicity: LD50 Dermal (Rabbit): > 2,000 mg/kg

**Titanium oxide (TiO2):**
Acute oral toxicity: LD50 (Rat): > 7,500 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 6.82 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity: LD50 (Rabbit): > 10,000 mg/kg

**Skin corrosion/irritation**
Not classified based on available information.

**Skin sensitization**
Not classified based on available information.

**Respiratory or skin sensitization**

**Respiratory sensitization**
Not classified based on available information.
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Date of first issue: 02-20-2000

Germ cell mutagenicity
Not classified based on available information.

Components:

Baloxavir Marboxil:
Genotoxicity in vitro: Method: Mutagenicity (Salmonella typhimurium - reverse mutation assay)
Result: negative
Method: OECD Test Guideline 473
Result: negative

Genotoxicity in vivo: Method: OECD Test Guideline 474
Result: negative

Carcinogenicity
May cause cancer.

Components:

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

IARC
Group 2B: Possibly carcinogenic to humans
Titanium oxide (TiO2) 13463-67-7

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
Known to be human carcinogen
Talc (Mg3H2(SiO3)4) 14807-96-6
(Silica, Crystalline (Respirable Size))

Reproductive toxicity
Not classified based on available information.

Components:

Baloxavir Marboxil:
Effects on fetal development: Species: Rat
Application Route: Oral
Dose: 1000 milligram per kilogram
Duration of Single Treatment: 12 d
Result: No effects on fetal development.

Species: Rabbit
Application Route: Oral
Dose: 100 milligram per kilogram
Duration of Single Treatment: 12 d
Result: No effects on fetal development.
STOT-single exposure
Not classified based on available information.

Components:

Talc (Mg₃H₂(SiO₃)₄):
Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure
Not classified based on available information.

Components:

Baloxavir Marboxil:
Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Talc (Mg₃H₂(SiO₃)₄):
Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Repeated dose toxicity

Components:

Baloxavir Marboxil:
Species : Rat
NOAEL : mg/kg bw/day, 2000
Application Route : Oral
Exposure time : 2 Weeks
Remarks : Subacute toxicity

Aspiration toxicity
Not classified based on available information.

Components:

Talc (Mg₃H₂(SiO₃)₄):
No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Baloxavir Marboxil:
Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10.6 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
GLP: yes
Remarks: average measured concentration
NOEC (Danio rerio (zebra fish)): 10.6 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
GLP: yes  
Remarks: average measured concentration

**Toxicity to daphnia and other aquatic invertebrates** :
EC50 (Daphnia magna (Water flea)): > 17.4 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
GLP: yes  
Remarks: measured initial concentration

NOEC (Daphnia magna (Water flea)): 17.4 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: measured initial concentration

**Toxicity to algae/aquatic plants** :
ErC50 (Desmodesmus subspicatus (green algae)): 9.28 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes  
Remarks: average measured concentration

NOErC (Desmodesmus subspicatus (green algae)): 1.75 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes  
Remarks: average measured concentration

EyC50 (Desmodesmus subspicatus (green algae)): 4.76 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes  
Remarks: average measured concentration

**Toxicity to microorganisms** :
(activated sludge): Exposure time: 14 d  
Method: OECD Test Guideline 301F  
GLP: yes  
Remarks: no adverse influence on substrate biodegradation

**Cellulose:**
Ecotoxicology Assessment
Acute aquatic toxicity : This product has no known ecotoxicological effects.
Chronic aquatic toxicity : This product has no known ecotoxicological effects.

**Titanium oxide (TiO2):**
Toxicity to fish : LC0 (Leuciscus idus (Golden orfe)): > 1,000 mg/l  
Exposure time: 48 h

Toxicity to daphnia and other aquatic invertebrates : EC0 (Daphnia magna (Water flea)): 3 mg/l  
Exposure time: 720 h
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Ecotoxicology Assessment
Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Talc (Mg3H2(SiO3)4):
Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100,000 mg/l
Exposure time: 24 h

Ecotoxicology Assessment
Acute aquatic toxicity : This product has no known ecotoxicological effects.
Chronic aquatic toxicity : This product has no known ecotoxicological effects.
Toxicity Data on Soil : Not expected to adsorb on soil.
Other organisms relevant to the environment : No data available

Persistence and degradability

Components:

Baloxavir Marboxil:
Biodegradability : Result: Not readily biodegradable.
Biodegradation: < 10 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
GLP: yes

Physico-chemical
removability : Method: OECD Test Guideline 301F
Remarks: Not abiotically degradable

Bioaccumulative potential

Components:

Baloxavir Marboxil:
Partition coefficient: n-octanol/water : log Pow: 2.24
Method: calculated, consensus of various QSARs
log Pow: 2.46 (77 °F / 25 °C)
pH: 5
Method: OECD Test Guideline 117
GLP: yes

log Pow: 2.45 (77 °F / 25 °C)
pH: 7
Method: OECD Test Guideline 117
GLP: yes

log Pow: 2.46 (77 °F / 25 °C)
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pH: 9
Method: OECD Test Guideline 117
GLP: yes

Cellulose:
Partition coefficient: n-octanol/water
Remarks: No data available

Titanium oxide (TiO2):
Partition coefficient: n-octanol/water
Remarks: No data available

Talc (Mg3H2(SiO3)4):
Partition coefficient: n-octanol/water
Remarks: No data available

Mobility in soil
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).

Additional ecological information
An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Harmful to aquatic life with long lasting effects.

Components:

Talc (Mg3H2(SiO3)4):
Adsorbed organic bound halogens (AOX)
Remarks: Not applicable

Additional ecological information
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues
The product should not be allowed to enter drains, water courses or the soil.
Can be disposed as waste water, when in compliance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable

Domestic regulation

49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards: Carcinogenicity

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 112 (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 SOCM Intermediate or Final VOC's (40 CFR 60.489).
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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
This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know
Cellulose 9004-34-6

Pennsylvania Right To Know
Lactose-1-Hydrate 64044-51-5
Baloxavir Marboxil 1985606-14-1
Cellulose 9004-34-6
Crosclarmellose sodium 74811-65-7
2-Pyrrolidinone, 1-ethenyl-, homopolymer 9003-39-8

Maine Chemicals of High Concern
Product does not contain any listed chemicals

Vermont Chemicals of High Concern
Product does not contain any listed chemicals

Washington Chemicals of High Concern
Product does not contain any listed chemicals

California Prop. 65
WARNING: This product can expose you to chemicals including Titanium oxide (TiO2), which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances
2-Pyrrolidinone, 1-ethenyl-, homopolymer 9003-39-8

California Permissible Exposure Limits for Chemical Contaminants
Cellulose 9004-34-6

California Regulated Carcinogens
Talc (Mg3H2(SiO3)4) 14807-96-6

The ingredients of this product are reported in the following inventories:

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.
Baloxavir Marboxil
Crosclarmellose sodium
non hazardous compounds
sodium octadecyl fumarate

AICS : Not in compliance with the inventory
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NZIoC : Not in compliance with the inventory
ENCS : Not in compliance with the inventory
ISHL : Not in compliance with the inventory
KECI : Not in compliance with the inventory
PICCS : Not in compliance with the inventory
IECSC : Not in compliance with the inventory
TCSI : Not in compliance with the inventory
TSCA : Product contains substance(s) not listed on TSCA inventory.

TSCA list
No substances are subject to a Significant New Use Rule.
No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

NFPA:

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<tr>
<th>Health</th>
<th>Flammability</th>
<th>Instability</th>
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</thead>
<tbody>
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HMIS® IV:

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<tr>
<td>PHYSICAL HAZARD</td>
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</table>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA P0 : USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA : 8-hour, time-weighted average
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour
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AICS - Australian Inventory of Chemical Substances; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RO - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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