SAFETY DATA SHEET

ERIVEDGE(R) Capsules (150 mg)

Version: 1.4
Revision Date: 10-14-2021
Date of last issue: 01-23-2020
Date of first issue: 12-04-2015

SECTION 1. IDENTIFICATION

Product name: ERIVEDGE(R) Capsules (150 mg)
Product code: RO545-0815/F03
Common name(s), synonym(s) of the substance: ERIVEDGE Capsules 150 mg

Manufacturer or supplier's details
Company name of supplier: Genentech, Inc.
Address: 1 DNA Way
South San Francisco, CA 94080
USA
Telephone: 001-(650) 225-1000
E-mail address: info.sds@roche.com
Emergency telephone number: 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)

Eye irritation: Category 2A
Carcinogenicity: Category 1A
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure: Category 2

GHS label elements
Hazard pictograms: 
Signal Word: Danger
Hazard Statements: H319 Causes serious eye irritation.
H350 May cause cancer.
H360FD May damage fertility. May damage the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary Statements:

**Prevention:**
- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P260 Do not breathe dust.
- P264 Wash skin thoroughly after handling.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
- P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P308 + P313 IF exposed or concerned: Get medical advice/ attention.
- P337 + P313 If eye irritation persists: 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>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vismodegib</td>
<td>879085-55-9</td>
<td>35.29</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>20.54</td>
</tr>
<tr>
<td>Gelatins</td>
<td>9000-70-8</td>
<td>17.51</td>
</tr>
<tr>
<td>Lactose-1-Hydrate</td>
<td>64044-51-5</td>
<td>16.82</td>
</tr>
<tr>
<td>Starch, carboxymethyl ether, sodium salt</td>
<td>9063-38-1</td>
<td>4.12</td>
</tr>
<tr>
<td>2-Pyrrolidinone, 1-ethenyl- homopolymer</td>
<td>9003-39-8</td>
<td>2.47</td>
</tr>
<tr>
<td>Sulfuric acid monododecyl ester sodium salt (1:1)</td>
<td>151-21-3</td>
<td>1.65</td>
</tr>
<tr>
<td>Talc (Mg3H2(SiO3)4)</td>
<td>14807-96-6</td>
<td>0.82</td>
</tr>
<tr>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
<td>557-04-0</td>
<td>0.4</td>
</tr>
<tr>
<td>Titanium oxide (TiO2)</td>
<td>13463-67-7</td>
<td>0.35</td>
</tr>
<tr>
<td>Iron oxide (Fe3O4)</td>
<td>1317-61-9</td>
<td>0.02</td>
</tr>
<tr>
<td>Iron oxide (Fe2O3)</td>
<td>1309-37-1</td>
<td>0.01</td>
</tr>
</tbody>
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SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.
Show this material safety data sheet to the doctor in attendance.
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 skin irritation persists, call a physician.
If on skin, rinse well with water.
If on clothes, remove clothes.

In case of eye contact : Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
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.
Take victim immediately to hospital.
Rinse mouth with water.

Most important symptoms and effects, both acute and delayed : Causes serious eye irritation.
May cause cancer.
May damage fertility. May damage the unborn child.
May cause damage to organs through prolonged or repeated exposure.

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.

Unsuitable extinguishing media : High volume water jet

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:
Gaseous hydrogen chloride (HCl).
Sulfur oxides
Nitrogen oxides (NOx)  
Carbon oxides  
Sodium 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: Prevent any exposure  
Use personal protective equipment.  
Avoid dust formation.  
Avoid breathing dust.

Environmental precautions: Prevent product from entering drains. Prevent further leakage or spillage if safe to do so. If the product contaminates rivers and lakes or drains inform respective authorities.

Methods and materials for containment and cleaning up: Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

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

Advice on safe handling: Avoid formation of respirable particles. Do not breathe vapors/dust. Avoid exposure - obtain special instructions before use. Avoid contact with skin and eyes. For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area. Dispose of rinse water in accordance with local and national regulations.

Conditions for safe storage: Keep container tightly closed in a dry and well-ventilated place. 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.

Storage temperature: 15 °C to 30 °C  
Protect against light.  
Protect from moisture.
Further information on storage stability: No decomposition if stored and applied as directed.

Packaging material: Suitable material: Plastic container of HDPE, Polyethylene bag in metal drum, Stainless steel

### 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>Vismodegib</td>
<td>879085-55-9</td>
<td>IOEL</td>
<td>0.0003 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>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>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>2 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>2 mg/m³</td>
<td>ACGIH</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>
</tbody>
</table>

**Predicted No Effect Concentration (PNEC):**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vismodegib</td>
<td>Surface waters</td>
<td>6.9 µg/l</td>
</tr>
</tbody>
</table>
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Remarks: Based on chronic data

| Sodium dodecylsulfate | Fresh water | 0.176 mg/l |

**Engineering measures**: No data available

**Personal protective equipment**

**Respiratory protection**: In the case of dust or aerosol formation use respirator with an approved filter. Effective dust mask

**Hand protection**

In case of contact through splashing:

<table>
<thead>
<tr>
<th>Material</th>
<th>Nitrile rubber</th>
</tr>
</thead>
<tbody>
<tr>
<td>Break through time</td>
<td>&gt; 30 min</td>
</tr>
<tr>
<td>Glove thickness</td>
<td>&gt; 0.11 mm</td>
</tr>
</tbody>
</table>

In case of full contact:

<table>
<thead>
<tr>
<th>Material</th>
<th>butyl-rubber</th>
</tr>
</thead>
<tbody>
<tr>
<td>Break through time</td>
<td>&gt; 480 min</td>
</tr>
<tr>
<td>Glove thickness</td>
<td>&gt; 0.4 mm</td>
</tr>
</tbody>
</table>

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

**Eye protection**: Eye wash bottle with pure water  
Tightly fitting safety goggles  
Wear face-shield and protective suit for abnormal processing problems.

**Skin and body protection**: Choose body protection according to the amount and concentration of the dangerous substance at the work place.

**Protective measures**: Instruction of employees mandatory

**Hygiene measures**: When using do not eat or drink. When using do not smoke. Wash hands before breaks and at the end of workday.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**: capsules

**Color**: gray  
Pink

**Odor**: Not applicable

**Odor Threshold**: Not applicable
### SECTION 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reactivity</strong></td>
<td>No dangerous reaction known under conditions of normal use.</td>
</tr>
<tr>
<td><strong>Chemical stability</strong></td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td><strong>Possibility of hazardous reactions</strong></td>
<td>No decomposition if stored and applied as directed.</td>
</tr>
<tr>
<td><strong>Incompatible materials</strong></td>
<td>No data available</td>
</tr>
</tbody>
</table>
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: 63.49 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

Components:
Vismodegib:
Acute oral toxicity: LD50 Oral (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
GLP: yes

Cellulose:
Acute oral toxicity: LD50 Oral (Rat): > 5,000 mg/kg

Acute dermal toxicity:
LD50 Dermal (Rabbit): > 2,000 mg/kg

Lactose-1-Hydrate:
Acute oral toxicity: LD50 Oral (Rat): > 10,000 mg/kg

Acute inhalation toxicity: Acute toxicity estimate: > 30 mg/l
Test atmosphere: dust/mist
Method: Expert judgment

Acute dermal toxicity: Acute toxicity estimate: > 5,001 mg/kg
Method: Expert judgment

Sulfuric acid monododecyl ester sodium salt (1:1):
Acute oral toxicity: LD50 Oral (Rat): 1,200 mg/kg

Acute inhalation toxicity: Assessment: The component/mixture is moderately toxic after short term inhalation.

Acute dermal toxicity: LD50 Dermal (Rat, male and female): > 2,000 mg/kg

Titanium oxide (TiO2):
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 425
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Acute inhalation toxicity: LC50 (Rat): > 6.82 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity: LD50 (Rabbit): > 5,000 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Product:
Remarks: May cause skin irritation and/or dermatitis.

Components:

Vismodegib:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
GLP: yes

Sulfuric acid monododecyl ester sodium salt (1:1):
Result: Irritating to skin.

Talc (Mg3H2(SiO3)4):
Remarks: This information is not available.

Titanium oxide (TiO2):
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.

Product:
Remarks: May cause irreversible eye damage.

Components:

Sulfuric acid monododecyl ester sodium salt (1:1):
Result: Risk of serious damage to eyes.

Talc (Mg3H2(SiO3)4):
Remarks: This information is not available.

Titanium oxide (TiO2):
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405
Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Titanium oxide (TiO2):
Species: Guinea pig
Assessment: Does not cause skin sensitization.
Method: OECD Test Guideline 406

Germ cell mutagenicity
Not classified based on available information.

Components:

Vismodegib:
Genotoxicity in vitro:
Test Type: Ames test
Method: Mutagenicity (Salmonella typhimurium - reverse mutation assay)
Result: negative
GLP: yes
Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo:
Test Type: Micronucleus test
Species: Rat
Application Route: Oral
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.

Lactose-1-Hydrate:
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.

Sulfuric acid monododecyl ester sodium salt (1:1):
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.
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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
May damage fertility. May damage the unborn child.

Components:

Vismodegib:
Effects on fetal development
Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Embryo-fetal toxicity: LOEL: 10 mg/kg bw/day
Result: Teratogenicity and developmental toxicity
GLP: yes

Reproductive toxicity - Assessment
Presumed human reproductive toxicant, May damage fertility.
May damage the unborn child.

STOT-single exposure
Not classified based on available information.

Components:

Lactose-1-Hydrate:
Assessment
The substance or mixture is not classified as specific target organ toxicant, single exposure.

Sulfuric acid monododecyl ester sodium salt (1:1):
Assessment
May cause respiratory irritation.

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

STOT-repeated exposure
May cause damage to organs through prolonged or repeated exposure.

Components:

Vismodegib:
Assessment
May cause damage to organs through prolonged or repeated exposure.
Lactose-1-Hydrate:
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:
Vismodegib:
Species: Rat
NOAEL: <5 mg/kg/w
Application Route: Oral
Exposure time: 26 Weeks

Species: Mouse
NOAEL: 50 mg/kg bw/day
Application Route: Oral
Exposure time: 84 d
Remarks: Subchronic toxicity

Aspiration toxicity
Not classified based on available information.

Components:
Lactose-1-Hydrate:
No data available

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity
Components:
Vismodegib:
Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 1.5 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
GLP: yes

NOEC (Danio rerio (zebra fish)): 1.5 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
GLP: yes

Toxicity to daphnia and other aquatic invertebrates:

EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Test Type: Immobilization
Analytical monitoring: yes
Method: OECD Test Guideline 202
GLP: yes
Remarks: nominal concentration

NOEC (Daphnia magna (Water flea)): 0.85 mg/l
Exposure time: 48 h
Test Type: Immobilization
Analytical monitoring: yes
Method: OECD Test Guideline 202
GLP: yes
Remarks: average measured concentration

Toxicity to algae/aquatic plants:

ErC50 (Pseudokirchneriella subcapitata (algae)): 0.118 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes

EyC50 (Pseudokirchneriella subcapitata (algae)): 0.099 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes

NOEC (Pseudokirchneriella subcapitata (algae)): 0.069 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes
Remarks: nominal concentration

ErC50 (Desmodesmus subspicatus (green algae)): 0.95 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes
Remarks: nominal concentration

EyC50 (Desmodesmus subspicatus (green algae)): 0.52 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes
Remarks: nominal concentration

NOEC (Desmodesmus subspicatus (green algae)): 0.32 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes
Remarks: nominal concentration

NOEC (Daphnia magna (Water flea)): 1.5 mg/l
Exposure time: 21 d
Analytical monitoring: yes
Method: OECD Test Guideline 211
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GLP: yes
Remarks: nominal concentration

Lowest Observed Effect Concentration (Daphnia magna (Water flea)): 1.5 mg/l
Exposure time: 21 d
Analytical monitoring: yes
Method: OECD Test Guideline 211
GLP: yes
Remarks: nominal concentration

Toxicity to microorganisms: (activated sludge): 54 mg/l
Exposure time: 14 d
Remarks: no adverse influence on substrate biodegradation
nominal concentration

Cellulose:

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

Lactose-1-Hydrate:
Toxicity to fish: LC50: > 100 mg/l
Exposure time: 96 h
Toxicity to fish (Chronic toxicity): > 1 mg/l

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

Sulfuric acid monododecyl ester sodium salt (1:1):
Toxicity to fish: LC0 (Leuciscus idus (Golden orfe)): 29 mg/l
LC50 (Lepomis macrochirus (Bluegill sunfish)): 4.1 mg/l
Exposure time: 96 h
LC50 (Oncorhynchus mykiss (rainbow trout)): 3.6 mg/l
Exposure time: 96 h
NOEC (Pimephales promelas (fathead minnow)): 1.36 mg/l
Exposure time: 42 d

Toxicity to daphnia and other: EC50 (Daphnia magna (Water flea)): 5.55 mg/l
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aquatic invertebrates
Exposure time: 48 h

NOEC (Ceriodaphnia dubia (water flea)): 0.88 mg/l
Exposure time: 7 d

Toxicity to microorganisms
LC50 (activated sludge): 135 mg/l
Exposure time: 3 h
Test Type: EC50
Method: OECD Test Guideline 209

Ecotoxicology Assessment
Chronic aquatic toxicity: Harmful to aquatic life with long lasting effects.

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

Titanium oxide (TiO2):
Toxicity to fish
LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l
Exposure time: 96 h
Test Type: static test

LC50 (Cyprinodon variegatus (sheepshead minnow)): > 10,000 mg/l
Exposure time: 96 h
Test Type: semi-static test
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates
LC50 (Daphnia magna (Water flea)): > 1,000 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants
EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201
EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
Exposure time: 72 h
Method: ISO 10253

NOEC (Skeletonema costatum (marine diatom)): 5,600 mg/l
Exposure time: 72 h
Method: ISO 10253

Ecotoxicology Assessment
Toxicity Data on Soil : Not expected to adsorb on soil.
Other organisms relevant to the environment : No data available

Persistence and degradability
Components:
Vismodegib:
Biodegradability : aerobic
Inoculum: activated sludge, non-adapted
Theoretical oxygen demand
Result: Not readily biodegradable.
Exposure time: 28 d
Method: OECD Test Guideline 301F
GLP: yes

Sulfuric acid monododecyl ester sodium salt (1:1):
Biodegradability : Biodegradation: 90 %
Exposure time: 28 d
Method: OECD Test Guideline 301
Remarks: Readily biodegradable, according to appropriate OECD test.

Titanium oxide (TiO2):
Biodegradability : Remarks: Not applicable

Bioaccumulative potential
Components:
Vismodegib:
Partition coefficient: n-octanol/water : log Pow: 1.59
Method: OECD Test Guideline 117
GLP: yes

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

Lactose-1-Hydrate:
Partition coefficient: n-octanol/water : log Pow: -5.03

Sodium dodecylsulfate:
Bioaccumulation : Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 3.9 - 5.3
Exposure time: 3 d
Partition coefficient: n-octanol/water : log Pow: -2.03 (68 °F / 20 °C)
Method: OECD Test Guideline 107

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

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

Mobility in soil

Components:

Vismodegib:
Distribution among environmental compartments : Koc method
Medium: Soil
Koc: 2129 - 5001 ml/g
Method: OECD Test Guideline 106
Remarks: Slightly mobile in soils

Koc method
Medium: Sludge
Koc: 684 - 895 ml/g
Method: OECD Test Guideline 106

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.
Very toxic to aquatic life with long lasting effects.
SAFETY DATA SHEET

ERIVEDGE(R) Capsules (150 mg)

Components:

Sulfuric acid monododecyl ester sodium salt (1:1):
Additional ecological information: No data available

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. Do not contaminate ponds, waterways or ditches with chemical or used container. Send to a licensed waste management company.

Contaminated packaging: Empty remaining contents. Dispose of as unused product. 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
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Vismodegib (35%) mixture)
Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: UN 3077
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Vismodegib (35%) mixture)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 956
Packing instruction (passenger aircraft): 956
Environmentally hazardous: yes
SAFETY DATA SHEET

ERIVEDGE(R) Capsules (150 mg)

IMDG-Code
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Vismodegib (35%) mixture)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

49 CFR
UN/ID/NA number : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(Vismodegib (35%) mixture)
Class : 9
Packing group : III
Labels : CLASS 9
ERG Code : 171
Marine pollutant : no

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

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
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)
Serious eye damage or eye irritation

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).

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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 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

**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**
- Vismodegib 879085-55-9
- Cellulose 9004-34-6
- Gelatins 9000-70-8
- Lactose-1-Hydrate 64044-51-5
- Starch, carboxymethyl ether, sodium salt 9063-38-1

**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:
**AIIC** : Not in compliance with the inventory
**DSL** : This product contains the following components that are not on the Canadian DSL nor NDSL.

Vismodegib
SAFETY DATA SHEET

ERIVEDGE(R) Capsules (150 mg)

Version 1.4  Revision Date: 10-14-2021  Date of last issue: 01-23-2020
Date of first issue: 12-04-2015

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.
TECI: Not in compliance with the 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 704:

HMIS® IV:

Health 2 0
Flammability 0
Instability

HEALTH *
FLAMMABILITY 0
PHYSICAL HAZARD 0

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
ERIVEDGE(R) Capsules (150 mg)

SAFETY DATA SHEET

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
workday during a 40-hour workweek

OSHA P0 / TWA : 8-hour time weighted average
OSHA Z-1 / TWA : 8-hour time weighted average
OSHA Z-3 / TWA : 8-hour time weighted average

Revision Date : 10-14-2021

The GHS classification for skin irritation and/or sensitization of the pure ingredients causes a corresponding GHS classification for the whole formulation. In view of the nature of the formulated product (film-coated tablet, capsule, etc.) an over-interpretation of the potential hazard is possible.

Revision Date : 10-14-2021

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the
specific material designated and may not be valid for such material used in combination with any
other materials or in any process, unless specified in the text.

US / Z8 / 2010