SECTION 1. IDENTIFICATION

Product name: XOFLUZA(R) Granules for Oral Susp. 2 mg/ml

Product code: RO719-1686/F08

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)
Skin sensitization: Category 1
Carcinogenicity: Category 1A

GHS label elements
Hazard pictograms:

Signal Word: Danger
Hazard Statements:
H317 May cause an allergic skin reaction.
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.
P261 Avoid breathing dust.
P272 Contaminated work clothing must not be allowed out of
the workplace.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P302 + P352 If ON SKIN: Wash with plenty of soap and water.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P363 Wash contaminated clothing before reuse.

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>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>2.0</td>
</tr>
<tr>
<td>D-Mannitol</td>
<td>69-65-8</td>
<td>56.0</td>
</tr>
<tr>
<td>D-Glucitol, 4-O-.alpha.-D- glucopyranosyl-</td>
<td>585-88-6</td>
<td>35.0</td>
</tr>
<tr>
<td>Sodium chloride (NaCl)</td>
<td>7647-14-5</td>
<td>3.0</td>
</tr>
<tr>
<td>Silica</td>
<td>7631-86-9</td>
<td>2.0</td>
</tr>
<tr>
<td>2-Pyrrolidinone, 1-ethenyl-, homopolymer</td>
<td>9003-39-8</td>
<td>1.0</td>
</tr>
<tr>
<td>Sucralose</td>
<td>56038-13-2</td>
<td>0.5</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose acetate succinate</td>
<td>71138-97-1</td>
<td>0.3</td>
</tr>
<tr>
<td>Strawberry Flavour</td>
<td>Not Assigned</td>
<td>0.1</td>
</tr>
<tr>
<td>Talc (Mg3H2(SiO3)4)</td>
<td>14807-96-6</td>
<td>0.1</td>
</tr>
</tbody>
</table>

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 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.
- 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.
- Rinse mouth with water.

Most important symptoms and effects, both acute and delayed:
- May cause an allergic skin reaction.
- 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. |
| Unsuitable extinguishing media | High volume water jet |
| Specific hazards during firefighting | No information available. |
| Hazardous combustion products | In case of fire hazardous decomposition products may be produced such as: Hydrogen fluoride, Sulfur oxides, Nitrogen oxides (NOx). Carbon oxides, Gaseous hydrogen chloride (HCl), Sodium oxides. In case of fire hazardous decomposition products may be produced such as: Hydrogen fluoride, Sulfur oxides, Nitrogen oxides (NOx). |
| Further information | Standard procedure for chemical fires. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. |
| 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:
- 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.
- Local authorities should be advised if significant spillages cannot be contained.

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.
- Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

Conditions for safe storage:
- Keep container tightly closed in a dry and well-ventilated place.
- Electrical installations / working materials must comply with the technological safety standards.

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

Storage temperature:
- Protected from heat and light
- Protect from moisture.

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

Packaging material:
- Suitable material: Stainless steel, Polyethylene bag in metal drum
### 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>Silica</td>
<td>7631-86-9</td>
<td>TWA (Dust)</td>
<td>20 Million particles per cubic foot (Silica)</td>
<td>OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Dust)</td>
<td>80 mg/m³ / %SiO₂ (Silica)</td>
<td>OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>6 mg/m³ (Silica)</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable dust)</td>
<td>0.05 mg/m³ (Silica)</td>
<td>NIOSH REL</td>
</tr>
<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>Talc (Mg₃H₂(SiO₃)₄)</td>
<td>14807-96-6</td>
<td>TWA (Dust)</td>
<td>20 Million particles per cubic foot (Silica)</td>
<td>OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>2 mg/m³ (Silica)</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>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
<th>Remarks: Based on chronic data, Information refers to the main ingredient.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baloxavir Marboxil</td>
<td>Surface waters</td>
<td>9.2 µg/l</td>
<td></td>
</tr>
</tbody>
</table>

#### 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:

- **Material**: Nitrile rubber
- **Break through time**: > 30 min
- **Glove thickness**: > 0.11 mm
In case of full contact:

Material: butyl-rubber
Break through time: > 480 min
Glove thickness: > 0.4 mm

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

Skin and body protection:
Dust impervious protective suit
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Hygiene measures:
Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: granules
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
Flammability (solid, gas): Does not sustain combustion.
Flammability (liquids): Does not sustain combustion.
Self-ignition: No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
SAFETY DATA SHEET

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Vapor pressure : No data available
Relative vapor density : Not applicable
Relative density : No data available
Solubility(ies)
  Water solubility : No data available
  Solubility in other solvents : No data available
Partition coefficient: n-octanol/water : No data available
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity
  Viscosity, dynamic : Not applicable
  Viscosity, kinematic : Not applicable
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.

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
  : No decomposition if stored and applied as directed.
  Dust may form explosive mixture in air.
Conditions to avoid : No data available
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: > 200 mg/l
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method

Components:

Silica:
Acute oral toxicity : LD50 (Rat, male and female): > 5,000 mg/kg  
GLP: yes

Acute inhalation toxicity : LC50 (Rat, male and female): > 5.01 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 436  
GLP: yes  
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 Dermal (Rabbit): > 5,000 mg/kg  
Method: No information available.  
GLP: No information available.

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

Skin corrosion/irritation
Not classified based on available information.

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

Components:

Silica:
Species : Rabbit
Exposure time : 4 h
Method : OECD Test Guideline 404
Result : No skin irritation
GLP : No information available.

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

Strawberry Flavour:
Result : Irritating to skin.

Serious eye damage/eye irritation
Not classified based on available information.

Product:
Remarks : Product dust may be irritating to eyes, skin and respiratory
**Components:**

**Silica:**
- **Species:** Rabbit
- **Result:** No eye irritation
- **Exposure time:** 24 h
- **GLP:** No

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

**Strawberry Flavour:**
- **Result:** Irritating to eyes.

**Respiratory or skin sensitization**

**Skin sensitization**
May cause an allergic skin reaction.

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

**Product:**
- **Remarks:** Causes sensitization.

**Components:**

**Silica:**
- **Test Type:** Maximization Test
- **Species:** Guinea pig
- **Assessment:** Does not cause skin sensitization.
- **Method:** OECD Test Guideline 406
- **Result:** Did not cause sensitization on laboratory animals.
- **GLP:** Yes

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Silica:**
- **Genotoxicity in vitro:**
  - **Test Type:** Microbial mutagenesis assay (Ames test)
  - **Test system:** Salmonella typhimurium
  - **Metabolic activation:** with and without metabolic activation
  - **Method:** OECD Test Guideline 471
  - **Result:** negative
  - **GLP:** Yes
Test Type: Microbial mutagenesis assay (Ames test)
Test system: Escherichia coli
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 490
Result: negative
GLP: yes

Genotoxicity in vivo:
Species: Rat (male)
Cell type: Bone marrow
Application Route: Oral
Method: OECD Test Guideline 475
Result: negative
GLP: no

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:
Silica:
Species: Rat, male and female
Application Route: Oral
Exposure time: 2 Years
Frequency of Treatment: daily
Method: No information available.
Result: negative
GLP: No information available.

IARC
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.

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
Silica 7631-86-9
Reproductive toxicity
Not classified based on available information.

Components:

Silica:
Effects on fertility : Species: Rat, male and female
Application Route: Oral
Dose: 100, 300, 1000 mg/kg bw/day
General Toxicity Parent: NOAEL: >= 1,000 mg/kg body weight
General Toxicity F1: NOAEL: >= 1,000 mg/kg body weight
Method: OECD Test Guideline 416
GLP: yes

Effects on fetal development : Species: Mouse, female
Application Route: Oral
Dose: 13.4, 62.3, 289, 1340 mg/kg bw/day
Duration of Single Treatment: 6 - 15 d
General Toxicity Maternal: LOAEL: >= 1,340 mg/kg bw/day
Embryo-fetal toxicity.: NOAEL: >= 1,340 µg/kg body weight
Method: No information available.
GLP: No information available.

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:

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

Repeated dose toxicity

Components:

Silica:
Species: Rat, male and female
NOEL: 4000 mg/kg
Application Route: Oral
Exposure time: 13 Weeks
Method: OECD Test Guideline 408
GLP: yes

Baloxavir Marboxil:
Species: Rat
NOAEL: 2000 mg/kg bw/day
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:

Silica:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): > 5,000 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 203
GLP: no

Toxicity to daphnia and other aquatic invertebrates: EL50 (Daphnia magna (Water flea)): > 10,000 mg/l
End point: Immobilization
Exposure time: 24 h
SAFETY DATA SHEET

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Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 202
GLP: yes

Toxicity to algae/aquatic plants:
EC50 (Desmodesmus subspicatus (green algae)): > 173.1 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
Lowest Observed Effect Concentration (Daphnia magna (Water flea)): 149.2 mg/l
End point: mortality
Exposure time: 21 d
Test Type: semi-static test
Analytical monitoring: yes
Method: OECD Test Guideline 211
GLP: yes

Toxicity to microorganisms:
NOEC (activated sludge): 1,000 mg/l
End point: Respiration inhibition
Exposure time: 3 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 209
GLP: yes

Ecotoxicology Assessment
Toxicity Data on Soil:
Not expected to adsorb on soil.

Other organisms relevant to the environment:
No data available

Baloxxvir 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

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:

Silica:
Biodegradability: Remarks: Not applicable

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:

**Silicon dioxide:**
Partition coefficient: n-octanol/water
Remarks: Not applicable

**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)
pH: 9
Method: OECD Test Guideline 117
GLP: yes

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

**Strawberry Flavour:**
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
SAFETY DATA SHEET

XOFLUZA(R) Granules for Oral Susp. 2 mg/ml

Version 2.1  Revision Date: 10-15-2021  Date of last issue: 12-09-2020
Date of first issue: 11-02-2020

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).

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: Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with local regulations.

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
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

CERCLAReportable Quantity
This material does not contain any components with a CERCLA RQ.
SAFETY DATA SHEET

XOFLUZA(R) Granules for Oral Susp. 2 mg/ml

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
Respiratory or skin sensitization
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 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
Silica 7631-86-9

Pennsylvania Right To Know
D-Mannitol 69-65-8
D-Glucitol, 4-O-.alpha.-D-glucopyranosyl- 585-88-6
Sodium chloride (NaCl) 7647-14-5
Silica 7631-86-9

Maine Chemicals of High Concern
Silica 7631-86-9

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 Silica, 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
Silica 7631-86-9
2-Pyrrolidinone, 1-ethenyl-, homopolymer 9003-39-8

California Permissible Exposure Limits for Chemical Contaminants
Silica 7631-86-9

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.
Baloxavir Marboxil
Sucralose
Hydroxypropyl methylcellulose acetate succinate
Strawberry Flavour

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
SAFETY DATA SHEET

XOFLUZA(R) Granules for Oral Susp. 2 mg/ml

Version 2.1
Revision Date: 10-15-2021
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NFPA 704:

- Health: 2
- Flammability: 0
- Instability: 0

HMIS® IV:

- 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 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 Z-3 / TWA: 8-hour time weighted average
- 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
- HNIS: 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: Philippines Inventory of Chemicals
- IEC: International Electrotechnical Commission
- ICSD: International Commission on Safe Use of Desiccants
- ICSDS: International Commission on Safe Use of Desiccants
- ICSC: 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
- KECl: 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)
- 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

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SAFETY DATA SHEET

XOFLUZA(R) Granules for Oral Susp. 2 mg/ml

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; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals 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

Revision Date: 10-15-2021

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.

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