SAFETY DATA SHEET

XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)

SECTION 1. IDENTIFICATION

Product name : XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)

Product code : RO719-1686/F20

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)

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<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>0.2</td>
</tr>
<tr>
<td>D-Mannitol</td>
<td>69-65-8</td>
<td>6.0</td>
</tr>
<tr>
<td>D-Glucitol, 4-O-.alpha.-D-glucopyranosyl-</td>
<td>585-88-6</td>
<td>3.7</td>
</tr>
<tr>
<td>Sodium chloride (NaCl)</td>
<td>7647-14-5</td>
<td>0.3</td>
</tr>
<tr>
<td>Silica</td>
<td>7631-86-9</td>
<td>0.2</td>
</tr>
<tr>
<td>2-Pyrrolidinone, 1-ethenyl-, homopolymer</td>
<td>9003-39-8</td>
<td>0.1</td>
</tr>
</tbody>
</table>
SEASON 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 : None known.

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 : No information available.

Hazardous combustion products : Carbon oxides

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:
Refer to protective measures listed in sections 7 and 8.

Environmental precautions:
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up:
Wipe up with absorbent material (e.g. cloth, fleece).
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion:
Normal measures for preventive fire protection.

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:
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:
Do not freeze.
Protected from heat and light

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

Packaging material:
Suitable material: 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>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>
</tbody>
</table>
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Baloxavir Marboxil 1985606-14-1 IOEL 0.0025 mg/m³ Roche Industrial Hygiene Committee (RIHC)

Talc (Mg3H2(SiO3)4) 14807-96-6 TWA (Dust) 20 Million particles per cubic foot OSHA Z-3

TWA (Respirable particulate matter) 2 mg/m³ ACGIH

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: suspension

Color: white

Odor: No data available

Odor Threshold: No data available

pH: No data available

Melting point/range: No data available

Boiling point/boiling range: No data available

Flash point: does not flash
Evaporation rate : No data available
Self-ignition : Not applicable
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 : No data available
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 : No data available
Viscosity, kinematic : 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.
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.
Components:

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

**D-Mannitol:**
- **Acute oral toxicity**: LD50 Oral (Rat): 13,500 mg/kg
  - LD50 Oral (Mouse): 22,000 mg/kg
- **Acute inhalation toxicity**: Acute toxicity estimate: > 30 mg/l
  - Test atmosphere: dust/mist
  - Method: Expert judgment
- **Acute dermal toxicity**: Acute toxicity estimate: > 5,000 mg/kg
  - Method: Expert judgment

**Sodium chloride (NaCl):**
- **Acute oral toxicity**: LD50 Oral (Rat): 3,000 mg/kg
  - LD50 Oral (Mouse): 4,000 mg/kg
- **Acute inhalation toxicity**: Acute toxicity estimate: > 30 mg/l
  - Test atmosphere: dust/mist
  - Method: Expert judgment
- **Acute dermal toxicity**: LD50 Dermal (Rabbit): > 10,000 mg/kg

**Silica:**
- **Acute oral toxicity**: LD50 Oral (Rat): > 3,300 mg/kg
- **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.

**2-Pyrrolidinone, 1-ethenyl-, homopolymer:**
- **Acute oral toxicity**: LD50 Oral (Rat): > 10,000 mg/kg
- **Acute inhalation toxicity**: LC50 (Rat): 5.2 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Method: OECD Test Guideline 403
- **Acute dermal toxicity**: Acute toxicity estimate: > 5,001 mg/kg
  - Method: Expert judgment
Sucralose:
Acute oral toxicity : LD50 Oral (Rat): > 10,000 mg/kg

Hydroxypropyl methylcellulose acetate succinate:
Acute oral toxicity : Acute toxicity estimate (Rat): > 5,000 mg/kg
Method: Expert judgment

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

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Expert judgment

Skin corrosion/irritation
Not classified based on available information.

Components:

Sodium chloride (NaCl):
Species : Rabbit
Result : No skin irritation

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

2-Pyrrolidinone, 1-ethenyl-, homopolymer:
Species : Rabbit
Result : No skin irritation

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.

Components:

Sodium chloride (NaCl):
Species : Rabbit
Result : No eye irritation
**Silica:**
Species: Rabbit
Result: No eye irritation
Exposure time: 24 h
GLP: no

**2-Pyrrolidinone, 1-ethenyl-, homopolymer:**
Species: Rabbit
Result: No eye irritation

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

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

**Respiratory or skin sensitization**

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

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

**Components:**

**Sodium chloride (NaCl):**
Remarks: This information is not available.

**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

**Strawberry Flavour:**
Assessment: May cause sensitization by skin contact.

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

**Components:**

**Baloxxvir 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

Sodium chloride (NaCl):
Genotoxicity in vitro :
Test Type: Micronucleus test
Test system: mammalian cells
Method: Mutagenicity (micronucleus test)
Result: negative

Test Type: Ames test
Result: negative

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
Exposure time: 6, 24, and 48 h
Dose: 1.4, 14, 140, 500, 5000 mg/kg
Method: OECD Test Guideline 475
Result: negative
GLP: no

2-Pyrrolidinone, 1-ethenyl-, homopolymer:
Germ cell mutagenicity -
Assessment :
Tests on bacterial or mammalian cell cultures did not show mutagenic effects.

Carcinogenicity
Not classified based on available information.

Components:
D-Mannitol:
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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.

D-Glucitol, 4-O-.alpha.-D-glucopyranosyl-:
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:
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:
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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.

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.
STOT-single exposure
Not classified based on available information.

Components:

D-Mannitol:
Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

2-Pyrrolidinone, 1-ethenyl-, homopolymer:
Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

Hydroxypropyl methylcellulose acetate succinate:
Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

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.

D-Mannitol:
Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

2-Pyrrolidinone, 1-ethenyl-, homopolymer:
Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Hydroxypropyl methylcellulose acetate succinate:
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: 2000 mg/kg bw/day
Application Route: Oral
Exposure time: 2 Weeks
Remarks: Subacute toxicity

Aspiration toxicity
Not classified based on available information.

**Components:**

**D-Mannitol:**
No data available

**2-Pyrrolidinone, 1-ethenyl-, homopolymer:**
No data available

**Hydroxypropyl methylcellulose acetate succinate:**
No data available

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

Further information

**Components:**

**D-Mannitol:**
Remarks: Health injuries are not known or expected under normal use.

---

**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
### 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

### Sodium chloride (NaCl):
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 7,650 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 1,000 mg/l
Exposure time: 48 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

Silica:

Toxicity to fish: (Danio rerio (zebra fish)): 10,000 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 203
GLP: yes

Toxicity to daphnia and other aquatic invertebrates: (Daphnia magna (Water flea)): > 10,000 mg/l
End point: Immobilization
Exposure time: 24 h
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
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
Analytical monitoring: yes
Method: OECD Test Guideline 211
GLP: yes

Toxicity to microorganisms: NOEC (activated sludge): 1,000 mg/l
Exposure time: 3 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 209
Ecotoxicology Assessment
Toxicity Data on Soil : Not expected to adsorb on soil.
Other organisms relevant to the environment : No data available

**2-Pyrrolidinone, 1-ethenyl-, homopolymer:**
Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l
Exposure time: 96 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

**Hydroxypropyl methylcellulose acetate succinate:**
Toxicity to fish : LC50 (Fish): > 100 mg/l
Exposure time: 96 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

**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

D-Mannitol:
Biodegradability: Biodegradation: 68 %
Exposure time: 28 d

Sodium chloride (NaCl):
Biodegradability: Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

Silica:
Biodegradability: Remarks: Not applicable

2-Pyrrolidinone, 1-ethenyl-, homopolymer:
Biodegradability: Zahn-Wellens Test
Biodegradation: < 10 %
Exposure time: 15 d
Method: OECD Test Guideline 302B

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)
pH: 9
Method: OECD Test Guideline 117
GLP: yes
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**XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1.2</td>
<td>02-08-2021</td>
<td>11-11-2020</td>
<td>11-10-2020</td>
</tr>
</tbody>
</table>

### Chemicals

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Partition coefficient: n-octanol/water</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>D-Mannitol</td>
<td></td>
<td>log Pow: -3.10</td>
</tr>
<tr>
<td>D-Glucitol, 4-O-.alpha.-D-glucopyranosyl-</td>
<td></td>
<td>Remarks: No data available</td>
</tr>
<tr>
<td>Sodium chloride (NaCl)</td>
<td></td>
<td>Remarks: No data available</td>
</tr>
<tr>
<td>Silica</td>
<td></td>
<td>Remarks: Not applicable</td>
</tr>
<tr>
<td>2-Pyrrolidinone, 1-ethenyl-, homopolymer</td>
<td></td>
<td>Remarks: No data available</td>
</tr>
<tr>
<td>Sucralose</td>
<td></td>
<td>Remarks: No data available</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose acetate succinate</td>
<td></td>
<td>Remarks: No data available</td>
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<tr>
<td>Talc (Mg3H2(SiO3)4)</td>
<td></td>
<td>Remarks: No data available</td>
</tr>
<tr>
<td>Strawberry Flavour</td>
<td></td>
<td>Remarks: No data available</td>
</tr>
<tr>
<td>Water</td>
<td></td>
<td>Remarks: No data available</td>
</tr>
</tbody>
</table>

### 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).

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 : 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

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.
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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  
No SARA Hazards

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. Clean Water Act, Section 311, Table 116.4A.  
This product does not contain any Hazardous Chemicals listed under the U.S. Clean Water 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  
No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know  
Water  7732-18-5  
D-Mannitol  69-65-8  
D-Glucitol, 4-O-.alpha.-D-glucopyranosyl-  585-88-6

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

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
Sucralose

Hydroxypropyl methylcellulose acetate succinate

Strawberry Flavour

AICS : Not in compliance with the inventory

NZIoC : On the inventory, or 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
SAFETY DATA SHEET

XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)

Version 1.2
Revision Date: 02-08-2021
Date of last issue: 11-11-2020
Date of first issue: 11-10-2020

NFPA 704:

HMIS® IV:

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

AICS - Australian Inventory of Chemical Substances; AILC - 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
## SAFETY DATA SHEET

### XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)

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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 / 2004