SECTION 1. IDENTIFICATION

Product name : XOFLUZA Reconst. Oral Susp. 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)
Carcinogenicity : Category 1A

GHS label elements
Hazard pictograms :

Signal Word : Danger
Hazard Statements : H350 May cause cancer.
Precautionary Statements :
Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/
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Date of first issue: 11-10-2020

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

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>
<tr>
<td>Sucralose</td>
<td>56038-13-2</td>
<td>0.1</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose acetate succinate</td>
<td>71138-97-1</td>
<td>0.03</td>
</tr>
<tr>
<td>Talc (Mg3H2(SiO3)4)</td>
<td>14807-96-6</td>
<td>0.01</td>
</tr>
<tr>
<td>Strawberry Flavour</td>
<td>Not Assigned</td>
<td>0.01</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>&gt; 89.0</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

General advice : Do not leave the victim unattended.

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

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

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

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

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

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

SECTION 5. FIRE-FIGHTING MEASURES

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

Specific hazards during fire fighting: 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>
<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>
</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: No personal respiratory protective equipment normally required.

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.

**Eye protection**: Safety glasses

**Skin and body protection**: Protective suit

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

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**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
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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 (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.

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
SAFETY DATA SHEET

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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
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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:

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

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

Components:

D-Mannitol:
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.

Silica:
Species:
- Rat, male and female
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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
(Silica, Crystalline (Respirable Size))

Reproductive toxicity
Not classified based on available information.

Components:

Baloxxvir 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.
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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:

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

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
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

D-Mannitol:
Toxicity to fish:
LC50 (Fish): > 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

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 : 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 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
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Date of first issue: 11-10-2020

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

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
the environment

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

D-Mannitol:
Partition coefficient: n-octanol/water
log Pow: -3.10

D-Glucitol, 4-O-.alpha.-D-glucopyranosyl-:
Partition coefficient: n-octanol/water
Remarks: No data available

Sodium chloride (NaCl):
Partition coefficient: n-octanol/water
Remarks: No data available

Silica:
Partition coefficient: n-octanol/water
Remarks: Not applicable

2-Pyrrolidinone, 1-ethenyl-, homopolymer:
Partition coefficient: n-octanol/water
Remarks: No data available

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

Hydroxypropyl methylcellulose acetate succinate:
Partition coefficient: n-octanol/water
Remarks: No data available

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

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

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

Mobility in soil
No data available
Other adverse effects

Product:
Ozone-Depletion Potential: Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

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
UN RTDG
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.

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

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

SARA 311/312 Hazards : Carcinogenicity

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act
This product neither contains nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 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
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
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.

**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**: 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.
- **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 Reconst. Oral Susp. 2 mg/ml

Version 1.3
Revision Date: 10-15-2021
Date of last issue: 02-08-2021
Date of first issue: 11-10-2020

NFPA 704:

Health 0 0 0
Instability 0 0 0
Special hazard

HMIS® IV:

HEALTH 0
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
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3
Mineral Dusts
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

AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the
XOFLUZA Reconst. Oral Susp. 2 mg/ml

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