

**XOFLUZA(R) Granules for Oral Susp. 2 mg/ml**Version  
2.1Revision Date:  
10-15-2021Date of last issue: 12-09-2020  
Date of first issue: 11-02-2020**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 : US Chemtrec phone (800)-424-9300  
Emergency telephone number

**Recommended use of the chemical and restrictions on use**


Recommended use : Formulated pharmaceutical active substance  
Restrictions on use : For professional users only.

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**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

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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.

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**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Baloxavir Marboxil	1985606-14-1	2.0
D-Mannitol	69-65-8	56.0
D-Glucitol, 4-O-.alpha.-D-glucopyranosyl-	585-88-6	35.0
Sodium chloride (NaCl)	7647-14-5	3.0
Silica	7631-86-9	2.0
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8	1.0
Sucralose	56038-13-2	0.5
Hydroxypropyl methylcellulose acetate succinate	71138-97-1	0.3
Strawberry Flavour	Not Assigned	0.1
Talc (Mg <sub>3</sub> H <sub>2</sub> (SiO <sub>3</sub> ) <sub>4</sub> )	14807-96-6	0.1

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**SECTION 4. FIRST AID MEASURES**

General advice : Move out of dangerous area.  
Show this material safety data sheet to the doctor in attendance.  
Do not leave the victim unattended.

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

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- 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.

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**SECTION 5. FIRE-FIGHTING MEASURES**

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire fighting : 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.

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**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

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**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**
**Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Silica	7631-86-9	TWA (Dust)	20 Million particles per cubic foot (Silica)	OSHA Z-3
		TWA (Dust)	80 mg/m <sup>3</sup> / %SiO <sub>2</sub> (Silica)	OSHA Z-3
		TWA	6 mg/m <sup>3</sup> (Silica)	NIOSH REL
		TWA (Respirable dust)	0.05 mg/m <sup>3</sup> (Silica)	NIOSH REL
Baloxavir Marboxil	1985606-14-1	IOEL	0.0025 mg/m <sup>3</sup>	Roche Industrial Hygiene Committee (RIHC)
Talc (Mg <sub>3</sub> H <sub>2</sub> (SiO <sub>3</sub> ) <sub>4</sub> )	14807-96-6	TWA (Dust)	20 Million particles per cubic foot	OSHA Z-3
		TWA (Respirable)	2 mg/m <sup>3</sup>	NIOSH REL
		TWA (Respirable particulate matter)	2 mg/m <sup>3</sup>	ACGIH

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

Substance name	Environmental Compartment	Value
Baloxavir Marboxil	Surface waters	9.2 µg/l
	Remarks: Based on chronic data, Information refers to the main ingredient.	

**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

# SAFETY DATA SHEET

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	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.

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### 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

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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.

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**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

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**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

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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 (Mg<sub>3</sub>H<sub>2</sub>(SiO<sub>3</sub>)<sub>4</sub>):**

- 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



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system.

**Components:****Silica:**

Species : Rabbit  
Result : No eye irritation  
Exposure time : 24 h  
GLP : no

**Talc (Mg<sub>3</sub>H<sub>2</sub>(SiO<sub>3</sub>)<sub>4</sub>):**

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

**Strawberry Flavour:**

Assessment : May cause sensitization by skin contact.

**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

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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

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(Silica, Crystalline (Respirable Size))

Known to be human carcinogen

Talc (Mg<sub>3</sub>H<sub>2</sub>(SiO<sub>3</sub>)<sub>4</sub>)

14807-96-6

(Silica, Crystalline (Respirable Size))

**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 (Mg<sub>3</sub>H<sub>2</sub>(SiO<sub>3</sub>)<sub>4</sub>):**

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

**STOT-repeated exposure**

Not classified based on available information.

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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 (Mg<sub>3</sub>H<sub>2</sub>(SiO<sub>3</sub>)<sub>4</sub>):**

No data available

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

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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

**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

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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 (Mg<sub>3</sub>H<sub>2</sub>(SiO<sub>3</sub>)<sub>4</sub>):**
 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.

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Exposure time: 28 d  
Method: OECD Test Guideline 301F  
GLP: yesPhysico-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 QSARslog Pow: 2.46 (77 °F / 25 °C)  
pH: 5  
Method: OECD Test Guideline 117  
GLP: yeslog Pow: 2.45 (77 °F / 25 °C)  
pH: 7  
Method: OECD Test Guideline 117  
GLP: yeslog 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

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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 (Mg<sub>3</sub>H<sub>2</sub>(SiO<sub>3</sub>)<sub>4</sub>):**

Adsorbed organic bound halogens (AOX) : Remarks: Not applicable

Additional ecological information : No data available

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**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.

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**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

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**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** : 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 SOCM 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](http://www.P65Warnings.ca.gov).

**XOFLUZA(R) Granules for Oral Susp. 2 mg/ml**
Version  
2.1Revision Date:  
10-15-2021Date of last issue: 12-09-2020  
Date of first issue: 11-02-2020**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
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**California Regulated Carcinogens**

Talc (Mg <sub>3</sub> H <sub>2</sub> (SiO <sub>3</sub> ) <sub>4</sub> )	14807-96-6
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**The ingredients of this product are reported in the following inventories:**

AICC	: 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.

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**SECTION 16. OTHER INFORMATION**

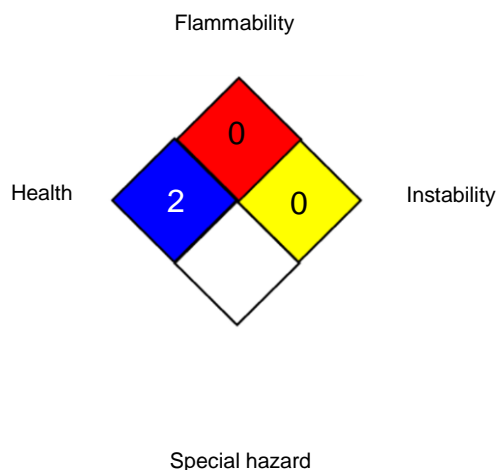
**XOFLUZA(R) Granules for Oral Susp. 2 mg/ml**

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**NFPA 704:**



**HMIS® IV:**

<b>HEALTH</b>	*	<b>2</b>
<b>FLAMMABILITY</b>		<b>0</b>
<b>PHYSICAL HAZARD</b>		<b>0</b>

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; 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; 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); 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

# SAFETY DATA SHEET

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

Version  
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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.

US / Z8 / 2010