

**XOFLUZA Granules for Oral Susp. 2 mg/ml**Version  
2.1Revision Date:  
04/01/2026Date of last issue: 01/21/2026  
Date of first issue: 06/16/2025**SECTION 1. IDENTIFICATION**

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

Product code : RO719-1686/F08-00

**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

In case of emergencies: : US CHEMTREC PHONE (800)-424-9300

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

Recommended use : Formulated pharmaceutical active substance

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**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)****Hazards for the product as supplied**

Combustible dust

Carcinogenicity : Category 1A

**Other hazards**

None known.

**GHS label elements**

Hazard pictograms :



Signal Word : Danger

Hazard Statements : May form combustible dust concentrations in air.  
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.

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P280 Wear protective gloves, protective clothing, eye protection and face protection.

**Response:**

P308 + P313 IF exposed or concerned: Get medical advice/attention.

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Baloxavir Marboxil	1985606-14-1*	2	-
D-Mannitol	69-65-8*	56	-
D-Glucitol, 4-O-.alpha.-D-glucopyranosyl-	585-88-6*	35	-
Sodium chloride (NaCl)	7647-14-5*	3	-
Silica	7631-86-9*	2	-
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8*	1	-
Sucralose	56038-13-2*	0.5	-
Cellulose, 2-hydroxypropyl methyl ether	9004-65-3*	0.3	-
Strawberry Flavour	-	0.1	-
Talc (Mg <sub>3</sub> H <sub>2</sub> (SiO <sub>3</sub> ) <sub>4</sub> )	14807-96-6*	0.1	-

\* Indicates that the identifier is a CAS No.

### SECTION 4. FIRST AID MEASURES

General advice : Do not leave the victim unattended.

If inhaled : 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 : Wash off with soap and water.
- In case of eye contact : 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.
- Most important symptoms and effects, both acute and delayed : May cause cancer.
- Protection of first-aiders : First Aid responders should pay attention to self-protection and use the recommended protective clothing
- Notes to physician : Treat symptomatically.

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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 : Carbon oxides  
Gaseous hydrogen chloride (HCl).  
Sodium oxides  
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**

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- Personal precautions, protective equipment and emergency procedures : Avoid dust formation.  
Refer to protective measures listed in sections 7 and 8.
- Environmental precautions : If the product contaminates rivers and lakes or drains inform respective authorities.
- Methods and materials for containment and cleaning up : Pick up and arrange disposal without creating dust.  
Sweep up and shovel.  
Keep in suitable, closed containers for disposal.

**SECTION 7. HANDLING AND STORAGE**

- Advice on protection against fire and explosion : Provide appropriate exhaust ventilation at places where dust is formed.
- 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.
- Materials to avoid : No materials to be especially mentioned.
- Storage temperature : Protect 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, glass

**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	PEL (respirable)	0.05 mg/m <sup>3</sup>	OSHA CARC
		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	OSHA Z-3

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			particles per cubic foot	
		TWA (respirable dust fraction)	2 mg/m3	OSHA P0
		TWA (Respirable)	2 mg/m3	NIOSH REL
		TWA (Respirable particulate matter)	2 mg/m3	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.	

**Personal protective equipment**

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

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 : General industrial hygiene practice.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

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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

Self-ignition : No data available

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 : Not applicable

Relative density : No data available

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

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Oxidizing properties : No data available

Particle characteristics  
Particle Size Distribution : No data available

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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 : Stable under recommended storage conditions.  
No hazards to be specially mentioned.  
Dust may form explosive mixture in air.

Conditions to avoid : No data available

Incompatible materials : Not applicable

Hazardous decomposition products : No hazardous decomposition products are known.

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**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Not classified due to lack of data.

**Product:**Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation methodAcute inhalation toxicity : Acute toxicity estimate: > 200 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method**Components:****Silica:**Acute oral toxicity : LD50 (Rat, male and female): > 5,000 mg/kg  
GLP: yesAcute 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 toxicityAcute dermal toxicity : LD50 Dermal (Rabbit): > 5,000 mg/kg  
Method: No information available.

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GLP: No information available.

**Baloxavir Marboxil:**

Acute oral toxicity : LD50 Oral (Rat): &gt; 2,000 mg/kg

**Skin corrosion/irritation**

Not classified due to lack of data.

**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.

**Serious eye damage/eye irritation**

Not classified due to lack of data.

**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.

**Respiratory or skin sensitization****Skin sensitization**

Not classified due to lack of data.

**Respiratory sensitization**

Not classified due to lack of data.

**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

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Not classified due to lack of data.

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

- Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)  
Test system: Salmonella typhimurium  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 471  
Result: negative  
GLP: yes
- Test Type: Microbial mutagenesis assay (Ames test)  
Test system: Escherichia coli  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 471  
Result: negative  
GLP: yes
- Test Type: In vitro mammalian cell gene mutation test  
Test system: mouse lymphoma cells  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 490  
Result: negative  
GLP: yes
- Genotoxicity in vivo : Species: Rat (male)  
Cell type: Bone marrow  
Application Route: Oral  
Method: OECD Test Guideline 475  
Result: negative  
GLP: no

**Baloxavir Marboxil:**

- Genotoxicity in vitro : Method: Mutagenicity (Salmonella typhimurium - reverse mutation assay)  
Result: negative
- Method: OECD Test Guideline 473  
Result: negative
- Genotoxicity in vivo : Method: OECD Test Guideline 474  
Result: negative

**Carcinogenicity**

May cause cancer.

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

- Species : Rat, male and female  
Application Route : Oral  
Exposure time : 2 Years  
Method : No information available.

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Result : negative  
 GLP : No information available.

<b>IARC</b>	Group 1: Carcinogenic to humans	
	Silica (Silica dust, crystalline)	7631-86-9
	Group 2A: Probably carcinogenic to humans	
	Talc (Mg3H2(SiO3)4)	14807-96-6
<b>OSHA</b>	OSHA specifically regulated carcinogen	
	Silica (crystalline silica)	7631-86-9
<b>NTP</b>	Known to be human carcinogen	
	Silica (Silica, Crystalline (Respirable Size))	7631-86-9

**Reproductive toxicity**

Not classified due to lack of data.

**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.

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Not classified due to lack of data.

**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 due to lack of data.

**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, 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 due to lack of data.

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

No data available

**Further information****Product:**

Remarks : No data available

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- 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  
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

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Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10.6 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
GLP: yes  
Remarks: average measured concentration

NOEC (Danio rerio (zebra fish)): 10.6 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
GLP: yes  
Remarks: average measured concentration

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 17.4 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
GLP: yes  
Remarks: measured initial concentration

NOEC (Daphnia magna (Water flea)): 17.4 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: measured initial concentration

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 9.28 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes  
Remarks: average measured concentration

NOErC (Desmodesmus subspicatus (green algae)): 1.75 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes  
Remarks: average measured concentration

EyC50 (Desmodesmus subspicatus (green algae)): 4.76 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes  
Remarks: average measured concentration

Toxicity to microorganisms : (activated sludge): Exposure time: 14 d  
Method: OECD Test Guideline 301F  
GLP: yes  
Remarks: no adverse influence on substrate biodegradation

**Talc (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.

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

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

Other organisms relevant to the environment : No data available

**Persistence and degradability****Components:****Silica:**

Biodegradability : Remarks: Not applicable

**Baloxavir Marboxil:**Biodegradability : Result: Not readily biodegradable.  
Biodegradation: < 10 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F  
GLP: yesPhysico-chemical removability : Method: OECD Test Guideline 301F  
Remarks: Not abiotically degradable**Bioaccumulative potential****Components:****Silica:**

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

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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).Additional ecological  
information : No data available**Components:****Baloxavir Marboxil:**Results of PBT and vPvB  
assessment : Not persistent, bioaccumulative, and toxic (PBT).Endocrine disrupting  
potential : Does not have endocrine disrupting properties.**Talc (Mg<sub>3</sub>H<sub>2</sub>(SiO<sub>3</sub>)<sub>4</sub>):**Adsorbed organic bound  
halogens (AOX) : Remarks: Not applicableAdditional ecological  
information : No data available

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**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.

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**SECTION 14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

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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 IMO instruments**

Not applicable

**Domestic regulation****49 CFR**

Not regulated as a dangerous good

**Special precautions for user**Remarks : Not dangerous goods in the meaning of ADR/RID, ADN,  
IMDG-Code, ICAO/IATA-DGR

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**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** : Combustible dust  
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).

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### 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).

#### California List of Hazardous Substances

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

#### California Regulated Carcinogens

Silica 7631-86-9

#### The ingredients of this product are reported in the following inventories:

AU AIIC : Not in compliance with the inventory

CA. DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Baloxavir Marboxil

Sucralose

non hazardous compounds

NZ NZIoC : On the inventory, or in compliance with the inventory

JP ENCS : Not in compliance with the inventory

JP ISHL : Not in compliance with the inventory

**XOFLUZA Granules for Oral Susp. 2 mg/ml**

Version  
2.1

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- KR KECI : Not in compliance with the inventory
- PH PICCS : Not in compliance with the inventory
- CN IECSC : Not in compliance with the inventory
- TW TCSI : Not in compliance with the inventory
- US TSCA : Product contains substance(s) not listed on TSCA inventory.
- TH TECI : Not in compliance with the inventory

**TSCA list**

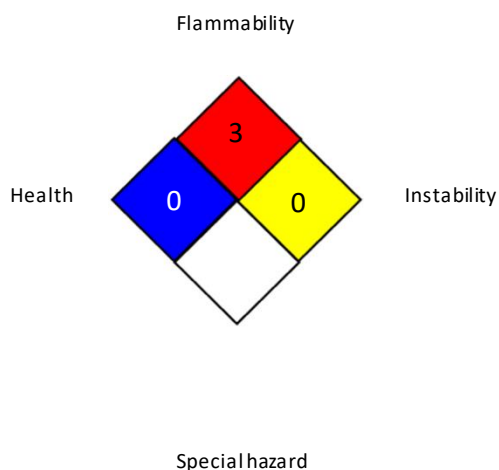
No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

**SECTION 16. OTHER INFORMATION**

**Further information**

**NFPA 704:**



**HMIS® IV / CED:**

<b>HEALTH</b>	<b>*</b>	<b>0</b>
<b>FLAMMABILITY</b>		<b>3</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 CARC : OSHA Specifically Regulated Chemicals/Carcinogens
- OSHA P0 : USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
- OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
- ACGIH / TWA : 8-hour, time-weighted average

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NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek  
OSHA CARC / PEL : Permissible exposure limit (PEL)  
OSHA P0 / TWA : 8-hour time weighted average  
OSHA Z-3 / TWA : 8-hour time weighted average

AllC - 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 Standardization; 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 Organization 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 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, Authorization 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; TECl - 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 : 04/01/2026

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

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