

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

Version 1.1 Revision Date: 08/05/2025 Date of last issue: 06/16/2025  
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**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 : US CHEMTREC PHONE (800)-424-9300  
In case of emergencies:

**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)**

Combustible dust

Carcinogenicity : Category 1A

**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.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

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

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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**

Chemical name	CAS-No.	Concentration (% w/w)
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
Sucratose	56038-13-2	0.5
Hydroxypropyl methylcellulose acetate succinate	71138-97-1	0.3
Strawberry Flavour	Not Assigned	0.1
Talc (Mg3H2(SiO3)4)	14807-96-6	0.1

**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.

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 : May cause cancer.

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delayed

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**

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.

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**SECTION 7. HANDLING AND STORAGE**

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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

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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	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)
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

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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.

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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

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
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	:	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 No data available
Incompatible materials	:	No data available Not applicable
Hazardous decomposition products	:	No data available

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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 method

Acute inhalation toxicity : Acute toxicity estimate: > 200 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method

**Components:****D-Mannitol:**

Acute oral toxicity : LD50 Oral (Rat): 13,500 mg/kg  
LD50 Oral (Mouse): 22,000 mg/kg

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

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

**Sodium chloride (NaCl):**

Acute oral toxicity : LD50 Oral (Rat): 3,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 42 mg/l  
Test atmosphere: dust/mist

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

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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 due to lack of data.

**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.

**Serious eye damage/eye irritation**

Not classified due to lack of data.

**Components:****Sodium chloride (NaCl):**

Species : Rabbit  
Result : No eye irritation

**Silica:**

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

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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

**Germ cell mutagenicity**

Not classified due to lack of data.

**Components:****Sodium chloride (NaCl):**

Genotoxicity in vitro	:	Test Type: Microbial mutagenesis assay (Ames test) Metabolic activation: with and without metabolic activation Method: Mutagenicity (micronucleus test) Result: negative
Genotoxicity in vivo	:	Test Type: Chromosome aberration test in vitro Species: Rat (female) Cell type: Bone marrow Application Route: Intraperitoneal injection Method: OECD Test Guideline 475 Result: positive

**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

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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:****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  
Application Route : Oral  
Exposure time : 2 Years  
Method : No information available.  
Result : negative

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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** OSHA specifically regulated carcinogen  
Silica  
(crystalline silica) 7631-86-9

**NTP** 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:  $\geq$  1,000 mg/kg body weight  
General Toxicity F1: NOAEL:  $\geq$  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:  $\geq$  1,340 mg/kg bw/day  
Embryo-fetal toxicity.: NOAEL:  $\geq$  1,340  $\mu$ g/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:****D-Mannitol:**

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:****D-Mannitol:**

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:****D-Mannitol:**

No data available

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

Remarks : No data available

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Remarks : Health injuries are not known or expected under normal use.

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****D-Mannitol:**Toxicity to fish : LC50 (Fish): > 100 mg/l  
Exposure time: 96 h

Toxicity to fish (Chronic toxicity) : &gt; 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 hLC50 (Lepomis macrochirus (Bluegill sunfish)): 5,840 mg/l  
Exposure time: 96 hToxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 874 mg/l  
Exposure time: 48 h  
Test Type: static testLC50 (Daphnia magna (Water flea)): 4,136 mg/l  
Exposure time: 48 h  
Test Type: static test  
Method: OECD Test Guideline 202Toxicity to algae/aquatic plants : EC50: 2,430 mg/l  
Exposure time: 120 h  
Test Type: static test  
Method: OECD Test Guideline 201Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 252 mg/l  
Exposure time: 33 d  
Test Type: flow-through test  
Method: OECD Test Guideline 210  
GLP: no

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Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia): 314 mg/l  
Exposure time: 21 d  
Test Type: semi-static test  
Method: OECD Test Guideline 211

**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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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  
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

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Method: OECD Test Guideline 301F

GLP: yes

Remarks: no adverse influence on substrate biodegradation

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

**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:****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: Not applicable

**Silica:**

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

**Baloxavir Marboxil:**

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Partition coefficient: n-octanol/water	:	log Pow: 2.24 Method: calculated, consensus of various QSARs
		log Pow: 2.46 (77 °F / 25 °C) pH: 5 Method: OECD Test Guideline 117 GLP: yes
		log Pow: 2.45 (77 °F / 25 °C) pH: 7 Method: OECD Test Guideline 117 GLP: yes
		log Pow: 2.46 (77 °F / 25 °C) pH: 9 Method: OECD Test Guideline 117 GLP: yes

**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

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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**

Not regulated as a dangerous good

**IATA-DGR**

Not regulated as a dangerous good

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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

**Special precautions for user**

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

**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**

Components	CAS-No.	Component TPQ (lbs)
<b>SARA 311/312 Hazards</b>	: Combustible dust Carcinogenicity	

**Clean Air Act**

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

**Clean Water Act**

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

**US State Regulations****Massachusetts Right To Know**

Silica 7631-86-9

**Pennsylvania Right To Know**

D-Mannitol	69-65-8
D-Glucitol, 4-O-.alpha.-D-glucopyranosyl-	585-88-6

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Sodium chloride (NaCl)	7647-14-5
Silica	7631-86-9

**Maine Chemicals of High Concern**

Silica	7631-86-9
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**Vermont Chemicals of High Concern****Washington Chemicals of High Concern****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
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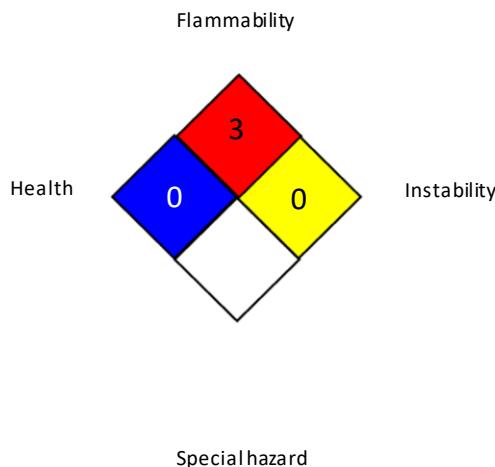
**The ingredients of this product are reported in the following inventories:**

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  Sucratose  Hydroxypropyl methylcellulose acetate succinate  NOTUPDATED_non hazardous compounds  Butyric acid ethyl ester
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

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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:**

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 CARC	: OSHA Specifically Regulated Chemicals/Carcinogens
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)

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; KECI - Korea Existing Chemicals Inventory; LC50

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- 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, 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 : 08/05/2025

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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