

**XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)**Version  
1.2Revision Date:  
02-08-2021Date of last issue: 11-11-2020  
Date of first issue: 11-10-2020**SECTION 1. IDENTIFICATION**

Product name : XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)  
Product code : RO719-1686/F20

**Manufacturer or supplier's details**

Company name of supplier : Genentech, Inc.  
Address : 1 DNA Way  
South San Francisco, CA 94080  
USA  
Telephone : 001-(650) 225-1000  
E-mail address : info.sds@roche.com  
Emergency telephone : 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.

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

Not a hazardous substance or mixture.

**GHS label elements**

Not a hazardous substance or mixture.

**Other hazards**

None known.

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

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Baloxavir Marboxil	1985606-14-1	0.2
D-Mannitol	69-65-8	6.0
D-Glucitol, 4-O-.alpha.-D-glucopyranosyl-	585-88-6	3.7
Sodium chloride (NaCl)	7647-14-5	0.3
Silica	7631-86-9	0.2
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8	0.1

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Sucralose	56038-13-2	0.1
Hydroxypropyl methylcellulose acetate succinate	71138-97-1	0.03
Talc (Mg <sub>3</sub> H <sub>2</sub> (SiO <sub>3</sub> ) <sub>4</sub> )	14807-96-6	0.01
Strawberry Flavour	Not Assigned	0.01
Water	7732-18-5	> 89.0

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**SECTION 4. FIRST AID MEASURES**

- General advice : Do not leave the victim unattended.
- If inhaled : Move to fresh air.  
If unconscious, place in recovery position and seek medical advice.  
If symptoms persist, call a physician.
- In case of skin contact : If on skin, rinse well with water.
- In case of eye contact : Immediately flush eye(s) with plenty of water.  
Remove contact lenses.  
Protect unharmed eye.  
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Rinse mouth with water.
- Most important symptoms and effects, both acute and delayed : None known.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

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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.
- Specific hazards during fire fighting : No information available.
- Hazardous combustion products : Carbon oxides
- Further information : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.

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**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : Refer to protective measures listed in sections 7 and 8.
- Environmental precautions : Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).  
Keep in suitable, closed containers for disposal.

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**SECTION 7. HANDLING AND STORAGE**

- Advice on protection against fire and explosion : Normal measures for preventive fire protection.
- Advice on safe handling : For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.
- Conditions for safe storage : Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Materials to avoid : No materials to be especially mentioned.
- Storage temperature : Do not freeze.  
Protected from heat and light
- Further information on storage stability : No decomposition if stored and applied as directed.
- Packaging material : Suitable material: glass bottles

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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

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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 particulate matter)	2 mg/m <sup>3</sup>	ACGIH

**Engineering measures** : No data available

**Personal protective equipment**

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

Material : Protective gloves

Remarks : Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.

Eye protection : Safety glasses

Skin and body protection : Protective suit

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

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : suspension

Color : white

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

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Evaporation rate                      : No data available

Self-ignition                      : Not applicable

Upper explosion limit / Upper flammability limit                      : No data available

Lower explosion limit / Lower flammability limit                      : No data available

Vapor pressure                      : No data available

Relative vapor density                      : No data available

Relative density                      : No data available

Solubility(ies)

    Water solubility                      : No data available

    Solubility in other solvents                      : No data available

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

Autoignition temperature                      : No data available

Decomposition temperature                      : No data available

Viscosity

    Viscosity, dynamic                      : No data available

    Viscosity, kinematic                      : No data available

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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.

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.

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

**D-Mannitol:**

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

LD50 Oral (Mouse): 22,000 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l  
Test atmosphere: dust/mist  
Method: Expert judgmentAcute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Expert judgment**Sodium chloride (NaCl):**

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

LD50 Oral (Mouse): 4,000 mg/kg

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

Acute dermal toxicity : LD50 Dermal (Rabbit): &gt; 10,000 mg/kg

**Silica:**

Acute oral toxicity : LD50 Oral (Rat): &gt; 3,300 mg/kg

Acute inhalation toxicity : LC50 (Rat, male and female): > 5.01 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 436  
GLP: yes  
Assessment: The substance or mixture has no acute inhalation toxicityAcute dermal toxicity : LD50 Dermal (Rabbit): > 5,000 mg/kg  
Method: No information available.  
GLP: No information available.**2-Pyrrolidinone, 1-ethenyl-, homopolymer:**

Acute oral toxicity : LD50 Oral (Rat): &gt; 10,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): 5.2 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403Acute dermal toxicity : Acute toxicity estimate: > 5,001 mg/kg  
Method: Expert judgment

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Acute oral toxicity : LD50 Oral (Rat): &gt; 10,000 mg/kg

**Hydroxypropyl methylcellulose acetate succinate:**Acute oral toxicity : Acute toxicity estimate (Rat): > 5,000 mg/kg  
Method: Expert judgmentAcute inhalation toxicity : Acute toxicity estimate: > 30 mg/l  
Test atmosphere: dust/mist  
Method: Expert judgmentAcute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Expert judgment**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Sodium chloride (NaCl):**Species : Rabbit  
Result : No skin irritation**Silica:**Species : Rabbit  
Exposure time : 4 h  
Method : OECD Test Guideline 404  
Result : No skin irritation  
GLP : No information available.**2-Pyrrolidinone, 1-ethenyl-, homopolymer:**Species : Rabbit  
Result : No skin irritation**Talc (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.

**Components:****Sodium chloride (NaCl):**Species : Rabbit  
Result : No eye irritation

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

**2-Pyrrolidinone, 1-ethenyl-, homopolymer:**

Species : Rabbit  
Result : No eye irritation

**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**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

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

Remarks : This information is not available.

**Silica:**

Test Type : Maximization Test  
Species : Guinea pig  
Assessment : Does not cause skin sensitization.  
Method : OECD Test Guideline 406  
Result : Did not cause sensitization on laboratory animals.  
GLP : yes

**Strawberry Flavour:**

Assessment : May cause sensitization by skin contact.

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Baloxavir Marboxil:**

Genotoxicity in vitro : Method: Mutagenicity (Salmonella typhimurium - reverse mutation assay)  
Result: negative

Method: OECD Test Guideline 473  
Result: negative



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Genotoxicity in vivo : Method: OECD Test Guideline 474  
Result: negative

**Sodium chloride (NaCl):**

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

Test Type: Ames test  
Result: negative

**Silica:**

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)  
Test system: Salmonella typhimurium  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 471  
Result: negative  
GLP: yes

Test Type: Microbial mutagenesis assay (Ames test)  
Test system: Escherichia coli  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 471  
Result: negative  
GLP: yes

Test Type: In vitro mammalian cell gene mutation test  
Test system: mouse lymphoma cells  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 490  
Result: negative  
GLP: yes

Genotoxicity in vivo : Species: Rat (male)  
Cell type: Bone marrow  
Application Route: Oral  
Exposure time: 6, 24, and 48 h  
Dose: 1.4, 14, 140, 500, 5000 mg/kg  
Method: OECD Test Guideline 475  
Result: negative  
GLP: no

**2-Pyrrolidinone, 1-ethenyl-, homopolymer:**

Germ cell mutagenicity - Assessment : Tests on bacterial or mammalian cell cultures did not show mutagenic effects.

**Carcinogenicity**

Not classified based on available information.

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

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Remarks : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**D-Glucitol, 4-O-.alpha.-D-glucopyranosyl-:**

Remarks : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**Reproductive toxicity**

Not classified based on available information.

**Components:**
**Baloxavir Marboxil:**

Effects on fetal development : Species: Rat  
 Application Route: Oral  
 Dose: 1000 milligram per kilogram  
 Duration of Single Treatment: 12 d  
 Result: No effects on fetal development.

Species: Rabbit  
 Application Route: Oral  
 Dose: 100 milligram per kilogram  
 Duration of Single Treatment: 12 d  
 Result: No effects on fetal development.

**Silica:**

Effects on fertility : Species: Rat, male and female  
 Application Route: Oral  
 Dose: 100, 300, 1000 mg/kg bw/day  
 General Toxicity Parent: NOAEL: >= 1,000 mg/kg body weight  
 General Toxicity F1: NOAEL: >= 1,000 mg/kg body weight  
 Method: OECD Test Guideline 416  
 GLP: yes

Effects on fetal development : Species: Mouse, female  
 Application Route: Oral  
 Dose: 13.4, 62.3, 289, 1340 mg/kg bw/day  
 Duration of Single Treatment: 6 - 15 d  
 General Toxicity Maternal: LOAEL: >= 1,340 mg/kg bw/day  
 Embryo-fetal toxicity.: NOAEL: >= 1,340 µg/kg body weight  
 Method: No information available.  
 GLP: No information available.

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Not classified based on available information.

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

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

**2-Pyrrolidinone, 1-ethenyl-, homopolymer:**

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

**Hydroxypropyl methylcellulose acetate succinate:**

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

**Talc (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.

**Components:****Baloxavir Marboxil:**

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

**D-Mannitol:**

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

**2-Pyrrolidinone, 1-ethenyl-, homopolymer:**

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

**Hydroxypropyl methylcellulose acetate succinate:**

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

**Talc (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.

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Species : Rat  
NOAEL : 2000 mg/kg bw/day  
Application Route : Oral  
Exposure time : 2 Weeks  
Remarks : Subacute toxicity

**Aspiration toxicity**

Not classified based on available information.

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

No data available

**2-Pyrrolidinone, 1-ethenyl-, homopolymer:**

No data available

**Hydroxypropyl methylcellulose acetate succinate:**

No data available

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

No data available

**Further information****Components:****D-Mannitol:**

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

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Baloxavir Marboxil:**

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

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

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Remarks: average measured concentration

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

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

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

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

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

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

**D-Mannitol:**

Toxicity to fish : LC50 (Fish): > 100 mg/l  
Exposure time: 96 h

Toxicity to fish (Chronic toxicity) : > 1 mg/l

**Ecotoxicology Assessment**

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

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

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

Other organisms relevant to the environment : No data available

**Sodium chloride (NaCl):**

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

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

**Ecotoxicology Assessment**

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

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

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

Other organisms relevant to                              : No data available  
 the environment

**Silica:**

Toxicity to fish                                      : (Danio rerio (zebra fish)): 10.000 mg/l  
 End point: mortality  
 Exposure time: 96 h  
 Test Type: static test  
 Analytical monitoring: no  
 Method: OECD Test Guideline 203  
 GLP: yes

Toxicity to daphnia and other                      : (Daphnia magna (Water flea)): > 10,000 mg/l  
 aquatic invertebrates                                      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                                      : EC50 (Desmodesmus subspicatus (green algae)): > 173.1  
 plants    mg/l  
 Exposure time: 72 h  
 Test Type: static test  
 Analytical monitoring: yes  
 Method: OECD Test Guideline 201  
 GLP: yes

Toxicity to daphnia and other                      : Lowest Observed Effect Concentration (Daphnia magna  
 aquatic invertebrates                                      (Water flea)): 149.2 mg/l  
 (Chronic toxicity)    End point: mortality  
 Exposure time: 21 d  
 Analytical monitoring: yes  
 Method: OECD Test Guideline 211  
 GLP: yes

Toxicity to microorganisms                              : NOEC (activated sludge): 1,000 mg/l  
 Exposure time: 3 h  
 Test Type: static test  
 Analytical monitoring: no  
 Method: OECD Test Guideline 209

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GLP: yes

**Ecotoxicology Assessment**

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

Other organisms relevant to  
the environment : No data available**2-Pyrrolidinone, 1-ethenyl-, homopolymer:**Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l  
Exposure time: 96 h**Ecotoxicology Assessment**

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

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

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

Other organisms relevant to  
the environment : No data available**Hydroxypropyl methylcellulose acetate succinate:**Toxicity to fish : LC50 (Fish): > 100 mg/l  
Exposure time: 96 h**Ecotoxicology Assessment**

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

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

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

Other organisms relevant to  
the environment : No data available**Talc (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

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Biodegradability : Result: Not readily biodegradable.  
Biodegradation: < 10 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F  
GLP: yes

Physico-chemical : Method: OECD Test Guideline 301F  
removability : Remarks: Not abiotically degradable

**D-Mannitol:**

Biodegradability : Biodegradation: 68 %  
Exposure time: 28 d

**Sodium chloride (NaCl):**

Biodegradability : Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

**Silica:**

Biodegradability : Remarks: Not applicable

**2-Pyrrolidinone, 1-ethenyl-, homopolymer:**

Biodegradability : Zahn-Wellens Test  
Biodegradation: < 10 %  
Exposure time: 15 d  
Method: OECD Test Guideline 302B

**Bioaccumulative potential****Components:****Baloxavir Marboxil:**

Partition coefficient: n- : log Pow: 2.24  
octanol/water : Method: calculated, consensus of various QSARs

log Pow: 2.46 (77 °F / 25 °C)  
pH: 5  
Method: OECD Test Guideline 117  
GLP: yes

log Pow: 2.45 (77 °F / 25 °C)  
pH: 7  
Method: OECD Test Guideline 117  
GLP: yes

log Pow: 2.46 (77 °F / 25 °C)  
pH: 9  
Method: OECD Test Guideline 117  
GLP: yes



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octanol/water : log Pow: -3.10**D-Glucitol, 4-O-.alpha.-D-glucoopyranosyl-:**Partition coefficient: n-  
octanol/water : Remarks: No data available**Sodium chloride (NaCl):**Partition coefficient: n-  
octanol/water : Remarks: No data available**Silica:**Partition coefficient: n-  
octanol/water : Remarks: Not applicable**2-Pyrrolidinone, 1-ethenyl-, homopolymer:**Partition coefficient: n-  
octanol/water : Remarks: No data available**Sucralose:**Partition coefficient: n-  
octanol/water : Remarks: No data available**Hydroxypropyl methylcellulose acetate succinate:**Partition coefficient: n-  
octanol/water : Remarks: No data available**Talc (Mg<sub>3</sub>H<sub>2</sub>(SiO<sub>3</sub>)<sub>4</sub>):**Partition coefficient: n-  
octanol/water : Remarks: No data available**Strawberry Flavour:**Partition coefficient: n-  
octanol/water : Remarks: No data available**Water:**Partition coefficient: n-  
octanol/water : Remarks: No data available**Mobility in soil**

No data available

**Other adverse effects****Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82

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

### Components:

#### **Talc (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 : Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Do not re-use empty containers.

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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** : No SARA Hazards

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

**Clean Air Act**

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

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

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

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 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**

No components are subject to the Massachusetts Right to Know Act.

**Pennsylvania Right To Know**

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

**Maine Chemicals of High Concern**

Product does not contain any listed chemicals

**Vermont Chemicals of High Concern**

Product does not contain any listed chemicals

**Washington Chemicals of High Concern**

Product does not contain any listed chemicals

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

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

Baloxavir Marboxil

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Sucralose

Hydroxypropyl methylcellulose acetate succinate

Strawberry Flavour

- AICS : Not in compliance with the inventory
- NZIoC : On the inventory, or in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- KECI : Not in compliance with the inventory
- PICCS : Not in compliance with the inventory
- IECSC : Not in compliance with the inventory
- TCSI : Not in compliance with the inventory
- TSCA : Product contains substance(s) not listed on TSCA inventory.

**TSCA list**

No substances are subject to a Significant New Use Rule.

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

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**SECTION 16. OTHER INFORMATION**

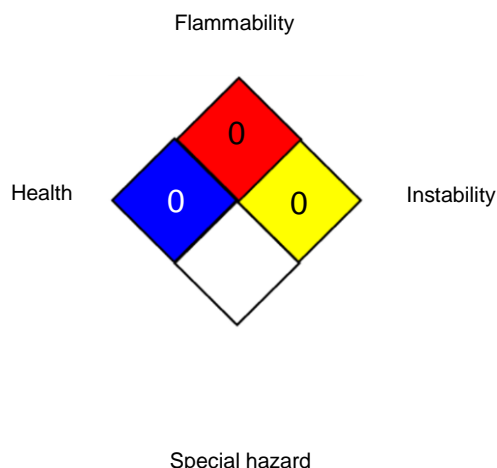
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**NFPA 704:**



**HMIS® IV:**

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

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

**Full text of other abbreviations**

- ACGIH : USA. ACGIH Threshold Limit Values (TLV)
- NIOSH REL : USA. NIOSH Recommended Exposure Limits
- OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
- ACGIH / TWA : 8-hour, time-weighted average
- NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
- OSHA Z-3 / TWA : 8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; 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 - 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

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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; 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 : 02-08-2021

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.

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