

XOFLUZATM Granules for Oral Suspension

Version
1.0

Revision Date:
11-02-2020

Date of last issue: -
Date of first issue: 11-02-2020

SECTION 1. IDENTIFICATION

Product name : XOFLUZATM Granules for Oral Suspension
Product code : RO719-1686/F08

Manufacturer or supplier's details

Company name of supplier : Genentech, Inc.
Address : DNA Way 1
94080 South San Francisco
CA
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)

Skin sensitization : Category 1
Carcinogenicity : Category 1A

GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H317 May cause an allergic skin reaction.
H350 May cause cancer.

Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.
P272 Contaminated work clothing must not be allowed out of

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the workplace.

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

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

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

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P363 Wash contaminated clothing before reuse.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

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

SECTION 4. FIRST AID MEASURES

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

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

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- In case of skin contact : If on skin, rinse well with water.
- In case of eye contact : Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Rinse mouth with water.
- Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.
May cause cancer.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire fighting : No information available.
- Hazardous combustion products : In case of fire hazardous decomposition products may be produced such as:
Hydrogen fluoride
Sulfur oxides
Nitrogen oxides (NO_x)
- Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Avoid dust formation.
Avoid breathing dust.
- Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.
If the product contaminates rivers and lakes or drains inform

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respective authorities.

Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Avoid dust formation.
Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling : Avoid formation of respirable particles.
Do not breathe vapors/dust.
Avoid exposure - obtain special instructions before use.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.
Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.
Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions : See label, package insert or internal guidelines

Storage temperature : to 25 °C
Protect against light.

Further information on storage stability : No decomposition if stored and applied as directed.

Packaging material : Suitable material: glass bottles, Polyethylene bag in metal drum

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

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		TWA (Dust)	80 mg/m ³ / %SiO ₂ (Silica)	OSHA Z-3
		TWA	6 mg/m ³ (Silica)	NIOSH REL
Baloxavir Marboxil	1985606-14-1	IOEL	0.004 mg/m ³	Roche Industrial Hygiene Committee (RIHC)
Talc (Mg ₃ H ₂ (SiO ₃) ₄)	14807-96-6	TWA (Dust)	20 Million particles per cubic foot	OSHA Z-3
		TWA (Respirable particulate matter)	2 mg/m ³	ACGIH

Engineering measures : No data available

Personal protective equipment

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.
Effective dust mask

Hand protection

Material : Protective gloves

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

Eye protection : Eye wash bottle with pure water
Tightly fitting safety goggles

Skin and body protection : Dust impervious protective suit
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Hygiene measures : Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : granules

Color : white, light yellow

Odor : Not applicable

Odor Threshold : Not applicable

pH : Not applicable

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Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Does not sustain combustion.
Flammability (liquids)	:	Does not sustain combustion.
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	Not applicable
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	No decomposition if stored and applied as directed. Dust may form explosive mixture in air.
Conditions to avoid	:	No data available

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Incompatible materials : No data available

Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified based on available information.

Product:Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation 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 Oral (Rat): > 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.**Baloxavir Marboxil:**

Acute oral toxicity : LD50 Oral (Rat): > 2,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks : May cause skin irritation and/or dermatitis.

Components:**Silica:**Species : Rabbit
Exposure time : 4 h
Method : OECD Test Guideline 404
Result : No skin irritation

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GLP : No information available.

Talc (Mg₃H₂(SiO₃)₄):

Remarks : This information is not available.

Strawberry Flavour:

Result : Irritating to skin.

Serious eye damage/eye irritation

Not classified based on available information.

Product:

Remarks : Product dust may be irritating to eyes, skin and respiratory system.

Components:**Silica:**Species : Rabbit
Result : No eye irritation
Exposure time : 24 h
GLP : no**Talc (Mg₃H₂(SiO₃)₄):**

Remarks : This information is not available.

Strawberry Flavour:

Result : Irritating to eyes.

Respiratory or skin sensitization**Skin sensitization**

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Product:

Remarks : Causes sensitization.

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

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Assessment : May cause sensitization by skin contact.

Germ cell mutagenicity

Not classified based on available information.

Components:

Silica:

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

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

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.

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.

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

NTP Known to be human carcinogen
Talc (Mg₃H₂(SiO₃)₄) 14807-96-6
(Silica, Crystalline (Respirable Size))

Reproductive toxicity

Not classified based on available information.

Components:**Silica:**

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

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

Baloxavir Marboxil:

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

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

STOT-single exposure

Not classified based on available information.

Components:**Talc (Mg₃H₂(SiO₃)₄):**

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

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Not classified based on available information.

Components:**Baloxavir Marboxil:**

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

Talc (Mg₃H₂(SiO₃)₄):

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

Repeated dose toxicity**Components:****Baloxavir Marboxil:**Species : Rat
NOAEL : mg/kg bw/day, 2000
Application Route : Oral
Exposure time : 2 Weeks
Remarks : Subacute toxicity**Aspiration toxicity**

Not classified based on available information.

Components:**Talc (Mg₃H₂(SiO₃)₄):**

No data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****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: yesToxicity to daphnia and other aquatic invertebrates : (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

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GLP: yes

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 173.1 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 aquatic invertebrates (Chronic toxicity) : Lowest Observed Effect Concentration (Daphnia magna (Water flea)): 149.2 mg/l
 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
 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

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- 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 (Mg₃H₂(SiO₃)₄):

- Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100,000 mg/l
 Exposure time: 24 h

Ecotoxicology Assessment

- Acute aquatic toxicity : This product has no known ecotoxicological effects.
- Chronic aquatic toxicity : This product has no known ecotoxicological effects.
- Toxicity Data on Soil : Not expected to adsorb on soil.
- Other organisms relevant to the environment : No data available

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: yes

- Physico-chemical : Method: OECD Test Guideline 301F

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removability

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 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

Talc (Mg₃H₂(SiO₃)₄):Partition coefficient: n-
octanol/water

: Remarks: No data available

Strawberry Flavour:Partition coefficient: n-
octanol/water

: Remarks: No data available

Mobility in soil

No data available

Other adverse effects**Product:**

Ozone-Depletion Potential

: Regulation: 40 CFR Protection of Environment; Part 82
Protection of Stratospheric Ozone - CAA Section 602 Class I
Substances
Remarks: This product neither contains, nor was
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).

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Components:

Talc (Mg₃H₂(SiO₃)₄):

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

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.

Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.

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 for product as supplied.

Domestic regulation

49 CFR

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

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.

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This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Respiratory or skin sensitization
Carcinogenicity**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.**Clean Air Act**

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

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

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

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

US State Regulations**Massachusetts Right To Know**

Silica 7631-86-9

Pennsylvania Right To KnowD-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**

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

California List of Hazardous SubstancesSilica 7631-86-9
2-Pyrrolidinone, 1-ethenyl-, homopolymer 9003-39-8**California Permissible Exposure Limits for Chemical Contaminants**

Silica 7631-86-9

California Regulated Carcinogens

Talc (Mg3H2(SiO3)4) 14807-96-6

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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

Sucralose

Hydroxypropyl methylcellulose acetate succinate

Strawberry Flavour

AICS : Not in compliance with the inventory

NZIoC : Not in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

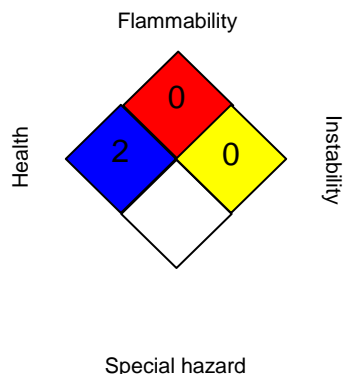
TSCA : Product contains substance(s) not listed on TSCA inventory.

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

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HEALTH	*	2
FLAMMABILITY		0
PHYSICAL HAZARD		0

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

Full text of other abbreviations

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); EC_x - Concentration associated with x% response; EHS - Extremely Hazardous Substance; EL_x - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErC_x - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC₅₀ - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC₅₀ - Lethal Concentration to 50 % of a test population; LD₅₀ - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the

XOFLUZATM Granules for Oral Suspension

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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

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