SAFETY DATA SHEET

Genentech
A Member of the Roche Group

XOFLUZA Reconst. Oral Susp. 2 mg/ml

Version	Revision Date:	Date of last issue: 02-08-2021
1.3	10-15-2021	Date of first issue: 11-10-2020

SECTION 1. IDENTIFICATION

Product name	:	XOFLUZA Reconst. Oral Susp. 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		
Emergency telephone number	:	US Chemtrec phone (800)-424-9300

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)

Carcinogenicity	:	Category 1A

GHS label elements

Hazard pictograms :

Signal Word	:	Danger
Hazard Statements	:	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.

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	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
Sucralose	56038-13-2	0.1
Hydroxypropyl methylcellulose acetate succinate	71138-97-1	0.03
Talc (Mg3H2(SiO3)4)	14807-96-6	0.01
Strawberry Flavour	Not Assigned	0.01
Water	7732-18-5	> 89.0

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	:	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.
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.

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.

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

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/m3 / %SiO2 (Silica)	OSHA Z-3
		TWA	6 mg/m3 (Silica)	NIOSH REL
		TWA (Respirable dust)	0.05 mg/m3 (Silica)	NIOSH REL
Baloxavir Marboxil	1985606-14-1	IOEL	0.0025 mg/m3	Roche Industrial Hygiene Committee (RIHC)

Predicted No Effect Concentration (PNEC):

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

Engineering measures : No data available

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

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

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
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

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

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified based on available information.

Components:

Baloxavir Marboxil:

Acute oral toxicity	:	LD50 Oral (Rat): > 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 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

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): > 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
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.

2-Pyrrolidinone, 1-ethenyl-, homopolymer:

Acute oral toxicity : LD50 Oral (Rat): > 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 403

Acute dermal toxicity : Acute toxicity estimate: > 5,001 mg/kg
Method: Expert judgment

Sucralose:

Acute oral toxicity : LD50 Oral (Rat): > 10,000 mg/kg

Hydroxypropyl methylcellulose acetate succinate:

Acute oral toxicity : Acute toxicity estimate (Rat): > 5,000 mg/kg
Method: Expert judgment

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

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 (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.

Components:

Sodium chloride (NaCl):

Species : Rabbit
Result : No eye irritation

Silica:

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

2-Pyrrolidinone, 1-ethenyl-, homopolymer:

Species : Rabbit
Result : No eye irritation

Talc (Mg3H2(SiO3)4):

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

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
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

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
Frequency of Treatment	:	daily
Method	:	No information available.
Result	:	negative
GLP	:	No information available.

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

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

NTP Known to be human carcinogen

Silica	7631-86-9
(Silica, Crystalline (Respirable Size))	

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.

STOT-single exposure

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 (Mg3H2(SiO3)4):

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:

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 (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	:	2000 mg/kg bw/day
Application Route	:	Oral
Exposure time	:	2 Weeks

Remarks : Subacute toxicity

Silica:

Species	:	Rat, male and female
NOEL	:	4000 mg/kg
Application Route	:	Oral
Exposure time	:	13 Weeks
Method	:	OECD Test Guideline 408
GLP	:	yes

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 (Mg3H2(SiO3)4):

No data available

Further information

Components:

D-Mannitol:

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

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

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):

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 7,650 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 1,000 mg/l 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 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

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

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 (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 : No data available

the environment

Persistence and degradability

Components:

Baloxavir Marboxil:

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

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: 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 (Mg3H2(SiO3)4):

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 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 (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	:	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.

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

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

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

SARA 311/312 Hazards : 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 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

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

Silica	7631-86-9

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Prop. 65

WARNING: This product can expose you to chemicals including Silica, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

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 Sucralose Hydroxypropyl methylcellulose acetate succinate Strawberry Flavour
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

TSCA list

No substances are subject to a Significant New Use Rule.

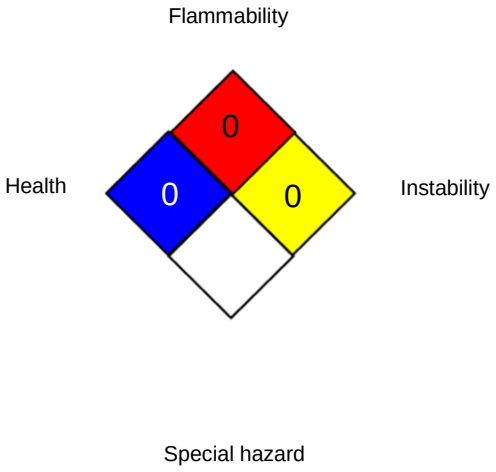
No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

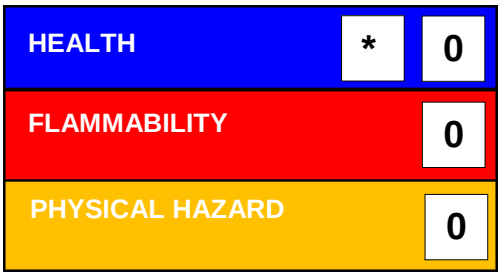
XOFLUZA Reconst. Oral Susp. 2 mg/ml

Version	Revision Date:	Date of last issue: 02-08-2021
1.3	10-15-2021	Date of first issue: 11-10-2020

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

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; 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 Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 10-15-2021

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

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