

XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)
Version
1.1Revision Date:
11-11-2020Date of last issue: 11-10-2020
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 : DNA Way 1
 94080 South San Francisco
 CA
 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)**

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

XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)
Version
1.1Revision Date:
11-11-2020Date of last issue: 11-10-2020
Date of first issue: 11-10-2020

Sucralose	56038-13-2	0.1
Hydroxypropyl methylcellulose acetate succinate	71138-97-1	0.03
Talc (Mg ₃ H ₂ (SiO ₃) 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 : None known.
- 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.

XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)

Version
1.1

Revision Date:
11-11-2020

Date of last issue: 11-10-2020
Date of first issue: 11-10-2020

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

Contains no substances with occupational exposure limit values.

Engineering measures : No data available

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

Material : Protective gloves

SAFETY DATA SHEET

XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)

Version
1.1

Revision Date:
11-11-2020

Date of last issue: 11-10-2020
Date of first issue: 11-10-2020

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

XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)

Version 1.1	Revision Date: 11-11-2020	Date of last issue: 11-10-2020 Date of first issue: 11-10-2020
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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

XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)

Version 1.1 Revision Date: 11-11-2020 Date of last issue: 11-10-2020
Date of first issue: 11-10-2020

Acute dermal toxicity : LD50 Dermal (Rabbit): > 10,000 mg/kg

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 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:

XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)Version
1.1Revision Date:
11-11-2020Date of last issue: 11-10-2020
Date of first issue: 11-10-2020

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.

XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)Version
1.1Revision Date:
11-11-2020Date of last issue: 11-10-2020
Date of first issue: 11-10-2020**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: negativeMethod: OECD Test Guideline 473
Result: negativeGenotoxicity 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: negativeTest 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: yesTest Type: Microbial mutagenesis assay (Ames test)
Test system: Escherichia coli
Metabolic activation: with and without metabolic activation

XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)Version
1.1Revision Date:
11-11-2020Date of last issue: 11-10-2020
Date of first issue: 11-10-2020Method: OECD Test Guideline 471
Result: negative
GLP: yesTest 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: yesGenotoxicity 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:**

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-glucoopyranosyl-:

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:**

XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)Version
1.1Revision Date:
11-11-2020Date of last issue: 11-10-2020
Date of first issue: 11-10-2020

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.

XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)Version
1.1Revision Date:
11-11-2020Date of last issue: 11-10-2020
Date of first issue: 11-10-2020**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 (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**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

XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)Version
1.1Revision Date:
11-11-2020Date of last issue: 11-10-2020
Date of first issue: 11-10-2020**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**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 concentrationNOEC (Danio rerio (zebra fish)): 10.6 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
GLP: yes
Remarks: average measured concentrationToxicity 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 concentrationNOEC (Daphnia magna (Water flea)): 17.4 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: measured initial concentrationToxicity to algae : ErC50 (Desmodesmus subspicatus (green algae)): 9.28 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes
Remarks: average measured concentrationNOErC (Desmodesmus subspicatus (green algae)): 1.75 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes
Remarks: average measured concentrationEyC50 (Desmodesmus subspicatus (green algae)): 4.76 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes

XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)

 Version
 1.1

 Revision Date:
 11-11-2020

 Date of last issue: 11-10-2020
 Date of first issue: 11-10-2020

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 : (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 aquatic invertebrates : (Daphnia magna (Water flea)): > 10,000 mg/l
 End point: Immobilization

XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)Version
1.1Revision Date:
11-11-2020Date of last issue: 11-10-2020
Date of first issue: 11-10-2020Exposure time: 24 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 202
GLP: yes

Toxicity to algae : 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

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

XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)Version
1.1Revision Date:
11-11-2020Date of last issue: 11-10-2020
Date of first issue: 11-10-2020**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 the environment : No data available

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

XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)Version
1.1Revision Date:
11-11-2020Date of last issue: 11-10-2020
Date of first issue: 11-10-2020Biodegradation: < 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 QSARslog Pow: 2.46 (77 °F / 25 °C)
pH: 5
Method: OECD Test Guideline 117
GLP: yeslog Pow: 2.45 (77 °F / 25 °C)
pH: 7
Method: OECD Test Guideline 117
GLP: yeslog Pow: 2.46 (77 °F / 25 °C)
pH: 9
Method: OECD Test Guideline 117
GLP: yes**D-Mannitol:**

Partition coefficient: n-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

XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)Version
1.1Revision Date:
11-11-2020Date of last issue: 11-10-2020
Date of first issue: 11-10-2020**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.

XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)Version
1.1Revision Date:
11-11-2020Date of last issue: 11-10-2020
Date of first issue: 11-10-2020**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**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.

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 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.

XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)Version
1.1Revision Date:
11-11-2020Date of last issue: 11-10-2020
Date of first issue: 11-10-2020

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

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

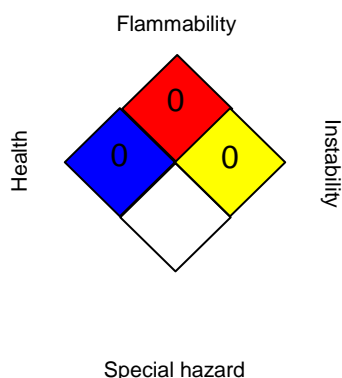
TCSI : Not in compliance with the inventory

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.

XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)
Version
1.1Revision Date:
11-11-2020Date of last issue: 11-10-2020
Date of first issue: 11-10-2020
SECTION 16. OTHER INFORMATION
NFPA:

HMIS® IV:

HEALTH	/	0
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

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 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

XOFLUZA(TM) Reconstituted Oral Suspension (2 mg/ml)

Version
1.1

Revision Date:
11-11-2020

Date of last issue: 11-10-2020
Date of first issue: 11-10-2020

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 : 11-11-2020

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.

US / Z8 / 1810