

## XOFLUZA(TM) (Baloxavir Marboxil) Tablets 20mg

Version 1.0                      Revision Date: 02-20-2020                      Date of last issue: -  
Date of first issue: 02-20-2020

### SECTION 1. IDENTIFICATION

Product name : XOFLUZA(TM) (Baloxavir Marboxil) Tablets 20mg  
Product code : RO719-1686/F04  
Common name(s), syno- : XOFLUZA Film Coated Tablets 20 mg  
nym(s) of the substance : XOFLUZA F.C. Tablets 20 mg  
BS11564, BS11395

#### 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 num- : ber

#### Recommended use of the chemical and restrictions on use

Recommended use : Formulated pharmaceutical active substance  
Restrictions on use : For professional users only.


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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with 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.

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attention.**Storage:**

P405 Store locked up.

**Disposal:**P501 Dispose of contents/ container to an approved waste dis-  
posal plant.**Other hazards**

None known.

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

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Baloxavir Marboxil	1985606-14-1	15.7
Lactose-1-Hydrate	64044-51-5	61.3
Cellulose	9004-34-6	9.0
Croscarmellose sodium	74811-65-7	4.3
2-Pyrrolidinone, 1-ethenyl-, homo- polymer	9003-39-8	4.3
sodium octadecyl fumarate	4070-80-8	1.3
Titanium oxide (TiO <sub>2</sub> )	13463-67-7	< 1.2
Talc (Mg <sub>3</sub> H <sub>2</sub> (SiO <sub>3</sub> ) <sub>4</sub> )	14807-96-6	0.2
non hazardous compounds	Not Assigned	2.7

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**SECTION 4. FIRST AID MEASURES**

- General advice : Do not leave the victim unattended.
- If inhaled : Move to fresh air.  
If unconscious, place in recovery position and seek medical advice.  
If symptoms persist, call a physician.
- In case of skin contact : If on skin, rinse well with water.
- In case of eye contact : Immediately flush eye(s) with plenty of water.  
Remove contact lenses.  
Protect unharmed eye.  
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.

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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 : Do not allow run-off from fire fighting to enter drains or water courses.
- Hazardous combustion products : In case of fire hazardous decomposition products may be produced such as:  
Hydrogen fluoride  
Sulfur oxides  
Nitrogen oxides (NOx)  
Carbon oxides
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.  
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
- 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 : Avoid dust formation.
- Environmental precautions : Prevent product from entering drains.
- Methods and materials for containment and cleaning up : Pick up and arrange disposal without creating dust.  
Sweep up and shovel.  
Keep in suitable, closed containers for disposal.

**SECTION 7. HANDLING AND STORAGE**

- Advice on protection against fire and explosion : Provide appropriate exhaust ventilation at places where dust is formed.
- Advice on safe handling : For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.
- Conditions for safe storage : Containers which are opened must be carefully resealed and

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kept upright to prevent leakage.  
 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 : Protected from heat and light
- Further information on storage stability : No decomposition if stored and applied as directed.
- Packaging material : Suitable material: Blister packages, Stainless steel, glass bottles

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**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**
**Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Baloxavir Marboxil	1985606-14-1	IOEL	0.004 mg/m <sup>3</sup>	Roche Industrial Hygiene Committee (RIHC)
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Total dust)	15 mg/m <sup>3</sup>	OSHA P0
		TWA (respirable dust fraction)	5 mg/m <sup>3</sup>	OSHA P0
Titanium oxide (TiO <sub>2</sub> )	13463-67-7	TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Total dust)	10 mg/m <sup>3</sup>	OSHA P0
		TWA	10 mg/m <sup>3</sup> (Titanium dioxide)	ACGIH
Talc (Mg <sub>3</sub> H <sub>2</sub> (SiO <sub>3</sub> ) <sub>4</sub> )	14807-96-6	TWA (Dust)	20 Million particles per cubic foot	OSHA Z-3
		TWA (Respirable fraction)	2 mg/m <sup>3</sup>	ACGIH

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Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

Material : Protective gloves

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

Eye protection : Safety glasses

Skin and body protection : Protective suit

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

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : tablet

Color : white, light yellow

Odor : Not applicable

Odor Threshold : Not applicable

pH : Not applicable

Melting point/range : No data available

Boiling point/boiling range : No data available

Evaporation rate : No data available

Self-ignition : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : Not applicable

Relative density : No data available

Solubility(ies)

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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 : No data available

Oxidizing properties : No data available

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Stable under recommended storage conditions.  
No hazards to be specially mentioned.

Incompatible materials : No data available

Hazardous decomposition products : No data available

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**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Not classified based on available information.

**Product:**

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 95.26 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

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

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

**Cellulose:**

Acute oral toxicity                      : LD50 Oral (Rat): > 5,000 mg/kg

Acute dermal toxicity                      : LD50 Dermal (Rabbit): > 2,000 mg/kg

**Titanium oxide (TiO<sub>2</sub>):**

Acute oral toxicity                      : LD50 (Rat): > 7,500 mg/kg

Acute inhalation toxicity                      : LC50 (Rat): > 6.82 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

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

**Skin corrosion/irritation**

Not classified based on available information.

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

Remarks                      : This information is not available.

**Serious eye damage/eye irritation**

Not classified based on available information.

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

Remarks                      : This information is not available.

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Germ cell mutagenicity**

Not classified based on available information.

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

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

Method: OECD Test Guideline 473  
Result: negative

Genotoxicity in vivo                      : Method: OECD Test Guideline 474

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Result: negative

**Carcinogenicity**

May cause cancer.

**Components:**

**Cellulose:**

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**                      Group 2B: Possibly carcinogenic to humans  
Titanium oxide (TiO2)                      13463-67-7

**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:**

**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.

**STOT-repeated exposure**

Not classified based on available information.



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

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

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

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

No data available

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Baloxavir Marboxil:**Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10.6 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
GLP: yes  
Remarks: average measured 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 concentration

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- 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

**Cellulose:**
**Ecotoxicology Assessment**

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

**Titanium oxide (TiO<sub>2</sub>):**

- Toxicity to fish : LC0 (Leuciscus idus (Golden orfe)): > 1,000 mg/l  
 Exposure time: 48 h
- Toxicity to daphnia and other aquatic invertebrates : EC0 (Daphnia magna (Water flea)): 3 mg/l  
 Exposure time: 720 h

**Ecotoxicology Assessment**

- Toxicity Data on Soil : Not expected to adsorb on soil.
- Other organisms relevant to the environment : No data available

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

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

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- 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

**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

**Cellulose:**

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

**Titanium oxide (TiO<sub>2</sub>):**

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

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octanol/water

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

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

**Mobility in soil**

No data available

**Other adverse effects**

**Product:**

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

Additional ecological information : An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.  
Harmful to aquatic life with long lasting effects.

**Components:**

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

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

Additional ecological information : No data available

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**SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods**

Waste from residues : The product should not be allowed to enter drains, water courses or the soil.  
Can be disposed as waste water, when in compliance with local regulations.

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

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**SECTION 14. TRANSPORT INFORMATION**

**International Regulations**

**UNRTDG**

Not regulated as a dangerous good

**IATA-DGR**

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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**

Components	CAS-No.	Component TPQ (lbs)
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**SARA 311/312 Hazards** : Carcinogenicity

**Clean Air Act**

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

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

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

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

Cellulose	9004-34-6
Titanium oxide (TiO2)	13463-67-7

**Pennsylvania Right To Know**

Lactose-1-Hydrate	64044-51-5
Baloxavir Marboxil	1985606-14-1
Cellulose	9004-34-6
Croscarmellose sodium	74811-65-7

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2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8
Titanium oxide (TiO2)	13463-67-7

**Maine Chemicals of High Concern**

**Vermont Chemicals of High Concern**

**Washington Chemicals of High Concern**

**California Prop. 65**

WARNING: This product can expose you to chemicals including Titanium oxide (TiO2), which is/are known to the State of California to cause cancer. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

**California List of Hazardous Substances**

2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8
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**California Permissible Exposure Limits for Chemical Contaminants**

Cellulose	9004-34-6
Titanium oxide (TiO2)	13463-67-7

**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
- Croscarmellose sodium
- non hazardous compounds
- sodium octadecyl fumarate

- 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 : Substance(s) not listed on TSCA inventory

**TSCA list**

No substances are subject to a Significant New Use Rule.

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

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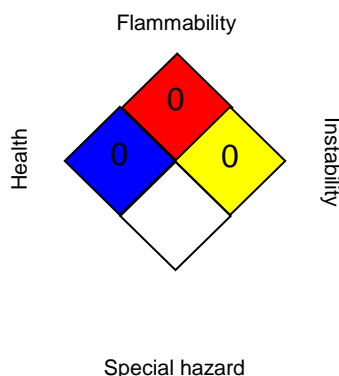
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**SECTION 16. OTHER INFORMATION**

**NFPA:**



**HMIS® IV:**

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

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 P0 : USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
- OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- 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 P0 / TWA : 8-hour time weighted average
- OSHA Z-1 / TWA : 8-hour time weighted average
- OSHA Z-3 / TWA : 8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; 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)

## XOFLUZA(TM) (Baloxavir Marboxil) Tablets 20mg

Version  
1.0

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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; 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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