Safety Data Sheet

XOFLUZA™ (Baloxavir Marboxil) Tablets 20mg

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name	XOFLUZA™ (Baloxavir Marboxil) Tablets 20mg
Product code	RO719-1686-F04
Synonyms	- S-033188 Tablets 20 mg - Baloxavir marboxil Tablets 20mg - XOFLUZA Tablets 20mg

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use	- pharmaceutical active substance	*1

1.3. Details of the supplier of the safety data sheet

Company information	Enquiries: Genentech, Inc. 1 DNA Way South San Francisco USA-CA 94080 United States of America Phone 001-(650) 225-1000 E-Mail info.sds@roche.com US Chemtrec phone: (800)-424-9300	Local representation:

1.4. Emergency telephone number

Emergency telephone number	US Chemtrec phone: (800)-424-9300

1 referring to: Baloxavir Marboxil

SECTION 2: Hazards identification

Classification of the substance or mixture / Label elements

GHS Classification: no classification and labelling according to GHS

Other hazards

Note: - no information available

SECTION 3: Composition/information on ingredients

Characterization	film-coated tablets containing 20 mg of RO7191686-000	
Ingredients	**Concentration**	**GHS-Classification (pure ingredient)**
Baloxavir Marboxil 1985606-14-1	16 %	
Lactose monohydrate 64044-51-5	64 %	
Croscarmellose sodium 74811-65-7	4 %	
Povidone 9003-39-8	4 %	
Microcrystalline cellulose 9004-34-6	9 %	

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact	-	no special measures necessary
Skin contact	-	no special measures necessary
Ingestion	-	let drink repeatedly plenty of water and induce vomiting (only if conscious), repeat several times

4.2. Most important symptoms and effects, both acute and delayed

Note	-	no information available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physician	-	treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	-	adapt extinguishing media to surrounding fire conditions
Flash point (liquid)		not applicable

5.2. Special hazards arising from the substance or mixture

Specific hazards - no particular hazards known

5.3. Advice for firefighters

Protection of fire-fighters - precipitate gases/vapours/mists with water spray

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions - ensure adequate ventilation

6.2. Environmental precautions

Environmental protection - do not allow to enter drains or waterways

6.3. Methods and material for containment and cleaning up

Methods for cleaning up - take up mechanically and dispose of

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Technical measures - no special measures necessary for correct usage

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - room temperature

Packaging materials - blister packages
- with a child resistant carton

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (USA) air
- OSHA-PEL: 5 mg/m3 (respirable dust fraction) *2
- OSHA-PEL: 15 mg/m3 (total dust) *2
- NIOSH-REL: 5 mg/m3 (respirable dust fraction) *2
- NIOSH-REL: 10 mg/m3 (total dust) *2
- ACGIH-TLV: 10 mg/m3 (inhalable particulate) *3
- ACGIH-TLV: 3 mg/m3 (respirable particulate) *3
- OSHA-PEL: 5 mg/m3 (respirable dust) *3
- OSHA-PEL: 15 mg/m3 (total dust) *3

	- ACGIH-TLV: 10 mg/m3	*4
	- OSHA-PEL: 15 mg/m3 (total dust)	*4
	- OSHA-PEL: 5 mg/m3 (respirable fraction)	*5
	- OSHA-PEL: 15 mg/m3 (total dust)	*5
Threshold value (Roche) air	- IOEL (Internal Occupational Exposure Limit): 0.004 mg/m3	*1

8.2. Exposure controls

Respiratory protection	- Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls. - respiratory protection not necessary during normal operations
Hand protection	- protective gloves
Eye protection	- safety glasses

1	referring to:	Baloxavir Marboxil
2	referring to:	Microcrystalline cellulose
3	referring to:	Croscarmellose sodium
4	referring to:	Titanium dioxide
5	referring to:	Lactose

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color	white to slightly yellow	
Form	oblong-shaped film-coated tablet	
Solubility	161 g/l, water (20 °C)	*5
	15 mg/l, water (20 °C)	*1
	1’891 mg/l, ethanol (20 °C)	*1
	8’554 mg/l, methanol (20 °C)	*1
	77’307 mg/l, acetonitrile (20 °C)	*1
	214’517 mg/l, DMSO (dimethyl sulfoxide) (20 °C)	*1
	227’317 mg/l, dimethyl formamide (20 °C)	*1
Partition coefficient	log P_{ow} -5.03 (octanol/water) (calculated)	*5
	log P_{ow} 2.24 (octanol/water) (calculated)	*1
pH value (20 °C)	4 to 6.6 (100 g/l)	*5

9.2. Other information

Note	- no information available

1	referring to:	Baloxavir Marboxil
5	referring to:	Lactose

SECTION 10: Stability and reactivity

10.1. Reactivity

Note - no information available

10.2. Chemical stability

Note - no information available

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Conditions to avoid - warming

10.5. Incompatible materials

Note - no information available

10.6. Hazardous decomposition products

Note - no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- LD_{50} > 10'000 mg/kg (oral, rat)	*5
	- LD_{50} > 2'000 mg/kg (oral, rat)	*1
Subacute toxicity	- NOAEL 2'000 mg/kg/d (oral, rat, 2 weeks)	*1
Local effects	- no information available	
Sensitization	- no information available	
Mutagenicity	- negative (various in vivo and in vitro test systems)	*1
Carcinogenicity	- no information available	
Reproductive toxicity	- based on available data, the classification criteria are not met (1000 mg/kg/d; oral, rat)	*1
	- based on available data, the classification criteria are not met (oral, rabbit); NOAEL: 100 mg/kg/d	*1
STOT-single exposure	- no information available	

STOT-repeated exposure	-	no indication for "Specific Target Organ Toxicity"	*1
	-	2000 mg/kg/d (oral, rat)	*1
Aspiration hazard	-	no information available	
Potential Health Effects	-	Exposure: Inhalation, Ingestion, Skin contact, Eye contact	
	-	Carcinogenicity: not listed by NTP, IARC or OSHA	

1 referring to: Baloxavir Marboxil
5 referring to: Lactose

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	-	barely toxic for fish (nominal concentration > 100 mg/l) (Leuciscus idus) $LC_0 \geq 1000$ mg/l	*4

12.2. Persistence and degradability

Inherent biodegradability	-	inherently biodegradable	*2

12.3. Bioaccumulative potential

Note	-	no information available	

12.4. Mobility in soil

Note	-	no information available	

12.5. Results of PBT and vPvB assessment

PBT/vPvB	-	substance does not meet the criteria for PBT or vPvB	*5

12.6. Other adverse effects

Note	-	not biodegradable (inorganic)	*4

2 referring to: Microcrystalline cellulose
4 referring to: Titanium dioxide
5 referring to: Lactose

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues	- observe local/national regulations regarding waste disposal - medicines should not be disposed of via wastewater - return to supplier or hand over to authorized disposal company - DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use takeback programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a takeback program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.

SECTION 14: Transport information

Note	- not classified as Dangerous Good according to the Dangerous Goods Regulations, proper shipping name non-regulated

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

TSCA Status	- FDA Exemption - not on inventory
Reporting Requirements	- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material. - In New Jersey, report all releases, which are likely to endanger the public health, harm the environment or cause a complaint, to the NJDEPE Hotline and to local officials. - State and local regulations vary and may impose additional reporting requirements.

SECTION 16: Other information

Note	- none
Edition documentation	- changes from previous version in sections 13

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.