

Safety Data Sheet

# XOFLUZA™ (Baloxavir Marboxil) Tablets 40mg

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

### 1.1. Product identifier

Product name XOFLUZA™ (Baloxavir Marboxil) Tablets 40mg  
 Product code RO719-1686-F13  
 Synonyms - Baloxavir marboxil Tablets 40mg  
 - XOFLUZA Tablets 40mg  
 - S-033188 Tablets 40 mg

### 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:
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### 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

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## SECTION 3: Composition/information on ingredients

Characterization film-coated tablets containing 40 mg of RO7191686-000

<b>Ingredients</b>	<b>Concentration</b>	<b>GHS-Classification (pure ingredient)</b>
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

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## 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/m <sup>3</sup> (respirable dust fraction)	*2
	- OSHA-PEL: 15 mg/m <sup>3</sup> (total dust)	*2
	- NIOSH-REL: 5 mg/m <sup>3</sup> (respirable dust fraction)	*2
	- NIOSH-REL: 10 mg/m <sup>3</sup> (total dust)	*2
	- ACGIH-TLV: 10 mg/m <sup>3</sup> (inhalable particulate)	*3
	- ACGIH-TLV: 3 mg/m <sup>3</sup> (respirable particulate)	*3
	- OSHA-PEL: 5 mg/m <sup>3</sup> (respirable dust)	*3
	- OSHA-PEL: 15 mg/m <sup>3</sup> (total dust)	*3

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- ACGIH-TLV: 10 mg/m<sup>3</sup> \*4
- OSHA-PEL: 15 mg/m<sup>3</sup> (total dust) \*4
- OSHA-PEL: 5 mg/m<sup>3</sup> (respirable fraction) \*5
- OSHA-PEL: 15 mg/m<sup>3</sup> (total dust) \*5

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.004 mg/m<sup>3</sup> \*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<sub>ow</sub> -5.03 (octanol/water) \*5  
(calculated)  
log P<sub>ow</sub> 2.24 (octanol/water) \*1  
(calculated)

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

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## 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 <sub>50</sub> > 10'000 mg/kg (oral, rat)	*5
	- LD <sub>50</sub> > 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	

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STOT-repeated exposure	- no indication for "Specific Target Organ Toxicity" - 2000 mg/kg/d (oral, rat)	*1 *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 <sub>0</sub> ≥ 1000 mg/l	*4
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### 12.2. Persistence and degradability

Inherent biodegradability	- inherently biodegradable	*2
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### 12.3. Bioaccumulative potential

Note	- no information available	
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### 12.4. Mobility in soil

Note	- no information available	
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### 12.5. Results of PBT and vPvB assessment

PBT/vPvB	- substance does not meet the criteria for PBT or vPvB	*5
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### 12.6. Other adverse effects

Note	- not biodegradable (inorganic)	*4
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*2 referring to:	Microcrystalline cellulose	
*4 referring to:	Titanium dioxide	
*5 referring to:	Lactose	

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## 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.