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

1.3. 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

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

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baloxavir Marboxil</td>
<td>16 %</td>
<td></td>
</tr>
<tr>
<td>1985606-14-1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactose monohydrate</td>
<td>64 %</td>
<td></td>
</tr>
<tr>
<td>64044-51-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>4 %</td>
<td></td>
</tr>
<tr>
<td>74811-65-7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Povidone</td>
<td>4 %</td>
<td></td>
</tr>
<tr>
<td>9003-39-8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9 %</td>
<td></td>
</tr>
<tr>
<td>9004-34-6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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
XOFLUZATM (Baloxavir Marboxil) Tablets 20mg

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

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.004 mg/m³

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)
- 15 mg/l, water (20 °C)
- 1'891 mg/l, ethanol (20 °C)
- 8'554 mg/l, methanol (20 °C)
- 77'307 mg/l, acetonitrile (20 °C)
- 214'517 mg/l, DMSO (dimethyl sulfoxide) (20 °C)
- 227'317 mg/l, dimethyl formamide (20 °C)

Partition coefficient
- \( \log P_{ow} -5.03 \) (octanol/water) (calculated)
- \( \log P_{ow} 2.24 \) (octanol/water) (calculated)

pH value (20 °C) 4 to 6.6 (100 g/l)

9.2. Other information

Note - no information available

*1 referring to: Baloxavir Marboxil
*5 referring to: Lactose

*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 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
- $\text{LD}_{50} > 10'000\text{ mg/kg (oral, rat)}$ $^5$
- $\text{LD}_{50} > 2'000\text{ mg/kg (oral, rat)}$ $^1$

Subacute toxicity
- $\text{NOAEL} 2'000\text{ mg/kg/d (oral, rat, 2 weeks)}$ $^1$

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); $\text{NOAEL}: 100\text{ mg/kg/d}$ $^1$

STOT-single exposure - no information available
**STOT-repeated exposure**  - no indication for "Specific Target Organ Toxicity"  
- 2000 mg/kg/d (oral, rat)  

**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

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**SECTION 12: Ecological information**

**12.1. Toxicity**

**Ecotoxicity**  - barely toxic for fish (nominal concentration > 100 mg/l) (Leuciscus idus)  
LC0 ≥ 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.