POLIVYTM Lyophilized Powder in Vials 140 mg

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

1.1. Product identifier

Product name: POLIVYTM Lyophilized Powder in Vials 140 mg
Product code: SAP-10197697
Synonyms: - Polatuzumab Vedotin Lyophilized Vials
- Anti-CD79b-vc-MMAE with excipients lyophilized
- RO554-1077/F02-02

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

Use: - pharmaceutical active substance (antineoplastic)

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

Local representation:

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: Polatuzumab vedotin
SECTION 2: Hazards identification

Classification of the substance or mixture / Label elements

GHS Classification

Health Hazards:

3.1 Acute toxicity (Category 3)
   H331 Toxic if inhaled.
3.1 Acute toxicity (Category 2)
   H300 Fatal if swallowed.
3.5 Germ cell mutagenicity (Category 1B)
   H340 May cause genetic defects.
3.7 Reproductive toxicity (Category 1B)
   H360D May damage the unborn child.

Signalword: Danger

Label:

Precautionary statements:
- P201 Obtain special instructions before use.
- P233 Keep container tightly closed.
- P280 Wear protective gloves/ protective clothing / eye protection / face protection.
- P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
- P302 + P352 IF ON SKIN: Wash with plenty of water/
- P304 + P310 IF INHALED: Immediately call a POISON CENTER or doctor/physician.
- P309 + P310 IF exposed or if you feel unwell: Immediately call a POISON CENTER or doctor/physician.

Other hazards

Note
- no information available

SECTION 3: Composition/information on ingredients

Characterization
Polatuzumab Vedotin with other inactive ingredients

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<th>Ingredients</th>
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<th>GHS-Classification (pure ingredient)</th>
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<td>Polatuzumab vedotin</td>
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<td>Sucrose</td>
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Disodium succinate ~ 2.5%
150-90-3

For the full text of the ‘Hazard statements’ mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact - rinse immediately with tap water for at least 20 minutes - open eyelids forcibly

Skin contact - remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents

Inhalation - remove the casualty to fresh air and keep him/her calm
- in the event of symptoms get medical treatment

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, water spray jet, dry powder, foam, carbon dioxide

Flash point (liquid) not applicable

5.2. Special hazards arising from the substance or mixture

Specific hazards - consider dust explosion hazard

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 - prevent any exposure
### 6.2. Environmental precautions

Environmental protection
- if the substance reaches waters or the sewer system, inform the competent authority

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up
- collect solids (avoid dust formation) and hand over to waste removal

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Suitable materials
- glass

#### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions
- 2 - 8 °C
  - protected from light

Validity
- see "best use before" date stated on the label, any remaining reconstituted solution should be discarded

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

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

Threshold value (Roche) air
- IOEL (Internal Occupational Exposure Limit): 0.00005 mg/m³

#### 8.2. Exposure controls

General protective and hygiene measures
- instruction of employees mandatory

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 is recommended for dusty operations

Hand protection
- protective gloves (eg made of neoprene, nitrile or butyl rubber)
Eye protection - safety glasses

*1 referring to: Polatuzumab vedotin
*2 referring to: Sucrose

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color white or practically white
Form sterile, lyophilized powder
Solubility soluble, water

9.2. Other information
Note - no information available

SECTION 10: Stability and reactivity

10.1. Reactivity
Note - no information available

10.2. Chemical stability
Stability - stable under the conditions mentioned in chapter 7

10.3. Possibility of hazardous reactions
Note - no information available

10.4. Conditions to avoid
Conditions to avoid - light
- warming
- humidity

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$_{50}$  
  - > 0.1 to < 0.2 mg/kg (i.v., rat)  
  - 1 to 2 mg/kg (i.v., mouse)

#### Subacute toxicity
- NOEL  
  - 0.097 mg/kg/w (i.v., rat, 4 weeks)
- LOEL  
  - 2 mg/kg (i.v., rat, 3 weeks)
- STD  
  - 10 mg/kg/w (i.v., rat, 3 weeks)

#### Local effects
- no information available

#### Sensitization
- no information available

#### Mutagenicity
- evidence of aneugenicity and clastogenicity

#### Carcinogenicity
- no information available

#### Reproductive toxicity
- teratogenic and embryotoxic

#### STOT-single exposure
- no information available

#### STOT-repeated exposure
- no information available

#### 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: Polatuzumab vedotin

*3 referring to: MMAE Monomethyl Auristatin E

## SECTION 12: Ecological information

### 12.1. Toxicity

#### Ecotoxicity
- Desmodesmus subspicatus  
  - ErC$_{50}$ (72 h) > 100 mg/l (nominal concentration)
  - EyC$_{50}$ (72 h) > 100 mg/l (nominal concentration)
  - NOEC (72 h) 100 mg/l (nominal concentration)  
    - (OECD No. 201)  
- Daphnia magna  
  - EC$_{50}$ (48 h) > 100 mg/l (nominal concentration)
  - NOEC (48 h) 100 mg/l (nominal concentration)  
    - (OECD No. 202)  
- zebrafish  
  - LC$_{50}$ (96 h) > 100 mg/l (nominal concentration)
  - NOEC (96 h) 100 mg/l (nominal concentration)  
    - (OECD No. 203)

*1
12.2. Persistence and degradability

- barely inhibitory on aerobic bacterial reproduction (activated sludge) (activated sludge) concentration (28 d) 21.2 mg/l (Manometric Respirometry Test, OECD No. 301 F) *1

**Ready biodegradability**
- readily biodegradable
  77 % BOD/ThOD, 28 d (Manometric Respirometry Test, OECD No. 301 F) *1

**Abiotic degradation**
- not abiotically degradable 21.2 mg/l; Oxitop (Manometric respirometry test, OECD no. 301 F, abiotic control) *1

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

**Note** - no information available

12.6. Other adverse effects

**Note** - no information available

*1 referring to: Polatuzumab vedotin

SECTION 13: Disposal considerations

**13.1. Waste treatment methods**

Waste from residues - observe local/national regulations regarding waste disposal
- incinerate in qualified installation with flue gas scrubbing

SECTION 14: Transport information

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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
- R&D 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

Full text of H-Statements referred to under section 3
H300 Fatal if swallowed.
H330 Fatal if inhaled.
H340 May cause genetic defects.
H360D May damage the unborn child.

Note
- Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user.
- This product may be shipped using De Minimis Quantity Exceptions, if the requirements of US 49 CFR §173.4b and ICAO 5.6/IATA 2.6.10 are met.

Edition documentation
- changes from previous version in sections 8

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.