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

1.1. Product identifier
Product name: GAZYVA(R) Vials (1,000 mg/40 ml)
Product code: SAP-10144955
Synonyms: - GA101 liquid product in vials

1.2. Relevant identified uses of the substance or mixture and uses advised against
Use: - pharmaceutical active substance (antineoplastic) *1

1.3. Details of the supplier of the safety data sheet
Company information: Genentech, Inc.
1 DNA Way
South San Francisco
USA-CA 94080
United States of America

Enquiries: info.sds@roche.com
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: Obinutuzumab

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
Obinutuzumab and other inactive ingredients

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Concentration</th>
<th>GHS-Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obinutuzumab 949142-50-1</td>
<td>~ 2 %</td>
<td>(pure ingredient)</td>
</tr>
</tbody>
</table>

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

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
GAZYVA(R) Vials (1,000 mg/40 ml)

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 - no special environmental precautions required

6.3. Methods and material for containment and cleaning up

Methods for cleaning up - rinse with plenty of water

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Suitable materials - glass

Note - do not shake the solution

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - 2 - 8 °C
- protected from light
- do not freeze

Validity - 36 months, 2 to 8 °C, see expiry date on the label, after opening the content should be used within a short period

Packaging materials - keep it in the outer carton in order to protect from light
- glass vials, colourless

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.01 mg/m³

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 (eg made of neoprene, nitrile or butyl rubber)
**GAZYVA(R) Vials (1,000 mg/40 ml)**

<table>
<thead>
<tr>
<th>Eye protection</th>
<th>safety glasses</th>
</tr>
</thead>
</table>

*1 referring to: Obinutuzumab

### SECTION 9: Physical and chemical properties

**9.1. Information on basic physical and chemical properties**

- **Color**: colorless to slightly brownish
- **Form**: sterile liquid

**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
- does not contain any antimicrobial preservative; therefore, care must be taken to ensure the sterility of the prepared solution

**10.3. Possibility of hazardous reactions**

- **Note**: no information available

**10.4. Conditions to avoid**

- **Conditions to avoid**: warming, shaking

**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

<table>
<thead>
<tr>
<th>Effect</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>no information available</td>
</tr>
<tr>
<td>Subchronic toxicity</td>
<td>NOAEL 30 mg/kg/w (i.v., cynomolgus monkey; 13 weeks) *1</td>
</tr>
<tr>
<td>Local effects</td>
<td>no information available</td>
</tr>
<tr>
<td>Sensitization</td>
<td>after parenteral application rare cases of hypersensitivity, including anaphylactic shock, can occur</td>
</tr>
<tr>
<td>Mutagenicity</td>
<td>no information available</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>no information available</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>no information available</td>
</tr>
<tr>
<td>STOT-single exposure</td>
<td>no information available</td>
</tr>
<tr>
<td>STOT-repeated exposure</td>
<td>no information available</td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>no information available</td>
</tr>
<tr>
<td>Potential Health Effects</td>
<td>Exposure: Inhalation, Ingestion, Skin contact, Eye contact</td>
</tr>
<tr>
<td></td>
<td>Carcinogenicity: formulation not listed by NTP, IARC or OSHA</td>
</tr>
</tbody>
</table>

*1 referring to: Obinutuzumab

### SECTION 12: Ecological information

#### 12.1. Toxicity

| Ecotoxicity   | monoclonal antibodies are proteins with highly specific affinity to a certain antigen; therefore, no appreciable ecotoxic potential is to be expected |

*1

#### 12.2. Persistence and degradability

| Ready biodegradability | globular proteins are generally well biodegradable |

*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: Obinutuzumab

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - observe local/national regulations regarding waste disposal

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

Edition documentation - changes from previous version in sections 3

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.