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

SECTION 3: Composition/information on ingredients

Characterization
Obinutuzumab and other inactive ingredients

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obinutuzumab</td>
<td>~ 2 %</td>
</tr>
<tr>
<td>CAS: 949142-50-1</td>
<td></td>
</tr>
</tbody>
</table>

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact - rinse immediately with tap water for 10 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
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)**

**Eye protection**  - safety glasses

*1 referring to: Obinutuzumab

## SECTION 9: Physical and chemical properties

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>colorless to slightly brownish</td>
</tr>
<tr>
<td>Form</td>
<td>sterile liquid</td>
</tr>
</tbody>
</table>

### 9.2. Other information

**Note** - no information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

**Note** - no information available

### 10.2. Chemical stability

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stability</td>
<td>stable under the conditions mentioned in chapter 7</td>
</tr>
<tr>
<td></td>
<td>- does not contain any antimicrobial preservative; therefore, care must be</td>
</tr>
<tr>
<td></td>
<td>taken to ensure the sterility of the prepared solution</td>
</tr>
</tbody>
</table>

### 10.3. Possibility of hazardous reactions

**Note** - no information available

### 10.4. Conditions to avoid

<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>warming</td>
</tr>
<tr>
<td></td>
<td>shaking</td>
</tr>
</tbody>
</table>

### 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

**Sensitization** - after parenteral application rare cases of hypersensitivity, including anaphylactic shock, can occur

**Subchronic toxicity** - NOAEL 30 mg/kg/w (i.v., cynomolgus monkey; 13 weeks) *¹

**Potential Health Effects** - Exposure: Inhalation, Ingestion, Skin contact, Eye contact

- Carcinogenicity: formulation not listed by NTP, IARC or OSHA

*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 by transport 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 (1-609-292-5560) 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 2, 7, 10

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.