

Safety Data Sheet

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

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	Local representation:
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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

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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 *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 (eg made of neoprene, nitrile or butyl rubber)

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Eye protection - safety glasses

*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

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- no information available	
Subchronic toxicity	- NOAEL 30 mg/kg/w (i.v., cynomolgus monkey; 13 weeks)	*1
Local effects	- no information available	
Sensitization	after parenteral application rare cases of hypersensitivity, including anaphylactic shock, can occur	
Mutagenicity	- no information available	
Carcinogenicity	- no information available	
Reproductive toxicity	- no information available	
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: 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
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12.2. Persistence and degradability

Ready biodegradability	- globular proteins are generally well biodegradable	*1
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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

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.