

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Product name AVASTIN(R) Vials (100 mg)

Product code SAP-10086726

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

Use - formulated pharmaceutical active substance (antineoplastic)

1.3. Details of the supplier of the safety data sheet

Company information

Enquiries:
Hoffmann-La Roche Inc.
340 Kingsland Street
USA-Nutley, N.J. 07110-1199
United States of America

Local representation:

Phone 001-973/235 50 00
E-Mail info.sds@roche.comUS Emergency phone: (800)-827-6243
US Chemtrec phone: (800)-424-9300**1.4. Emergency telephone number**

Emergency telephone number US emergency phone: (800)-827-6243

SECTION 2: Hazards identification**Emergency Overview**Form aqueous solution
sterile liquidColor clear to slightly opalescent
colourless to pale brownHazard Overview

- May cause allergic reactions.
- May cause birth defects based on animal data.

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| Potential Health Effects | <ul style="list-style-type: none">- Exposure: Inhalation, Ingestion, Skin contact, Eye contact- Target Organs: Hematopoietic/blood system, Immune System- Acute Effects: May cause allergic reactions., This material is not likely to be significantly absorbed via occupational routes of entry due to its chemical structure and large molecular weight.- Chronic Effects: May cause blood system effects.- Carcinogenicity: not listed by NTP, IARC or OSHA |
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Classification of the substance or mixture / Label elements

GHS Classification	no classification and labelling according to GHS
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Other hazards

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| Additional Health Information | <ul style="list-style-type: none">- Conditions aggravated: Hypersensitivity to this material and other materials in its chemical class.- Reproductive Toxicity: May cause birth defects. Since this material may effect the developing fetus, females planning to have a child and pregnant women should exercise caution regarding exposure.- It is also advisable for nursing mothers to exercise caution regarding exposure. |
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SECTION 3: Composition/information on ingredients

Characterization	bevacizumab and other inactive ingredients
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Ingredients	Concentration
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Bevacizumab	~ 2 %
CAS: 216974-75-3	

SECTION 4: First aid measures

4.1. Description of first aid measures

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| Eye contact | <ul style="list-style-type: none">- rinse immediately with tap water for 10 minutes - open eyelids forcibly |
| Skin contact | <ul style="list-style-type: none">- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents |
| Inhalation | <ul style="list-style-type: none">- 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	<ul style="list-style-type: none">- no information available
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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 - water spray jet, dry powder, foam, carbon dioxide
- 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 - no special precautions required

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 - collect spilled solutions with inert adsorbent and hand over to waste removal

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Suitable materials - aluminium, glass, enamel, stainless steel

Note - do not shake solution

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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	<ul style="list-style-type: none">- 2 - 8 °C- do not freeze- protected from light
Validity	<ul style="list-style-type: none">- 2 to 8 °C, in the unopened original container, see "best use before" date stated on the label
Packaging materials	<ul style="list-style-type: none">- vials

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air	<ul style="list-style-type: none">- IOEL (Internal Occupational Exposure Limit): 0.05 mg/m³	*1
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8.2. Exposure controls

Respiratory protection	<ul style="list-style-type: none">- 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	<ul style="list-style-type: none">- protective gloves (eg made of neoprene, nitrile or butyl rubber)
Eye protection	<ul style="list-style-type: none">- safety glasses

*1 referring to: Bevacizumab

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color	clear to slightly opalescent colourless to pale brown
Form	aqueous solution sterile liquid
Density	1.031 g/ml
pH value	5.9 to 6.3
Boiling temperature	~ 100 °C

9.2. Other information

Note	<ul style="list-style-type: none">- no information available
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SECTION 10: Stability and reactivity

10.1. Reactivity

Note - no information available

10.2. Chemical stability

Stability - 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

Note - no information available

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	- not bioavailable by oral administration	*1
	- NOEL 50 mg/kg (i.v., cynomolgus monkey)	*1

Chronic toxicity	- LOAEL 2 mg/kg/w (i.v., cynomolgus monkey; 26 weeks)	*1
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Reproductive toxicity	- teratogenic and embryotoxic (i.v., rabbit)	*1
	- should be administered during pregnancy only if the potential benefit justifies the potential risk to the fetus	*1

Note	- humanized monoclonal antibody which binds to and inactivates the vascular endothelial growth factor (VEGF)	*1
	- bevacizumab is effective in the treatment of advanced stages of colon and rectum carcinoma	*1
	- therapeutic dose: 5 mg/kg/2w	*1
	- elimination half-life: 20 d	*1
	- side effect(s) during therapy: tendency to bleeding, thrombophlebitis, proteinuria	*1

*1 referring to: Bevacizumab

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SECTION 12: Ecological information

12.1. Toxicity

- Ecotoxicity
- no adverse influence on substrate biodegradation (activated sludge)
concentration (14 d) 100 mg active substance/l
(Manometric Respirometry Test, OECD No. 301 F)
 - barely toxic for algae (nominal concentration = 100 mg/l), growth inhibition possibly due to turbidity caused by test substance
(Scenedesmus (=Desmodesmus) subspicatus)
ErC₅₀ (72 h) > 100 mg active substance/l
EbC₅₀ (72 h) ~ 100 mg active substance/l
NOEC (72 h) < 100 mg active substance/l
(OECD No. 201)
 - barely toxic for planktonic crustaceans (nominal concentration = 100 mg/l) (Daphnia magna)
EC₅₀ (48 h) > 100 mg active substance/l
NOEC (48 h) 100 mg active substance/l
(OECD No. 202)

12.2. Persistence and degradability

- Ready biodegradability
- readily biodegradable
78 % BOD/ThOD, 28 d
96 % DOC, 28 d
(Manometric Respirometry Test, OECD No. 301 F)

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

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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

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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 1, 9

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.