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
Synonyms: - AVASTIN(R) Vials (100 mg/4 ml)

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

Enquiries: Hoffmann-La Roche Inc.
340 Kingsland Street
USA-Nutley, N.J. 07110-1199
United States of America
Phone: 001-973/235 50 00
E-Mail: info.sds@roche.com

US 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 liquid

Color: colorless

Hazard Overview:
- May cause allergic reactions.
- May cause birth defects based on animal data.
**AVASTIN(R) Vials (100 mg)**

**Potential Health Effects**
- 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

**Classification of the substance or mixture / Label elements**

GHS Classification  
no classification and labelling according to GHS

**Other hazards**

Additional Health Information
- 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.

**SECTION 3: Composition/information on ingredients**

Characterization  
bevacizumab and other inactive ingredients

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bevacizumab</td>
<td>~ 2 %</td>
</tr>
<tr>
<td>CAS:</td>
<td>216974-75-3</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 - 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
AVASTIN(R) Vials (100 mg)

7.2. Conditions for safe storage, including any incompatibilities

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

Validity
- 2 to 8 °C, in the unopened original container, see "best use before" date stated on the label

Packaging materials
- vials

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.05 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)

Eye protection - safety glasses

*1 referring to: Bevacizumab

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color - colorless

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 - no information available
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
- NOEL 50 mg/kg (i.v., cynomolgus monkey)

Chronic toxicity
- LOAEL 2 mg/kg/w (i.v., cynomolgus monkey; 26 weeks)

Reproductive toxicity
- teratogenic and embryotoxic (i.v., rabbit)
- should be administered during pregnancy only if the potential benefit justifies the potential risk to the fetus

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

*1 referring to: Bevacizumab
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
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- 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
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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
### 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

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.
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1.1. Product identifier

Product name: AVASTIN(R) Vials (400 mg)
Product code: SAP-10062575
Synonyms: AVASTIN(R) Vials (400 mg/16 ml)

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.
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USA-Nutley, N.J. 07110-1199
United States of America

Phone: 001-973/235 50 00
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