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

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.
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

Local representation:
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 (400 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:
  - 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

<table>
<thead>
<tr>
<th>Characterization</th>
<th>bevacizumab and other inactive ingredients</th>
</tr>
</thead>
</table>

<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 (400 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 *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)

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

<table>
<thead>
<tr>
<th>Effect</th>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>- not bioavailable by oral administration</td>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>- side effect(s) during therapy: tendency to bleeding, thrombophlebitis, proteinuria</td>
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</table>

*1 Bevacizumab

*1 referring to: Bevacizumab
AVASTIN(R) Vials (400 mg)

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
AVASTIN(R) Vials (400 mg)

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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Form: aqueous solution, sterile liquid
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Classification of the substance or mixture / Label elements
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Other hazards
Additional Health Information
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