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

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:
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

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

SECTION 3: Composition/information on ingredients

Characterization bevacizumab and other inactive ingredients
**SECTION 4: First aid measures**

4.1. Description of first aid measures

Eye contact - rinse immediately with tap water for at least 20 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

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>clear to slightly opalescent colourless to pale brown</td>
</tr>
<tr>
<td>Form</td>
<td>aqueous solution</td>
</tr>
<tr>
<td></td>
<td>sterile liquid</td>
</tr>
<tr>
<td>Density</td>
<td>1.031 g/ml</td>
</tr>
<tr>
<td>pH value</td>
<td>5.9 to 6.3</td>
</tr>
<tr>
<td>Boiling temperature</td>
<td>~ 100 °C</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

**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>Aspect</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>- not bioavailable by oral administration</td>
</tr>
<tr>
<td></td>
<td>- NOEL 50 mg/kg (i.v., cynomolgus monkey)</td>
</tr>
<tr>
<td>Chronic toxicity</td>
<td>- LOAEL 2 mg/kg/w (i.v., cynomolgus monkey; 26 weeks)</td>
</tr>
<tr>
<td>Local effects</td>
<td>- no information available</td>
</tr>
<tr>
<td>Sensitization</td>
<td>- no information available</td>
</tr>
<tr>
<td>Mutagenicity</td>
<td>- no information available</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>- no information available</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>- teratogenic and embryotoxic (i.v., rabbit)</td>
</tr>
<tr>
<td></td>
<td>- critical exposure in human after parenteral administration only</td>
</tr>
<tr>
<td></td>
<td>- parenteral administration to pregnant women can cause fetal harm</td>
</tr>
<tr>
<td>STOT-single exposure</td>
<td>- no information available</td>
</tr>
<tr>
<td>STOT-repeated exposure</td>
<td>- no information available</td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>- no information available</td>
</tr>
<tr>
<td>Note</td>
<td>- humanized monoclonal antibody which binds to and inactivates</td>
</tr>
<tr>
<td></td>
<td>the vascular endothelial growth factor (VEGF)</td>
</tr>
<tr>
<td></td>
<td>- therapeutic dose: 5 mg/kg/2w</td>
</tr>
<tr>
<td></td>
<td>- elimination half-life: 20 d</td>
</tr>
<tr>
<td></td>
<td>- side effect(s) during therapy: tendency to bleeding,</td>
</tr>
<tr>
<td></td>
<td>thrombophlebitis, proteinuria</td>
</tr>
<tr>
<td>Potential Health Effects</td>
<td>- Exposure: Inhalation, Ingestion, Skin contact, Eye contact</td>
</tr>
<tr>
<td></td>
<td>- Carcinogenicity: not listed by NTP, IARC or OSHA</td>
</tr>
<tr>
<td>Additional Health Information</td>
<td>- Conditions aggravated: Hypersensitivity to this material and other</td>
</tr>
<tr>
<td></td>
<td>materials in its chemical class.</td>
</tr>
</tbody>
</table>

*1 referring to: Bevacizumab

### SECTION 12: Ecological information

#### 12.1. Toxicity

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ecotoxicity</td>
<td>- no adverse influence on substrate biodegradation (activated sludge)</td>
</tr>
<tr>
<td></td>
<td>concentration (14 d) 100 mg active substance/l</td>
</tr>
<tr>
<td></td>
<td>(Manometric Respirometry Test, OECD No. 301 F)</td>
</tr>
</tbody>
</table>
AVASTIN(R) Vials (400 mg)

- barely toxic for algae (nominal concentration = 100 mg/l), growth inhibition possibly due to turbidity caused by test substance (Scenedesmus (=Desmodesmus) subspicatus)
  ErC_{50} (72 h) > 100 mg active substance/l
  EbC_{50} (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)
  EC_{50} (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

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

<table>
<thead>
<tr>
<th>TSCA Status</th>
<th>- FDA Exemption - not on inventory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reporting Requirements</td>
<td>- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.</td>
</tr>
<tr>
<td></td>
<td>- 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.</td>
</tr>
<tr>
<td></td>
<td>- State and local regulations vary and may impose additional reporting requirements.</td>
</tr>
</tbody>
</table>

**SECTION 16: Other information**

| Edition documentation | - changes from previous version in sections 11 |

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.