## 1. Identification of the substance/preparation and of the company/undertaking

<table>
<thead>
<tr>
<th>Product name</th>
<th>Bevacizumab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product code</td>
<td>SAP-12043605</td>
</tr>
<tr>
<td>Use</td>
<td>pharmaceutical active substance (antineoplastic)</td>
</tr>
<tr>
<td>Company information</td>
<td>Enquiries: F. Hoffmann-La Roche AG Postfach CH-4070 Basel Switzerland</td>
</tr>
<tr>
<td></td>
<td>Phone +41-61/688 54 80</td>
</tr>
<tr>
<td></td>
<td>Fax +41-61/681 72 76</td>
</tr>
<tr>
<td></td>
<td>E-Mail <a href="mailto:info.sds@roche.com">info.sds@roche.com</a></td>
</tr>
</tbody>
</table>

## 2. Hazard identification

<table>
<thead>
<tr>
<th>GHS Classification</th>
<th>no classification and labelling according to CLP (EC Regulation 1272/2008)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Note</td>
<td>no classification and labelling according to EU directives 67/548/EEC and 1999/45/EC</td>
</tr>
</tbody>
</table>

## 3. Composition/Information on ingredients

| Characterization      | monoclonal antibody recombinant humanised immunoglobulin of isotype IgG1 |
| Synonyms              | Avastin |
| CAS number            | 216974-75-3 |
| Roche number          | Ro4876646-000 |
| Molecular mass        | ~ 149000 g/mol glycosylated |

## 4. 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 |
Bevacizumab

Note to physician - treat symptomatically

5. Fire-fighting measures

Suitable extinguishing media - water spray jet, dry powder, foam, carbon dioxide
- adapt extinguishing media to surrounding fire conditions

Protection of fire-fighters - precipitate gases/vapours/mists with water spray

6. Accidental release measures

Methods for cleaning up - collect spilled solutions with inert adsorbent and hand over to waste removal

7. Handling and storage

Handling

Suitable materials - aluminium, glass, enamel, stainless steel

Note - do not shake solution *1

Storage

Storage conditions - -20 °C
- 2 - 8 °C *1
- do not freeze *1
- protected from light *1

Validity - 2 to 8 °C, in the unopened original container, see "best use before" date stated on the label *1

*1 referring to: Avastin, 2.5% aqueous solution of Bevacizumab with excipients

8. Exposure controls/Personal protection

Engineering Measures - see 7.

Monitoring

Threshold value (Roche) air - Category 1 (Roche Group Directive K1, Annex 3): IOEL >=100 µg/m3

Personal protective equipment

Respiratory protection - respiratory protection not necessary during normal operations
Hand protection - protective gloves (eg made of neoprene, nitrile or butyl rubber)
Eye protection - safety glasses
# Bevacizumab

## 9. Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>colourless to brownish</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 g/cm³</td>
</tr>
<tr>
<td>pH value</td>
<td>~ 6.2</td>
</tr>
<tr>
<td>Boiling temperature</td>
<td>~ 100 °C</td>
</tr>
</tbody>
</table>

**Note**
- bevacizumab is not crystallised but purified in solution and formulated to Avastin

*1 referring to: Avastin, 2.5% aqueous solution of Bevacizumab with excipients

## 10. Stability and reactivity

**Stability**
- does not contain any antimicrobial preservative; therefore, care must be taken to ensure the sterility of the prepared solution

*1 referring to: Avastin, 2.5% aqueous solution of Bevacizumab with excipients

## 11. Toxicological information

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

- **Sensitization**
  - anaphylactic reactions may occur following the intravenous application of proteins; rare cases of hypersensitivity have been described

- **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**
- humanised 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: Avastin, 2.5% aqueous solution of Bevacizumab with excipients
# Bevacizumab

## 12. Ecological information

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

| Ecotoxicity |
| - 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) |

| Ecotoxicity |
| - 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) |

| Ecotoxicity |
| - no adverse influence on substrate biodegradation (activated sludge) concentration (14 d) 100 mg active substance/l  
| (Manometric Respirometry Test, OECD No. 301 F) |

*1 referring to: Avastin, 2.5% aqueous solution of Bevacizumab with excipients

## 13. Disposal considerations

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

## 14. Transport information

Note - not classified by transport regulations

## 15. Regulatory information

Water hazard class (Germany) - not hazardous for water (own classification according to directive VwVwS of 17.05.1999)

*1 referring to: Avastin, 2.5% aqueous solution of Bevacizumab with excipients

## 16. Other information

Edition documentation - changes from previous version in sections 2, 3, 15

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.