# Safety Data Sheet

## Bevacizumab

according to Regulation (EU) nr. 1907/2006

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

### 1.1. Product identifier
- **Product name**: Bevacizumab
- **Product code**: Ro4876646-000

### 1.2. Relevant identified uses of the substance or mixture and uses advised against
- **Use**: pharmaceutical active substance (antineoplastic)

### 1.3. Details of the supplier of the safety data sheet
- **Company information**
  - **Enquiries**: F. Hoffmann-La Roche AG
  - **Postfach**: CH-4070 Basel
  - **Switzerland**
  - **Phone**: +41-61/688 54 80
  - **Fax**: +41-61/681 72 76
  - **E-Mail**: info.sds@roche.com

### 1.4. Emergency telephone number
- **Emergency telephone number**: Phone +41-61/688 54 80

## SECTION 2: Hazards identification

### 2.1. / 2.2. Classification of the substance or mixture / Label elements
- **GHS Classification**: no classification and labelling according to CLP (EC Regulation 1272/2008)

### 2.3. Other hazards
- **Note**: no information available

## SECTION 3: Composition/information on ingredients
- **Characterization**: monoclonal antibody recombinant humanised immunoglobulin of isotype IgG1
- **Synonyms**: Avastin
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

5.2. Special hazards arising from the substance or mixture

Specific hazards - Does not present a fire hazard

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
Bevacizumab

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
- -20 °C

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

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

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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Form  - aqueous solution
- sterile liquid

*1
Bevacizumab

Density 1.031 g/ml
pH value 5.9 to 6.3
Boiling temperature ~ 100 °C

9.2. Other information
Note - bevacizumab is not crystallised but purified in solution and formulated to Avastin

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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

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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)
Bevacizumab

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

**Local effects**
- no information available

**Sensitization**
- anaphylactic reactions may occur following the intravenous application of proteins; after inhalative exposure no cases of hypersensitivity have been described

**Mutagenicity**
- no information available

**Carcinogenicity**
- no information available

**Reproductive toxicity**
- teratogenic and embryotoxic (i.v., rabbit)
- critical exposure in human after parenteral administration only
- parenteral administration to pregnant women can cause fetal harm

**STOT-single exposure**
- no information available

**STOT-repeated exposure**
- no information available

**Aspiration hazard**
- no information available

**Note**
- humanised monoclonal antibody which binds to and inactivates the vascular endothelial growth factor (VEGF)
- therapeutic dose: 5 mg/kg/2w
- elimination half-life: 20 d
- side effect(s) during therapy: tendency to bleeding, thrombophlebitis, proteinuria

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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) *1

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

PBT/vPvB - substance does not meet the criteria for PBT or vPvB

12.6. Other adverse effects

Note - no information available

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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

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water hazard class (Germany) not hazardous for water (own classification according to directive VwVwS of 17.05.1999) *1

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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.