



Safety Data Sheet

Bevacizumab

according to Regulation (EC) No 1907/2006

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

Product name	Bevacizumab
Product code	Ro4876646-000
Use	- pharmaceutical active substance (antineoplastic)
Company information	Enquiries: Local representation: 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

2. Hazards identification

Most important hazards	- No particular hazards known.
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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
Note to physician	- treat symptomatically

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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

- | | |
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| Methods for cleaning up | - collect spilled solutions with inert adsorbent and hand over to waste removal |
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7. Handling and storage

Handling

- | | |
|--------------------|---|
| Suitable materials | - aluminium, glass, enamel, stainless steel |
| Note | - do not shake solution *1 |

Storage

- | | |
|--------------------|---|
| Storage conditions | - -20 °C *1
- 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. |
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Monitoring

- | | |
|-----------------------------|---|
| Threshold value (Roche) air | - Category 1 (Roche Group Directive K1, Annex 3): IOEL ≥ 100 µg/m ³ |
|-----------------------------|---|

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 |

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9. Physical and chemical properties

Colour	colourless to brownish	*1
Form	aqueous solution sterile liquid	*1 *1
Density	~ 1 g/cm ³	*1
pH value	~ 6.2	*1
Boiling temperature	~ 100 °C	*1
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
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*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	*1
Chronic toxicity	- LOAEL 2 mg/kg/w (i.v., cynomolgus monkey; 26 weeks)	
Reproduction 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

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12. Ecological information

Ready biodegradability	- readily biodegradable 78 % BOD/ThOD, 28 d 96 % DOC, 28 d (Manometric Respirometry Test, OECD No. 301 F)	*1
Ecotoxicity	- 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)	*1
	- 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)	*1
	- no adverse influence on substrate biodegradation (activated sludge) concentration (14 d) 100 mg active substance/l (Manometric Respirometry Test, OECD No. 301 F)	*1
*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
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14. Transport information

Note	- not classified by transport regulations
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15. Regulatory information

Note	- no classification and labelling according to EU directives	
Water hazard class (Germany)	not hazardous for water (own classification according to directive VwVwS of 17.05.1999)	*1
*1	referring to:	Avastin, 2.5% aqueous solution of Bevacizumab with excipients

16. Other information

Edition documentation	- changes from previous version in sections 1, 2, 3, 8, 15, 16
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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.