

Version 2.1 Revision Date: 08.03.2018 SDS Number: 20841 Date of last issue: 16.02.2018
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SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

FASENRA

Details of the supplier of the safety data sheet

: ASTRAZENECA PTY LTD Emergency Telephone
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66 Talavera Rd, North Ryde
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AUSTRALIA
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SafetyDataSheets.AlderleyPark@astrazeneca.com

Alternative Names

MEDI563
Medi-563
P003-DS-T-100 mg/ml (P3)
P003-DS-T-50 mg/ml (P3)
P003-DS-T-30 mg/ml (P3)
P003-DS-T-20 mg/ml (P3)
P003-DS-T-10 mg/ml (P3)
P003-DS-A-20 mg/ml (P3)
P003-DS-A-2 mg/ml (P3)
Benralizumab

CAS No. : Not applicable

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Monoclonal antibody, Treatment of asthma and COPD

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards which do not result in classification

This is a monoclonal antibody and may have pharmacological effects.
See Section 11.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Benralizumab	1044511-01-4	0.2 -10

SECTION 4. FIRST AID MEASURES

If inhaled : Remove patient from exposure, keep warm and at rest.
Obtain medical attention if ill effects occur.

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- In case of skin contact : Wash skin with soap and water.
If symptoms (irritation or blistering) occur obtain medical attention.
- In case of eye contact : Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes.
Obtain medical attention if ill effects remain.
- If swallowed : Provided the patient is conscious, wash out mouth with water and give 200-300 ml of water to drink.
Do NOT induce vomiting as a First-Aid measure.
Obtain medical attention if ill effects occur.
- Most important symptoms and effects, both acute and delayed : Refer to sections 2 and 11
- Notes to physician : Symptomatic treatment and supportive therapy as indicated.
Emergency medical treatment advice varies within different countries.
For further information consult the Local National Poisons Information Services.
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SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use suitable extinguishing media for the surrounding fire.
- Unsuitable extinguishing media : -
- Specific hazards during firefighting : Non-combustible.
- Special protective equipment for firefighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.
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SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Ensure suitable personal protection during removal of spillages.
See Section 8.
- Environmental precautions : Prevent entry into drains unless inactivated or denatured.
- Methods and materials for containment and cleaning up : Absorb spillages onto sand, earth or any suitable adsorbent material.
Transfer to a container for disposal.
Wash the spillage area clean with water and detergent.
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SECTION 7. HANDLING AND STORAGE

- Advice on safe handling : Avoid contact with skin and eyes.
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Avoid generation of mist.

Conditions for safe storage : Keep containers properly sealed when not in use.
 Keep away from heat and direct sunlight.

Recommended storage temperature : 2 - 8 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Benralizumab	1044511-01-4	TWA	0.01 mg/m ³	COM

Engineering measures : The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment.

Prevent entry into drains unless inactivated or denatured.

Personal protective equipment

Respiratory protection : Use appropriate respiratory protective equipment.

Eye protection : Wear appropriate eye protection.

Skin and body protection : Wear appropriate protective clothing and gloves.

Protective measures : Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc. All the information above should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : Colourless to slightly yellow

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Odour : none

Odour Threshold : No data available

pH : 6

Melting point/range : No data available

Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Solubility(ies)

 Water solubility : No data available

 Solubility in other solvents : No data available

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

 Viscosity, dynamic : No data available

 Viscosity, kinematic : No data available

Explosive properties : No data available

Oxidizing properties : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No known reactivity hazard under normal conditions.

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Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : None known.
Conditions to avoid : Avoid elevated temperatures.
Incompatible materials : strong oxidising agents
Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Remarks: Unlikely to be toxic if swallowed.
Acute inhalation toxicity : Remarks: No information available.
Acute dermal toxicity : Remarks: No information available.

11.2 Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks: Unlikely to be corrosive to the skin.

11.3 Serious eye damage/eye irritation

Not classified based on available information.

Product:

Remarks: Unlikely to be a severe irritant to the eye.

11.4 Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Product:

Remarks: Exposure is unlikely to result in an adverse immune response.

Chronic toxicity

11.5 Germ cell mutagenicity

Not classified based on available information.

Product:

Germ cell mutagenicity - : Not expected to be genotoxic., Large protein molecules are

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Assessment not expected to cross the nuclear or mitochondrial membranes.

11.6 Carcinogenicity

Not classified based on available information.

Product:

Carcinogenicity - Assessment : Not expected to be carcinogenic.

11.7 Reproductive toxicity

Not classified based on available information.

Product:

Reproductive toxicity - Assessment : There is no evidence of a teratogenic potential or any other adverse effects on reproductive function.

11.8 STOT - single exposure

Not classified based on available information.

Product:

Remarks: No information available.

11.9 STOT - repeated exposure

Not classified based on available information.

Product:

Remarks: Intravenous and subcutaneous studies in monkeys have shown no adverse effects.

11.10 Aspiration toxicity

Not classified based on available information.

Product:

No information available.

Further information

Product:

Remarks: This is a monoclonal antibody and may have pharmacological effects.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Toxicity to fish :
Remarks: Monoclonal antibodies are unlikely to be toxic to aquatic organisms.

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Persistence and degradability

Product:

Biodegradability : Remarks: Expected to be biodegradable

Bioaccumulative potential

Product:

Bioaccumulation : Remarks: Unlikely to be bioaccumulative.

Mobility in soil

Product:

Mobility : Remarks: No information available.

Distribution among environmental compartments : Remarks: No information available.

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Disposal should be in accordance with local, state or national legislation.

Contaminated packaging : Empty container will retain residue. Observe all hazard precautions.

SECTION 14. TRANSPORT INFORMATION

Not classified as dangerous in the meaning of transport regulations.

SECTION 15. REGULATORY INFORMATION

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

In order to comply with legal duties it is necessary to consult local and national legislation.

Standard for the Uniform Scheduling of Medicines and Poisons : No poison schedule number allocated

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Prohibition/Licensing Requirements : There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

The components of this product are reported in the following inventories:

REACH : Not listed

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

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AICS : Not listed

ENCS : Not listed

ISHL : Not listed

IECSC : Not listed

TCSI : Not listed

TSCA : Not On TSCA Inventory

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; CPR - Controlled Products Regulations; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure

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Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Further information

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Other information : Minor changes:, 13

Date format : dd.mm.yyyy

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