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3.3	07.11.2018	21043	Date of first issue: 30.05.2017

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

1.1 Product identifier

DURVALUMAB

Details of the supplier of the safety data sheet : ASTRAZENECA
1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge
CB2 0AA
UNITED KINGDOM
+ 44 20 3749 5000

SafetyDataSheets.AlderleyPark@astrazeneca.com

Emergency Telephone
+44 (0) 1235 239 670

Alternative Names
IMFINZI
MEDI4736

REACH No. : -
CAS No. : Not applicable
EC No. : Not applicable

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

Use of the Substance/Mixture : Monoclonal antibody Potential anti-cancer agent

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
This is a monoclonal antibody and may have pharmacological effects.
See Section 11.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Durvalumab	1428935-60-7 -		>= 1 - <= 20

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

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

In case of skin contact : Wash skin with soap and water.

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.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : Refer to sections 2 and 11

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : 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.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use suitable extinguishing media for the surrounding fire.

Unsuitable extinguishing media : -

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting : Low fire hazard.

5.3 Advice for firefighters

Special protective equipment : A self contained breathing apparatus and suitable protective

for firefighters clothing should be worn in fire conditions.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Ensure suitable personal protection during removal of spillages.

6.2 Environmental precautions

Environmental precautions : Prevent entry into drains unless inactivated or denatured.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

For personal protection see section 8., For disposal considerations see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Avoid contact with skin and eyes.

7.2 Conditions for safe storage, including any incompatibilities

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

Recommended storage temperature : 2 - 8 °C

7.3 Specific end use(s)

Specific use(s) : Not applicable, refer to Section 1

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Durvalumab	1428935-60-7	TWA	0.01 mg/m3	COM; HYG

8.2 Exposure controls

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, sewers or watercourses.

Personal protective equipment

Eye protection	:	Wear appropriate eye protection.
Skin and body protection	:	Wear appropriate protective clothing and gloves.
Respiratory protection	:	Use appropriate respiratory protective equipment.
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

9.1 Information on basic physical and chemical properties

Appearance	:	Aqueous mixture, or, lyophilised cake
Colour	:	white to off-white
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	6
Melting point/range	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	No data available
Flammability (solid, gas)	:	The product is not flammable.
Upper explosion limit / Upper	:	No data available

flammability limit

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	:	Not applicable.
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	Not applicable

9.2 Other information

Molecular weight	:	149 kDA

SECTION 10: Stability and reactivity

10.1 Reactivity

No known reactivity hazard under normal conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	:	None known.

10.4 Conditions to avoid

Conditions to avoid	:	Avoid elevated temperatures.

10.5 Incompatible materials

Materials to avoid	:	Strong oxidizing agents Water-reactive substances

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

11.1.1 Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Remarks: Unlikely to be toxic if swallowed.
Acute inhalation toxicity	:	Remarks: Unlikely to cause local effects in the airways.
Acute dermal toxicity	:	Remarks: No information available.

11.1.2 Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks	:	Unlikely to be corrosive to the skin.

11.1.3 Serious eye damage/eye irritation

Not classified based on available information.

Product:

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

11.1.4 Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Product:

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

11.1.5 Germ cell mutagenicity

Not classified based on available information.

Product:

Germ cell mutagenicity- Assessment	:	Not expected to be genotoxic., Large protein molecules are not expected to cross the nuclear or mitochondrial membranes.

11.1.6 Carcinogenicity

Not classified based on available information.

Product:

Carcinogenicity - Assessment : Not expected to be carcinogenic.

11.1.7 Reproductive toxicity

Not classified based on available information.

Product:

Reproductive toxicity - Assessment : No information available.

11.1.8 STOT - single exposure

Not classified based on available information.

Product:

Remarks : May cause effects as described under repeated exposure.(STOT)

11.1.9 STOT - repeated exposure

Not classified based on available information.

Product:

Remarks : May cause fatigue, nausea, diarrhoea and skin rashes.
May affect the immune system.
(observed in patients treated intravenously)

11.1.10 Aspiration toxicity

Not classified based on available information.

Product:

No information available.

SECTION 12: Ecological information

12.1 Toxicity

Product:

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

12.2 Persistence and degradability

Product:

Biodegradability : Remarks: Expected to be biodegradable

12.3 Bioaccumulative potential

Product:

Bioaccumulation : Remarks: Unlikely to be bioaccumulative.

12.4 Mobility in soil

Product:

Mobility	:	Remarks: No information available.
Distribution among environmental compartments	:	Remarks: No information available.

12.5 Results of PBT and vPvB assessment

Product:

Assessment	:	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher..

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	:	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

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

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Regulation (EC) No 1005/2009 on substances that	:	Not applicable

deplete the ozone layer

Regulation (EC) No 850/2004 on persistent organic pollutants	:	Not applicable
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)	:	Not applicable

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

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

REACH	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. Durvalumab
AICS	:	Not in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Not On TSCA Inventory

15.2 Chemical safety assessment
A Chemical Safety Assessment is not required for this substance.

SECTION 16: Other information

Full text of other abbreviations

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AGW – Arbeitsplatzgrenzwert (Germany TRGS 900); AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; COM – In-house occupational exposure limit; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HYG – Analytical method for occupational exposure monitoring; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; 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; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; (Q)SAR - (Quantitative) Structure 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; Sen – Capable of causing respiratory sensitization; Sk – Can be absorbed through skin, thus contributing to systemic effects; STEL – Short-term exposure limit 15-minutes time-weighted average; TLV – Threshold Limit Value (ACGIH); TLV-C – Threshold Limit Value Ceiling limit (ACGIH); TWA – Long-term exposure limit 8h time-weighted average; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative.

Further information

Other information : Minor changes:
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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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