Version	Revision Date:	SDS Number:	Date of last issue: 07.11.2018
2.0	15.11.2019	21043	Date of first issue: 30.05.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

DURVALUMAB

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD
PO Box 131
66 Talavera Rd, North Ryde
NSW 2113
AUSTRALIA
+61 2 9978 3500

SafetyDataSheets.AlderleyPark@astrazeneca.com

Emergency Telephone
+44 (0) 1235 239 670

Alternative Names
IMFINZI
MEDI4736
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, Potential anti-cancer agent

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

Components

Chemical name	CAS-No.	Concentration (% w/w)
Durvalumab	1428935-60-7	1 -20

SECTION 4. 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.
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. For further detail consult the prescribing information.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Use suitable extinguishing media for the surrounding fire.
Unsuitable extinguishing media	:	-
Specific hazards during firefighting	:	Low fire hazard.
Special protective equipment for firefighters	:	A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

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.

SECTION 7. HANDLING AND STORAGE

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

		(Form of exposure)	parameters / Permissible concentration	
Durvalumab	1428935-60-7	TWA	0.2 mg/m3	COM; HYG

Engineering measures : Use appropriate controls (e.g. containment, ventilation) as specified in the workplace risk assessment to ensure that the defined occupational exposure limit is not exceeded.
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

Respiratory protection : Use appropriate respiratory protective equipment.

Eye protection : Use safety glasses to protect against direct contact with the product if the risk assessment does not support the selection of other 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 : 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 (liquids)	:	Will not burn
Upper explosion limit / Upper flammability limit	:	Not applicable
Lower explosion limit / Lower flammability limit	:	Not applicable
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	:	Not applicable
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	Not applicable
Molecular weight	:	149 kDA

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No known reactivity hazard under normal conditions.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	None known.

Conditions to avoid	:	No conditions producing hazardous situations known.
Incompatible materials	:	None known.
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: Unlikely to cause local effects in the airways.
Acute dermal toxicity	:	Remarks: Unlikely to be toxic since large proteins cannot be absorbed via the skin.

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	:	Inhalation 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 - Assessment	:	Not expected to be genotoxic., Large protein molecules are 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	:	A study in animals has shown that high doses produce embryo/foetotoxic effects., The relevance to humans is unknown.

11.8 STOT - single exposure

Not classified based on available information.

Product:

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

11.9 STOT - repeated exposure

Not classified based on available information.

Product:

Remarks	:	May cause fatigue, dyspnea and diarrhoea. May affect the immune system. (observed in patients treated intravenously) Relevance to humans by inhalation route is unknown.

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.

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

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:

TCSI	:	Not listed
TSCA	:	Substance(s) not listed on TSCA inventory
AICS	:	Not listed
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. Durvalumab
ENCS	:	Not listed
ISHL	:	Not listed
KECI	:	Not listed
IECSC	:	Not listed
CHINV	:	Not in compliance with the inventory
REACH	:	Not in compliance with the inventory
TRINV	:	Not in compliance with the inventory

SECTION 16. OTHER INFORMATION

Further information

Revision Date	:	15.11.2019
Other information	:	New significant SHE information: 8. New Occupational Exposure Limit Value Minor changes: 3 4 8 9 10 11 15 16
Date format	:	dd.mm.yyyy

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; CHINV - China Inventory; CMR - Carcinogen, Mutagen or Reproductive Toxicant; COM – In-house occupational exposure limit; CPR - Controlled Products Regulations; 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; 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; 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; 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); TRINV - Turkey Inventory; TSCA - Toxic Substances Control Act (United States); TWA – Long-term exposure limit 8h time-weighted average; 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

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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