

Version 3.1      Revision Date: 01.11.2017      SDS Number: 21043      Date of last issue: 30.05.2017  
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## SECTION 1. IDENTIFICATION

### 1.1 Product identifier

#### DURVALUMAB

Details of the supplier of the safety data sheet

: ASTRAZENECA  
P.O. Box 15437  
Wilmington, DE 19850-5437  
USA

Phone (24 hr.) Medical :  
(800) 236-9933  
(24 hr.) Chemical / Spill Emergency:  
INFOTRAC - (800) 535-5053

SafetyDataSheets.AlderleyPark@astrazeneca.com

#### 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 in accordance with 29 CFR 1910.1200

Not a hazardous substance or mixture.

#### GHS label elements

Not a hazardous substance or mixture.

#### Other hazards

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

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
Durvalumab	1428935-60-7	>= 1 - < 10

## 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.

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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.

### SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media : -

Specific hazards during fire fighting : Low fire hazard.

Special protective equipment for fire-fighters : 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.  
Eyewash station in work area.

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

Methods and materials for containment and cleaning up : Clear up spillages.  
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

#### Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type	Control	Basis
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		(Form of exposure)	parameters / Permissible concentration	
Durvalumab	1428935-60-7	TWA	0.01 mg/m <sup>3</sup>	COM; HYG

**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

**Respiratory protection** : As necessary, use NIOSH approved respiratory protection device consistent with the work place risk assessment. Consult a qualified safety and health professional for additional guidance, as needed.

**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** : Aqueous mixture, or, lyophilized cake

**Color** : white to off-white

**Odor** : No data available

**Odor 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

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Evaporation rate : No data available

Flammability (solid, gas) : The product is not flammable.

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor 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

Autoignition 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

Molecular weight : 149 kDA

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## 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 : Avoid elevated temperatures.

Incompatible materials : Strong oxidizing agents  
Water-reactive substances

Hazardous decomposition : No hazardous decomposition products are known.

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 products
 

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## 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: 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 sensitization

**Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Product:**

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

### 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.

**IARC** No ingredient of this product present at levels greater than or

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equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP**

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**11.7 Reproductive toxicity**

Not classified based on available information.

**Product:**

Reproductive toxicity - Assessment : No information available.

**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, nausea, diarrhoea and skin rashes.  
May affect the immune system.  
(observed in patients treated intravenously)

**11.10 Aspiration toxicity**

Not classified based on available information.

**Product:**

No information available.

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**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

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**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**

**Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances  
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

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**SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods**

Waste from residues : Disposal should be in accordance with local, state or national legislation.  
Waste, even small quantities, should never be poured down drains, sewers or water courses.  
Normal waste disposal is via incineration operated by an accredited disposal contractor.

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

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**SECTION 14. TRANSPORT INFORMATION**

Not classified as dangerous in the meaning of transport regulations.

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**SECTION 15. REGULATORY INFORMATION**

**EPCRA - Emergency Planning and Community Right-to-Know**

**CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

**SARA 304 Extremely Hazardous Substances Reportable Quantity**

This material does not contain any components with a section 304 EHS RQ.

**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

Ingredients	CAS-No.	Component TPQ (lbs)
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**SARA 311/312 Hazards** : No SARA Hazards

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**Clean Air Act**

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489).

**Clean Water Act**

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

**US State Regulations**

**Massachusetts Right To Know**

No components are subject to the Massachusetts Right to Know Act.

**Pennsylvania Right To Know**

Durvalumab 1428935-60-7

**New Jersey Right To Know**

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**California Prop. 65**

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

**The ingredients of this product are reported in the following inventories:**

REACH : Not listed

DSL : This product contains the following components that are not



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on the Canadian DSL nor NDSL.

Durvalumab

AICS	:	Not listed
ENCS	:	Not listed
ISHL	:	Not listed
IECSC	:	Not listed
TCSI	:	Not listed
TSCA	:	Not On TSCA Inventory

#### TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

## SECTION 16. OTHER INFORMATION

### Further information

#### Full text of other abbreviations

AGW – Arbeitsplatzgrenzwert (Germany TRGS 900); AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; COM – In-house occupational exposure limit; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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); MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; Sen – Capable of causing respiratory sensitization; Sk – Can be absorbed through skin, thus contributing to systemic effects;

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STEL – Short-term exposure limit 15-minutes time-weighted average; TLV – Threshold Limit Value (ACGIH); TLV-C – Threshold Limit Value Ceiling limit (ACGIH); 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

Minor changes:

3  
8  
15

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The information provided in this Material 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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