

ersion .1	Revision Date: 30.09.2023		S Number: 5400-00018	Date of last issue: 04.04.2023 Date of first issue: 23.02.2016
ection 1	: Identification			
Produ	uct name	:	Pembrolizum	ab Solid Formulation
	ifacturer or supplier's d			
Comp	bany	:	MSD	
Addre	ess	:	33 Whakatiki Upper Hutt - I	Street - Private Bag 908 New Zealand
Telep	hone	:	0800 800 543	3
Emer	gency telephone number	:	0800 764 766 CHEMCALL)	6 (0800 POISON) 0800 243 622 (0800
E-ma	il address	:	EHSDATAST	EWARD@msd.com
Reco	mmended use of the ch	nem	ical and restri	ctions on use
	mmended use ictions on use	:	Pharmaceutic Not applicable	
	Hazard identification			
	Classification		Cotogony 1	
Repro	oductive toxicity		Category 1	
	ific target organ toxicity - ated exposure (Oral)	:	Category 1 (I	mmune system)
GHS	label elements			
Haza	rd pictograms	:		
Signa	al word	:	Danger	
Haza	rd statements	:	H372 Causes	lamage the unborn child. damage to organs (Immune system) through repeated exposure if swallowed.
Preca	autionary statements	:	P264 Wash s P270 Do not	special instructions before use. kin thoroughly after handling. eat, drink or smoke when using this product. rotective gloves/ protective clothing/ eye prote



Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	525400-00018	Date of first issue: 23.02.2016

tion/ face protection.

#### **Response:**

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

### Storage:

P405 Store locked up.

#### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

#### Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling or other means.

### Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Sucrose	57-50-1	>= 70 -< 90
Pembrolizumab	1374853-91-4	>= 20 -< 30

#### Section 4: First-aid measures

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	:	If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	:	In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	:	If in eyes, rinse well with water. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	



Version 5.1	Revision Date: 30.09.2023		9S Number: 5400-00018	Date of last issue: 04.04.2023 Date of first issue: 23.02.2016	
Prote	ction of first-aiders	:	First Aid respond and use the reco	the eyes can lead to mechanical irritation. ers should pay attention to self-protection, mmended personal protective equipment al for exposure exists (see section 8).	
Notes	to physician	:	Treat symptomat	ically and supportively.	
Section 5	: Fire-fighting measure	S			
	ble extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide ( Dry chemical		
Unsui media	itable extinguishing	:	None known.		
	fic hazards during fire-	:	concentrations, a potential dust exp	dust; fine dust dispersed in air in sufficient and in the presence of an ignition source is a plosion hazard. bustion products may be a hazard to health.	
Haza ucts	rdous combustion prod-	:	Carbon oxides Nitrogen oxides (	NOx)	
Speci ods	Specific extinguishing meth- ods		cumstances and Use water spray	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. Iged containers from fire area if it is safe to d	
	al protective equipment efighters	:	Evacuate area. In the event of fire, wear self-contained breathing apparat Use personal protective equipment.		
ection 6	Accidental release me	eas	ures		
tive e	onal precautions, protec- quipment and emer- / procedures	:	Follow safe hand	tective equipment. ling advice (see section 7) and personal pro t recommendations (see section 8).	
Enviro	Environmental precautions		Retain and dispo	eakage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages	
	Methods and materials for containment and cleaning up		tainer for disposa Avoid dispersal of with compressed Dust deposits sh es, as these may	f dust in the air (i.e., clearing dust surfaces	

leased into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-



Version 5.1	Revision Date: 30.09.2023	SDS Number: 525400-00018	Date of last issue: 04.04.2023 Date of first issue: 23.02.2016
		Sections 13	regulations are applicable. and 15 of this SDS provide information regarding or national requirements.
Section 7:	Handling and storage	9	
Techr	nical measures	causing an Provide ade	icity may accumulate and ignite suspended dust explosion. quate precautions, such as electrical grounding g, or inert atmospheres.
Local/	Total ventilation		ventilation is unavailable, use with local exhaust
Advice	e on safe handling	: Do not get o Do not brea Do not swal Avoid conta Wash skin t Handle in ad practice, bas sessment Keep contai Minimize du Keep contai Keep away Take precau Do not eat,	low. ct with eyes. horoughly after handling. ccordance with good industrial hygiene and safety sed on the results of the workplace exposure as- ner tightly closed. st generation and accumulation. ner closed when not in use. from heat and sources of ignition. utionary measures against static discharges. drink or smoke when using this product. o prevent spills, waste and minimize release to the
Hygie	ne measures	: If exposure flushing sys place. When using	to chemical is likely during typical use, provide eye tems and safety showers close to the working do not eat, drink or smoke. minated clothing before re-use.
Condi	tions for safe storage	: Keep in pro Store locked Keep tightly	perly labelled containers. I up.
Mater	ials to avoid		with the following product types:

#### Section 8: Exposure controls/personal protection

### Components with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
Sucrose	57-50-1	WES-TWA	10 mg/m3	NZ OEL
		TWA	10 mg/m3	ACGIH
Pembrolizumab	1374853-91-	TWA	450 µg/m3 (OEB	Internal
	4		2)	



ersion .1	Revision Date: 30.09.2023	SDS Numb 525400-000				
Engiı	neering measures	Apply m Ensure dust col signed i work are	e workplace exposure concentrations. heasures to prevent dust explosions. that dust-handling systems (such as exhaust ducts, lectors, vessels, and processing equipment) are de- n a manner to prevent the escape of dust into the ea (i.e., there is no leakage from the equipment). ent ventilation is unavailable, use with local exhaust on.			
Perso	onal protective equip	ment				
Respiratory protection		sure as	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.			
	lter type protection		Particulates type			
Ma	aterial	: Chemic	Chemical-resistant gloves			
Remarks		on the c stance a determi applicat chemica glove m	Choose gloves to protect hands against chemicals dependi on the concentration and quantity of the hazardous sub- stance and specific to place of work. Breakthrough time is n determined for the product. Change gloves often! For speci- applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.			
Eye p	protection	: Wear th	Wear the following personal protective equipment: Safety goggles			
Skin and body protection :		: Select a resistan potentia Skin co	Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).			

### Section 9: Physical and chemical properties

Appearance	:	powder
Colour	:	white to off-white
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available

## SAFETY DATA SHEET



# **Pembrolizumab Solid Formulation**

/ersion 5.1	Revision Date: 30.09.2023		S Number: 5400-00018	Date of last issue: 04.04.2023 Date of first issue: 23.02.2016
Flash	n point	:	Not applicable	
Evap	oration rate	:	No data available	9
Flam	mability (solid, gas)	:	May form explos dling or other me	ive dust-air mixture during processing, han ans.
Flam	mability (liquids)	:	No data available	9
	er explosion limit / Upper nability limit	:	No data available	9
	er explosion limit / Lower nability limit	:	No data available	9
Vapo	our pressure	:	No data available	9
Relat	tive vapour density	:	No data available	9
Relat	tive density	:	No data available	9
Dens	iity	:	No data available	9
	bility(ies) /ater solubility	:	No data available	9
	tion coefficient: n- nol/water	:	No data available	9
	-ignition temperature	:	No data available	9
Deco	mposition temperature	:	No data available	9
Visco Vi	osity iscosity, dynamic	:	No data available	9
V	iscosity, kinematic	:	No data available	9
Explo	osive properties	:	Not explosive	
Oxidi	zing properties	:	The substance o	r mixture is not classified as oxidizing.
Mole	cular weight	:	No data available	9
Parti	cle size	:	No data available	2

## Section 10: Stability and reactivity

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	May form explosive dust-air mixture during processing, han-



Version 5.1	Revision Date: 30.09.2023		9S Number: 5400-00018	Date of last issue: 04.04.2023 Date of first issue: 23.02.2016			
tions			dling or other n Can react with	neans. strong oxidizing agents.			
Incom	itions to avoid npatible materials rdous decomposition icts	:	<ul> <li>Heat, flames and sparks. Avoid dust formation.</li> <li>Oxidizing agents</li> <li>No hazardous decomposition products are known.</li> </ul>				
Section 1	1: Toxicological inform	natio	on				
Expos	sure routes	:	Inhalation Skin contact Ingestion Eye contact				
	e toxicity lassified based on avail	able	information.				
<u>Comp</u>	oonents:						
Sucro Acute	ose: oral toxicity	:	LD50 (Rat): 29,	700 mg/kg			
-	corrosion/irritation lassified based on avail	able	information.				
	us eye damage/eye ir lassified based on avail						
Resp	iratory or skin sensiti	satio	'n				
	<b>sensitisation</b> lassified based on avail	able	information.				
-	iratory sensitisation lassified based on avail	able	information.				
Chro	nic toxicity						
	a <b>cell mutagenicity</b> lassified based on avail	able	information.				
<u>Com</u>	oonents:						
Sucro Geno	<b>ose:</b> toxicity in vitro	:	Test Type: In vi Result: negative	tro mammalian cell gene mutation test			
	<b>nogenicity</b> lassified based on avail	able	information.				



Version	Revision Date: 30.09.2023	SDS Number:	Date of last issue: 04.04.2023
5.1		525400-00018	Date of first issue: 23.02.2016

#### Reproductive toxicity

May damage the unborn child.

### **Components:**

#### Pembrolizumab:

Reproductive toxicity - As- : sessment

May damage the unborn child., Based on data from similar materials

#### STOT - single exposure

Not classified based on available information.

#### STOT - repeated exposure

Causes damage to organs (Immune system) through prolonged or repeated exposure if swallowed.

#### Components:

#### Pembrolizumab:

Target Organs	:	Immune system
Assessment	:	Causes damage to organs through prolonged or repeated
		exposure.

#### Repeated dose toxicity

#### **Components:**

#### Pembrolizumab:

Species :	Monkey
NOAEL :	200 mg/kg
Application Route :	Intravenous
Exposure time :	180 d
Remarks :	No significant adverse effects were reported
Species :	Dog
NOAEL :	200 mg/kg
Application Route :	Intravenous
Exposure time :	180 d
Remarks :	No significant adverse effects were reported

#### Aspiration toxicity

Not classified based on available information.

:

#### Experience with human exposure

#### **Components:**

#### Pembrolizumab:

Inhalation

### Target Organs: Immune system Symptoms: Cough, Fatigue, Nausea, pruritis, Rash, constipation, joint pain, Diarrhoea, Pneumonia, decrease in appetite,

Fever, anemia, neutropenia, musculoskeletal pain, Vomiting,



ersion .1	Revision Date: 30.09.2023	SDS Number: 525400-00018	Date of last issue: 04.04.2023 Date of first issue: 23.02.2016
		thyroid gland, l mune-mediate	adache, Shortness of breath, Hypofunction of May cause respiratory arrest., May cause, im- d pneumonitis, colitis, hepatitis, nephritis nage to fetus possible
ection 1	2: Ecological inform	ation	
No da <b>Persi</b>	oxicity ata available stence and degrada ata available	bility	
Bioad	ccumulative potentia	al	
Com	oonents:		
	<b>ose:</b> ion coefficient: n- ol/water	: Pow: < 1	
	<b>lity in soil</b> ata available		
	r adverse effects		

:	Do not dispose of waste into sewer.
	Dispose of in accordance with local regulations.
:	Empty containers should be taken to an approved waste han-
	dling site for recycling or disposal.
	If not otherwise specified: Dispose of as unused product.
	:

### Section 14: Transport information

### International Regulations

<b>UNRTDG</b> UN number Proper shipping name Class Subsidiary risk	: No : No	ot applicable ot applicable ot applicable ot applicable
Packing group Labels	: No	ot applicable ot applicable
IATA-DGR UN/ID No. Proper shipping name Class Subsidiary risk	: No : No	ot applicable ot applicable ot applicable ot applicable



	Date of first issue: 23.02.2016
Not applicable	
Not applicable Not applicable	
Not applicable	
Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable <b>Annex II of MARP</b> plied.	OL 73/78 and the IBC Code
Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable	
	Not applicable Not applicable

Section 15: Regulatory information

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

**HSNO Approval Number** 

not allocated

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

#### Section 16: Other information

Revision Date

NZ OEL / WES-TWA



## Pembrolizumab Solid Formulation

Versio 5.1	on Revision Date: 30.09.2023		0S Number: 5400-00018	Date of last issue: 04.04.2023 Date of first issue: 23.02.2016
F	urther information			
C	Sources of key data used to compile the Safety Data Sheet		Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Ager cy, http://echa.europa.eu/	
D	Date format		dd.mm.yyyy	
Full text of other abbreviation				
	NCGIH IZ OEL	:		eshold Limit Values (TLV) orkplace Exposure Standards for Atmospher-
А	CGIH / TWA	:	8-hour, time-weig	hted average

AIIC - Australian Inventory of Industrial Chemicals; 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; 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 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: TECI - Thailand Existing Chemicals Inventory: 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

: Workplace Exposure Standard - Time Weighted average

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text.





Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	525400-00018	Date of first issue: 23.02.2016

Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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