

read

Pembrolizumab Solid Formulation

Version 4.0	Revision Date: 06.04.2024		S Number: 5401-00019	Date of last issue: 30.09.2023 Date of first issue: 23.02.2016	
Section 1	l: Identification				
Prod	luct identifier	:	Pembrolizuma	ab Solid Formulation	
Reco	ommended use of the ch	nem	ical and restrie	ctions on use	
	ommended use rictions on use	:	PharmaceuticalNot applicable		
Man	ufacturer or supplier's d	leta	ils		
Com	pany	:	MSD		
Addr	ess	:	50 Tuas West Singapore - S	Drive Singapore 638408	
Telep	phone	:	+1-908-740-4	000	
Eme	Emergency telephone number		65 6697 2111	(24/7/365)	
E-ma	ail address	:	EHSDATAST	EWARD@msd.com	
Section 2	2: Hazard identification				
Clas	sification of the substar	nce	or mixture		
Repr	oductive toxicity	:	Category 1B		
	Specific target organ toxicity - repeated exposure (Oral)		Category 1 (Ir	nmune system)	
GHS	Label elements, includi	ing	precautionary	statements	
Haza	ard pictograms	:			
Signa	al word	:	Danger		
Haza	ard statements	:	 H360D May damage the unborn child. H372 Causes damage to organs (Immune system) throu prolonged or repeated exposure if swallowed. 		
Prec	autionary statements	:		special instructions before use.	
			P202 Do not h and understoo		

P260 Do not breathe dust.

P264 Wash skin thoroughly after handling.



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		P280 Wear pr	eat, drink or smoke when using this product. otective gloves/ protective clothing/ eye protec- ection/ hearing protection.
		Response: P308 + P313 attention.	IF exposed or concerned: Get medical advice/
		Storage: P405 Store lo	cked up.
		Disposal: P501 Dispose disposal plant	of contents/ container to an approved waste
•• Othe	r hazards which do r	not result in classifica	ation

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

Description of necessary first-aid measures				
General advice	 In the case of accident or if you feel unwell, seek medical advice 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. 			





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Most	important symptoms a	nd	effects, both ac	ute and delayed
Risks		:	May damage the	-
				e to organs through prolonged or repeated
			exposure if swa Contact with due	st can cause mechanical irritation or drying c
			the skin.	
Prote	ction of first-aiders	:	First Aid respon and use the rec	the eyes can lead to mechanical irritation. ders should pay attention to self-protection, ommended personal protective equipment tial for exposure exists (see section 8).
Indica	ation of any immediate	me		and special treatment needed
Treat	-	:		atically and supportively.
otion E	Eiro fighting moocuro	~		
ection 5.	Fire-fighting measure	5		
Exting	uishing media			
-	ble extinguishing media	:	Water spray	
			Alcohol-resistan	
			Carbon dioxide Dry chemical	(CO2)
Unsui media	table extinguishing	:	None known.	
Speci	al hazards arising from	n th	e substance or	mixture
Speci fightin	fic hazards during fire- g	:	concentrations, potential dust ex	g dust; fine dust dispersed in air in sufficient and in the presence of an ignition source is kplosion hazard. nbustion products may be a hazard to health
Hazaı	dous combustion prod-	:	Carbon oxides	
ucts			Nitrogen oxides	(NOx)
Speci	al protective actions fo	or fi	re-fighters	
	al protective equipment	:		ire, wear self-contained breathing apparatus
	efighters fic extinguishing meth-			otective equipment. ng measures that are appropriate to local cir
ods		•	cumstances and Use water spray	d the surrounding environment. / to cool unopened containers. aged containers from fire area if it is safe to
			so. Evacuate area.	
			Lvacuale aled.	

Personal precautions, protective equipment and emergency procedures

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Personal precautions	:	Use personal protective equipment.
		Follow safe handling advice (see section 7) and personal pro-
		tective equipment recommendations (see section 8).

Environmental precautions





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Environmental precautions :		Prevent further I Retain and disp Local authorities cannot be conta	
Methods and materials for containm Methods for cleaning up :		: Sweep up or var tainer for dispos Avoid dispersal with compresser Dust deposits sh es, as these ma leased into the a Local or nationa posal of this ma employed in the mine which regu	cuum up spillage and collect in suitable con- al. of dust in the air (i.e., clearing dust surfaces

Section 7: Handling and storage

Precautions for safe handling	
Technical measures	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation :	If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling :	 Do not get on skin or clothing. Do not breathe dust. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the
Hygiene measures :	environment. If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.



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Conditions for safe storage, including any incompatibilities

Conditions for safe storage	:	Keep in properly labelled containers. Store locked up. Keep tightly closed.
Materials to avoid	:	Store in accordance with the particular national regulations. Do not store with the following product types: Strong oxidizing agents

Section 8: Exposure controls/personal protection

Control parameters

Occupational Exposure Limits

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

Appropriate engineering control measures	:	Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are de- signed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). If sufficient ventilation is unavailable, use with local exhaust ventilation.
Individual protection measure	es	, such as personal protective equipment (PPE)
Eye/face protection	:	Wear the following personal protective equipment: Safety goggles
Skin protection	:	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).
Respiratory protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
Filter type Hand protection	:	Particulates type
Material	:	Chemical-resistant gloves
Remarks	:	Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous sub-



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			determined for th applications, we in chemicals of the glove manufactur end of workday.	fic to place of work. Breakthrough time is no e product. Change gloves often! For specia recommend clarifying the resistance to aforementioned protective gloves with the rer. Wash hands before breaks and at the
	9: Physical and chemica	l pro	-	
	earance	:	powder	
Colo		:	white to off-white	
Odo		:	No data availabl	
	ur Threshold	:	No data availabl	
рН		:	No data availabl	
	ing point/freezing point	:	No data availabl	
Initia rang	I boiling point and boiling e	:	No data availabl	e
Flas	h point	:	Not applicable	
Evap	poration rate	:	No data availabl	e
Flam	nmability (solid, gas)	:	May form explosed dling or other me	ive dust-air mixture during processing, han- eans.
Flam	nmability (liquids)	:	No data availabl	e
	er explosion limit / Upper mability limit	:	No data availabl	e
	er explosion limit / Lower mability limit	:	No data availabl	e
Vapo	our pressure	:	No data availabl	e
Rela	tive vapour density	:	No data availabl	e
Rela	tive density	:	No data availabl	e
Dens	sity	:	No data availabl	e
	bility(ies) /ater solubility	:	No data availabl	e
	tion coefficient: n-	:	No data availabl	e
	nol/water -ignition temperature	:	No data availabl	e





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Deco	omposition temperature	:	No data availabl	9	
Visco		:	No data availabl	e	
Vi	iscosity, kinematic	:	No data available	e	
Explo	osive properties	:	Not explosive		
Oxidi	izing properties	:	The substance of	r mixture is not classified as oxidizing.	
Mole	cular weight	:	No data available	e	
	Particle characteristics Particle size		No data availabl	e	
Section 1	0: Stability and reactiv	ity			
Cher	Reactivity Chemical stability Possibility of hazardous reac- tions		Stable under nor May form explos dling or other me	ive dust-air mixture during processing, han-	
Conc	Conditions to avoid		Heat, flames and sparks. Avoid dust formation.		

	Avoid dust formation.
Incompatible materials	: Oxidizing agents
Hazardous decomposition	: No hazardous decomposition products are known.
products	

Section 11: Toxicological information

Information on likely routes of exposure	:	Inhalation Skin contact
		Ingestion Eye contact
		,

Acute toxicity

Not classified based on available information.

Components:

Sucrose:

Acute oral toxicity : LD50 (Rat): 29,700 mg/kg

Skin corrosion/irritation

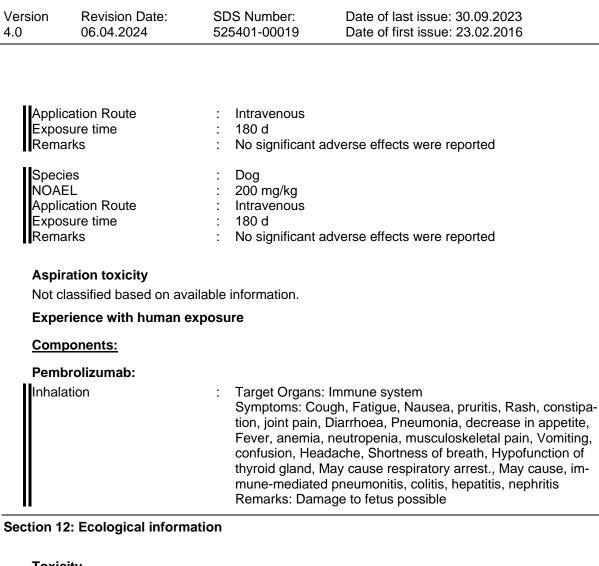
Not classified based on available information.





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Serio	ous eye damage/eye i	rritati	on					
Not c	lassified based on ava	ilable	information.					
Resp	iratory or skin sensit	isatio	on					
-	Skin sensitisation							
	lassified based on ava	llable	information.					
-	iratory sensitisation lassified based on ava	ilable	information.					
Germ	cell mutagenicity							
Not c	lassified based on ava	ilable	information.					
Com	ponents:							
Sucr								
Geno	toxicity in vitro	:	Test Type: In Result: negati	vitro mammalian cell gene mutation test ve				
	i nogenicity lassified based on ava	ilahle	information					
	oductive toxicity							
	damage the unborn ch	ild.						
Com	ponents:							
Pemb	orolizumab:							
Repro sessr	oductive toxicity - As- nent	:	May damage materials	the unborn child., Based on data from similar				
STO	Γ - single exposure							
Not c	lassified based on ava	ilable	information.					
	- repeated exposure							
Caus lowed		(Immu	ine system) thro	ough prolonged or repeated exposure if swal-				
Com	ponents:							
Pemb	orolizumab:							
	et Organs ssment	:	Immune syste Causes dama exposure.	m ge to organs through prolonged or repeated				
Repe	ated dose toxicity							
Com	ponents:							
Pemb	orolizumab:							
Spec	ies	:	Monkey					
NOA	EL	:	200 mg/kg					





Toxicity	
No data available	
Persistence and degradability	
No data available	
Bioaccumulative potential	
Components:	
Sucrose:	
Partition coefficient: n- : octanol/water	Pow: < 1
Mobility in soil	
No data available	
Other adverse effects No data available	



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Section 13: Disposal considerations

Disposal methods		
Waste from residues	:	Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
Contaminated packaging	:	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

UNRTDG UN number UN proper shipping name Transport hazard class(es) Subsidiary risk Packing group	:	Not applicable Not applicable Not applicable Not applicable Not applicable
Labels Environmentally hazardous	:	Not applicable no
IATA-DGR UN/ID No. UN proper shipping name Class Subsidiary risk Packing group Labels Packing instruction (cargo aircraft) Packing instruction (passen- ger aircraft)		Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable
IMDG-Code UN number UN proper shipping name	:	Not applicable Not applicable

UN proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
EmS Code	:	Not applicable
Marine pollutant	:	Not applicable

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable



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Section 15: Regulatory information

Safety, health and environmental regulations specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations. Environmental Protection and Management Act and : Not applicable Environmental Protection and Management (Hazardous Substances) Regulations Fire Safety (Petroleum and Flammable Materials) Not applicable : Regulations The components of this product are reported in the following inventories: AICS not determined : DSL : not determined

IECSC	:	not determined

Section 16: Other information

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Further information		
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 Agen- cy, http://echa.europa.eu/

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format	:	dd.mm.yyyy			
Full text of other abbreviations					
ACGIH SG OEL	:	USA. ACGIH Threshold Limit Values (TLV) Singapore. Workplace Safety and Health (General Provisions) Regulations - First Schedule Permissible Exposure Limits of Toxic Substances.			
ACGIH / TWA SG OEL / PEL (long term)	:	8-hour, time-weighted average Permissible Exposure Level (PEL) Long Term			

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



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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

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. 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.

SG / EN