



Version 5.10	Revision Date: 28.09.2024		S Number: 549-00026	Date of last issue: 30.09.2023 Date of first issue: 23.01.2015
SECTION	1. IDENTIFICATION			
Produ	Product identifier		Pembrolizumab	Liquid Formulation
Manu	ifacturer or supplier's	s deta	ils	
Comp		:	MSD	
Addre	ess	:	nº 1500 – Distrite	dador Antônio Loureiro Ramos, o Industrial · MG, Brazil 39404-620
Telep	Telephone		+55 (38) 3229 7	000
Emer	Emergency telephone		+55 (38) 3201 5	670
E-ma	il address	:	EHSDATASTEV	VARD@msd.com
Reco	mmended use of the	chem	ical and restriction	ons on use
	mmended use		Pharmaceutical	
Restr	ictions on use	:	Not applicable	
SECTION	2. HAZARDS IDENTI	FICAT	ION	
GHS	Classification in acco	ordan	ce with ABNT NB	R 14725 Standard
Repro	oductive toxicity	:	Category 1B	

Specific target organ toxicity - : Category 2 (Immune system) repeated exposure (Oral)

#### GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms	:	
Signal Word	:	Danger
Hazard Statements	:	H360D May damage the unborn child. H373 May cause damage to organs (Immune system) through prolonged or repeated exposure if swallowed.
Precautionary Statements	:	<b>Prevention:</b> P201 Obtain special instructions before use. P280 Wear protective gloves/ protective clothing/ eye protec- tion/ face protection.
		<b>Response:</b> P308 + P313 IF exposed or concerned: Get medical advice/



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		attention.	attention.					
		Storage:						
		P405 Store	locked up.					
None SECTION Subst	<ul> <li>hazards which do n known.</li> <li>3. COMPOSITION/IN ance / Mixture connents</li> </ul>							
Chem	ical name	CAS-No.	Classification	Concentration (% w/w)				
Sucro	se	57-50-1		>= 5 -< 10				
Pemb	rolizumab	1374853-91-4	Repr., 1B STOT RE, (Oral)(Immune sys- tem) , 1	>= 1 -< 5				

#### SECTION 4. 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	:	Flush eyes with water as a precaution. 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 Protection of first-aiders	:	May damage the unborn child. May cause damage to organs through prolonged or repeated exposure if swallowed. First Aid responders should pay attention to self-protection,
Notes to physician	:	and use the recommended personal protective equipment when the potential for exposure exists (see section 8). Treat symptomatically and supportively.

#### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray
		Alcohol-resistant foam
		Carbon dioxide (CO2)
		Dry chemical



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Unsu media	itable extinguishing a	:	None known.			
Spec fightir	ific hazards during fire ng	:	Exposure to co	Exposure to combustion products may be a hazard to health.		
Haza ucts	rdous combustion prod-	:	Carbon oxides Nitrogen oxides	s (NOx)		
Speci ods	Specific extinguishing meth- ods		Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to c so. Evacuate area.			
	ial protective equipment e-fighters	:		fire, wear self-contained breathing apparatus. rotective equipment.		
ECTION	6. ACCIDENTAL RELE	AS	E MEASURES			
tive e	onal precautions, protec- quipment and emer- y procedures	:	Follow safe har	rotective equipment. Indling advice (see section 7) and personal Indexton and the section 8).		
Envir	Environmental precautions		Prevent further Prevent spread oil barriers). Retain and disp	o the environment. leakage or spillage if safe to do so. ling over a wide area (e.g., by containment or pose of contaminated wash water. es should be advised if significant spillages ained.		
	ods and materials for ainment and cleaning up	:	For large spills, containment to can be pumped container. Clean up remain absorbent. Local or national disposal of this employed in the determine which Sections 13 an	ert absorbent material. provide diking or other appropriate keep material from spreading. If diked materia d, store recovered material in appropriate ining materials from spill with suitable al regulations may apply to releases and material, as well as those materials and items e cleanup of releases. You will need to h regulations are applicable. d 15 of this SDS provide information regarding national requirements.		

#### SECTION 7. HANDLING AND STORAGE

Technical measures	:	See Engineering measures under EXPOSURE
		CONTROLS/PERSONAL PROTECTION section.

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Local/Total ventilation Advice on safe handling		ventilation. Do not get on Do not breath Do not swallo Avoid contact Wash skin the Handle in acc practice, base assessment Keep containe Do not eat, dr	<ul> <li>Do not get on skin or clothing.</li> <li>Do not breathe mist or vapors.</li> <li>Do not swallow.</li> <li>Avoid contact with eyes.</li> <li>Wash skin thoroughly after handling.</li> <li>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure</li> </ul>				
Hygiene measures		flushing syste place. When using d	<ul> <li>If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working</li> </ul>				
Condit	ions for safe storage						
Materi	als to avoid	: Do not store v Strong oxidizi	vith the following product types: ng agents substances and mixtures				

#### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis			
Sucrose	57-50-1	TWA	10 mg/m <sup>3</sup>	ACGIH			
Pembrolizumab	1374853-91- 4	TWA	450 μg/m3 (OEB 2)	Internal			
Engineering measures			concentrations. ailable, use with local	exhaust			
Personal protective equipme	nt						
Respiratory protection	exposure ass	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.					
Filter type Hand protection		Particulates type					
Material	: Chemical-res	istant gloves					

#### Ingredients with workplace control parameters . . . . .



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-	Remarks Eye protection Skin and body protection		<ul> <li>Choose gloves to protect hands against chemicals dependent on the concentration specific to place of work. Breakthr time is not determined for the product. Change gloves of For special 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.</li> <li>Wear the following personal protective equipment: Safety glasses</li> <li>Select appropriate protective clothing based on chemic resistance data and an assessment of the local exposu potential. Skin contact must be avoided by using impervious protections.</li> </ul>				
SECTI	ON 9. PHYSICAL AND CHI	ЕМІС	0.0	aprons, boots, etc).			
	nysical state	:	suspension	-			
	olor	:	Colorless to pale	yellow			
0	dor	:	No data available	9			
0	dor Threshold	:	No data available	9			
pł	4	:	5,5				
M	elting point/freezing point	:	No data available	9			
	itial boiling point and boiling nge	:	No data available	9			
Fl	ash point	:	No data available	9			
E١	vaporation rate	:	No data available	9			
Fl	ammability (solid, gas)	:	Not applicable				
Fl	ammability (liquids)	:	No data available	9			
	oper explosion limit / Upper ammability limit	:	No data available	9			
	ower explosion limit / Lower ammability limit	:	No data available	9			
Va	apor pressure	:	No data available	9			
Re	elative vapor density	:	No data available	9			
Re	elative density	:	No data available	9			
De	ensity	:	No data available	9			
So	blubility(ies)						



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	Wa	ter solubility	:	No data available	9
		on coefficient: n- I/water	:	No data available	9
		nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	Viscos Visc	ity cosity, dynamic	:	No data available	9
	Viscosity, kinematic		:	No data available	9
	Explosive properties		:	Not explosive	
	Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Molecu	ular weight	:	No data available	9
	Particle Particle	e characteristics e size	:	No data available	9

#### SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. Can react with strong oxidizing agents.
Conditions to avoid Incompatible materials Hazardous decomposition products	: :	None known. Oxidizing agents No hazardous decomposition products are known.

#### SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of	:	Inhalation
exposure		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.

#### Serious eye damage/eye irritation

Not classified based on available information.

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Resp	iratory or skin sensit	ization		
Skin	sensitization			
Not cl	assified based on ava	ilable inf	ormation.	
-	iratory sensitization assified based on ava	ilable inf	ormation.	
	cell mutagenicity assified based on ava	ilahle inf	ormation	
	oonents:		ornation.	
Sucro	ose:			
Geno	toxicity in vitro		est Type: In esult: negati	vitro mammalian cell gene mutation test ve
	<b>nogenicity</b> assified based on ava	ilabla inf	ormation	
	oductive toxicity		ormation.	
-	lamage the unborn ch	ild.		
-	oonents:			
	orolizumab:			
	oductive toxicity - As-		lay damage aterials	the unborn child., Based on data from simila
	-single exposure assified based on ava	ilable inf	ormation	
	-repeated exposure			
	ause damage to orga	ns (Immi	une system)	through prolonged or repeated exposure if
<u>Comp</u>	oonents:			
Pemb	orolizumab:			
	t Organs sment	: C	nmune syste auses dama xposure.	m ge to organs through prolonged or repeated
Repe	ated dose toxicity			
<u>Com</u>	oonents:			
Pemb	orolizumab:			
Speci NOAE			lonkey 00 mg/kg	
Applic	ation Route		itravenous	
	sure time		80 d o significant	adverse effects were reported
Speci			og	adverse effects were reported



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Appl Expo	NOAEL : Application Route : Exposure time : Remarks :		200 mg/kg Intravenous 180 d No significant adverse effects were reported	
-	iration toxicity classified based on availa	able	information.	
Exp	erience with human exp	oosi	ure	
Com	ponents:			
Pem	brolizumab:			
Inha	lation	:	Symptoms: Cou tion, joint pain, I Fever, anemia, confusion, Head thyroid gland, M mune-mediated	Immune system Igh, Fatigue, Nausea, pruritis, Rash, constipa- Diarrhea, Pneumonia, decrease in appetite, neutropenia, musculoskeletal pain, Vomiting, dache, Shortness of breath, Hypofunction of lay cause respiratory arrest., May cause, im- pneumonitis, colitis, hepatitis, nephritis age to fetus possible
SECTION	I 12. ECOLOGICAL INF	ORI	MATION	
	t <b>oxicity</b> lata available			
	<b>sistence and degradabi</b> l lata available	lity		
Bioa	ccumulative potential			
<u>Com</u>	ponents:			
Parti	r <b>ose:</b> tion coefficient: n- nol/water	:	Pow: < 1	
	<b>ility in soil</b> lata available			
	er adverse effects lata available			

#### 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 handling site for recycling or disposal.	
	If not otherwise specified: Dispose of as unused product.	





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SECTION	14. TRANSPORT INI	FORMATION	
Interr	ational Regulations		
<b>UNR1</b> Not re	<b>DG</b> egulated as a dangero	ous good	
IATA- Not re	DGR egulated as a dangero	ous good	
-	-Code egulated as a dangero	ous good	
	port in bulk accordi	-	ARPOL 73/78 and the IBC Code
Dome	estic regulation		
<b>ANTT</b> Not re	gulated as a dangero	ous good	
-	al precautions for un oplicable	ser	
SECTION	15. REGULATORY II	NFORMATION	
		nmental regulations	/legislation specific for the substance or
mixtu Natior (LINA	<b>re</b> nal List of Carcinogen CH) . List of chemicals cor	ic Agents for Humans	s - : Not applicable
mixtu Natior (LINA Brazil Police	re nal List of Carcinogen CH) . List of chemicals cor	ic Agents for Humans	<ul> <li>s - : Not applicable</li> <li>al : Not applicable</li> <li>in the following inventories:</li> </ul>
mixtu Natior (LINA Brazil Police The in	re nal List of Carcinogen CH) . List of chemicals cor	ic Agents for Humans	<ul> <li>s - : Not applicable</li> <li>al : Not applicable</li> <li>in the following inventories:</li> </ul>
mixtu Natior (LINA Brazil Police The in AICS	re nal List of Carcinogen CH) . List of chemicals cor <b>hgredients of this pr</b>	ic Agents for Humans ntrolled by the Federa oduct are reported i : not determine	s - : Not applicable al : Not applicable in the following inventories:
mixtu Natior (LINA Brazil Police The in AICS DSL IECSC	re nal List of Carcinogen CH) . List of chemicals cor <b>hgredients of this pr</b>	ic Agents for Humans Introlled by the Federa oduct are reported to : not determine : not determine : not determine	s - : Not applicable al : Not applicable in the following inventories:
mixtu Natior (LINA Brazil Police The in AICS DSL IECS( SECTION Revis	re nal List of Carcinogen CH) . List of chemicals cor <b>ngredients of this pr</b>	ic Agents for Humans Introlled by the Federa oduct are reported to : not determine : not determine : not determine	s - : Not applicable al : Not applicable in the following inventories:
mixtu Natior (LINA Brazil Police The in AICS DSL IECSO SECTION Revis Date f Furth Sourc	re nal List of Carcinogen CH) . List of chemicals cor <b>ngredients of this pr</b> <b>16. OTHER INFORM</b> format <b>er information</b> es of key data used to ile the Material Safety	ic Agents for Humans htrolled by the Federa oduct are reported i i not determine i not determine i not determine ATION i 28.09.2024 i dd.mm.yyyy o : Internal techn	ical data, data from raw material SDSs, OECD
mixtu Natior (LINA Brazil Police The in AICS DSL IECSO SECTION Revis Date f Furth Sourc compi Data S	re nal List of Carcinogen CH) . List of chemicals cor <b>ngredients of this pr</b> <b>16. OTHER INFORM</b> format <b>er information</b> es of key data used to ile the Material Safety	ic Agents for Humans introlled by the Federa oduct are reported if introlled by the Federa oduct are reported if internate internate ATION i 28.09.2024 i dd.mm.yyyy o : Internat techn eChem Portat cy, http://echa	ical data, data from raw material SDSs, OECD



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ACGIH / TWA

: 8-hour, time-weighted 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

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 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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