according to GB/T 16483 and GB/T 17519



Pembrolizumab Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
6.0	2024/09/28	49558-00026	Date of first issue: 2015/01/23

1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	Pembrolizumab Liquid Formulation
Manufacturer or supplier's de	eta	ils
Company	:	MSD
Address	:	199 Wenhai North Road HEDA, Hangzhou - Zhejiang Province - CHINA 310018
Telephone	:	908-740-4000
Emergency telephone number	:	86-571-87268110
E-mail address	:	EHSDATASTEWARD@msd.com
Recommended use of the ch	em	ical and restrictions on use
Recommended use Restrictions on use	:	Pharmaceutical Not applicable

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance Colour Odour	:	suspension Colorless to pale yellow No data available
May damage the unborn child. posure.	Ma	y cause damage to organs through prolonged or repeated ex-
GHS Classification		
Reproductive toxicity	:	Category 1B
Specific target organ toxicity - repeated exposure	:	Category 2
GHS label elements		
Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H360D May damage the unborn child. H373 May cause damage to organs through prolonged or re-

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Preca	utionary statements	P202 Do not h and understoo P260 Do not b	special instructions before use. handle until all safety precautions have been read od. preathe mist or vapours. rotective gloves/ protective clothing/ eye protec-
		Response: P308 + P313 attention.	IF exposed or concerned: Get medical advice/
		Storage: P405 Store lo	cked up.
		Disposal: P501 Dispose disposal plant	e of contents/ container to an approved waste
Physic	cal and chemical haza	ards	

Not classified based on available information.

Health hazards

May damage the unborn child. May cause damage to organs through prolonged or repeated exposure.

Environmental hazards

Not classified based on available information.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Sucrose	57-50-1	>= 1 -< 10
Pembrolizumab	1374853-91-4	>= 1 -< 10

4. FIRST AID MEASURES

General advice	In the case of accident or if you fee vice immediately. When symptoms persist or in all ca advice.	
If inhaled	If inhaled, remove to fresh air.	

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	In case	of skin contact	:	of water.	, immediately flush skin with soap and plenty nated clothing and shoes. tion.
	In case	of eye contact	:	Thoroughly clean Flush eyes with w	shoes before reuse. vater as a precaution.
	If swallo	owed	:		tion if irritation develops and persists. NOT induce vomiting. tion.
	and effe delayed	nportant symptoms ects, both acute and d ion of first-aiders	:	Rinse mouth thore May damage the May cause damage exposure. First Aid responde and use the recor	oughly with water.
	Notes to	o physician	:		cally and supportively.
5. FI	REFIGH	TING MEASURES			
	Suitable	e extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical	
	Unsuita media	ble extinguishing	:	None known.	
	Specific fighting	hazards during fire-	:	Exposure to comb	pustion products may be a hazard to health.
	Hazard ucts	ous combustion prod-	:	Carbon oxides Nitrogen oxides (I	NOx)
	Specific ods	extinguishing meth-	:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do
	Special for firefi	protective equipment ghters	:		e, wear self-contained breathing apparatus. tective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :	Use personal protective equipment.
tive equipment and emer-	Follow safe handling advice (see section 7) and personal pro-
gency procedures	tective equipment recommendations (see section 8).

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Envir	onmental precautions	Prevent spreadir barriers). Retain and dispo	backage or spillage if safe to do so. ag over a wide area (e.g. by containment or oil ase of contaminated wash water. should be advised if significant spillages
	ods and materials for inment and cleaning up	For large spills, p ment to keep ma be pumped, store Clean up remain bent. Local or national posal of this mate employed in the mine which regul Sections 13 and	rt absorbent material. provide dyking or other appropriate contain- terial from spreading. If dyked material can e recovered material in appropriate container. ing materials from spill with suitable absor- regulations may apply to releases and dis- erial, as well as those materials and items cleanup of releases. You will need to deter- lations are applicable. 15 of this SDS provide information regarding ational requirements.

7. HANDLING AND STORAGE

Handling

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
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 mist or vapours. 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 as- sessment Keep container tightly closed. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.
Avoidance of contact	:	Oxidizing agents
Storage		
Conditions for safe storage	:	Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Materials to avoid	:	Do not store with the following product types:

SAFETY DATA SHEET according to GB/T 16483 and GB/T 17519

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		Strong oxidiz	ing agents		
Pack	aging material	: Unsuitable m	aterial: None kr	nown	
EXPOS	URE CONTROLS/PER	SONAL PROTECT	ION		
Com	ponents with workpla	ce control narame	ters		
	ponents	CAS-No.	Value type	Control parame-	Basis
00111			(Form of	ters / Permissible	Daolo
			exposure)	concentration	
Sucro	ose	57-50-1	TWA	10 mg/m3	ACGIH
Pemb	orolizumab	1374853-91-	TWA	450 µg/m3 (OEB	Interna
		4		2)	
-	neering measures onal protective equipr	If sufficient ve ventilation.		e concentrations. vailable, use with loca	l exhaust
	iratory protection			ntilation is not availabl	
Eye/f	lter type ace protection and body protection	ommended g : Particulates t : Wear the follo Safety glasse	uidelines, use r ype owing personal es	tes exposures outside espiratory protection. protective equipment: clothing based on ch	
	protection	resistance da potential. Skin contact	ta and an asse	ssment of the local ex d by using impervious	posure
M	aterial	: Chemical-res	istant gloves		
Re	emarks	on the concer stance and sp determined for applications, chemicals of glove manufa end of workd	ntration and qua becific to place or the product. (we recommend the aforementic acturer. Wash he ay.	nds against chemicals antity of the hazardous of work. Breakthrough Change gloves often! I clarifying the resistan oned protective gloves ands before breaks ar	s sub- time is n For specia ice to with the nd at the
Hygie	ene measures	eye flushing s ing place. When using o			

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А	ppearance	: s	uspension	
C	olour	: C	olorless to pale	yellow
C	dour	: N	o data available	
C	dour Threshold	: N	o data available	
р	Н	: 5	.5	
	lelting point/freezing point		o data available	
Ir	nitial boiling point and boiling ange	: N	o data available	
F	lash point	: N	o data available	
E	vaporation rate	: N	o data available	
F	lammability (solid, gas)	: N	ot applicable	
F	lammability (liquids)	: N	o data available	
	pper explosion limit / Upper ammability limit	: N	o data available	
	ower explosion limit / Lower ammability limit	: N	o data available	
V	apour pressure	: N	o data available	
R	elative vapour density	: N	o data available	
R	elative density	: N	o data available	
II C	ensity	: N	o data available	
S	olubility(ies) Water solubility	: N	o data available	
	artition coefficient: n-	: N	o data available	
	ctanol/water uto-ignition temperature	: N	o data available	
D	ecomposition temperature	: N	o data available	
V	iscosity Viscosity, dynamic	: N	o data available	
	Viscosity, kinematic	: N	o data available	

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Explo	sive properties	: No	t explosive			
Oxidi	zing properties	: The	e substance o	r mixture is not classified as oxidizing.		
Moleo	cular weight	: No data available				
	cle characteristics cle size	: No data available				
10. STAB	ILITY AND REACTIVITY	,				
Possi tions Cond Incon	nical stability bility of hazardous reac- itions to avoid npatible materials rdous decomposition	: Sta : Ca : No : Ox	ble under nor n react with st ne known. idizing agents	a reactivity hazard. mal conditions. rong oxidizing agents. ecomposition products are known.		
11. TOXIC	OLOGICAL INFORMAT	ION				
Expo	sure routes	Skir Inge	alation contact estion contact			
	Acute toxicity Not classified based on available information.					
Com	ponents:					
Sucre Acute	ose: e oral toxicity	: LD5	0 (Rat): 29,70	00 mg/kg		
-	Skin corrosion/irritation Not classified based on available information.					
	Serious eye damage/eye irritation Not classified based on available information.					
Resp	Respiratory or skin sensitisation					
-	Skin sensitisation Not classified based on available information.					
-	iratory sensitisation lassified based on availa	ble infor	mation.			
	cell mutagenicity lassified based on availa	ble infor	mation.			
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<u>Comp</u>	oonents:		
Sucro	ose:		
Geno	toxicity in vitro	: Test Type: I Result: nega	n vitro mammalian cell gene mutation test ative
	nogenicity assified based on ava	ailable information	
-	oductive toxicity	, ild	
-	lamage the unborn ch	1110.	
<u>Comp</u>	oonents:		
Pemb	orolizumab:		
Repro sessn	oductive toxicity - As- nent	: May damag materials	e the unborn child., Based on data from simila
STOT	- single exposure		
	- single exposure assified based on ava	ailable information.	
Not cl	assified based on ava		
Not cl STOT	assified based on ava	е	ed or repeated exposure
Not cl STOT May c	assified based on ava - repeated exposur cause damage to orga	е	ed or repeated exposure.
Not cl STOT May c <u>Comr</u>	assified based on ava - repeated exposur cause damage to organ conents:	е	ed or repeated exposure.
Not cl STOT May c <u>Comp</u> Pemb	assified based on ava - repeated exposur cause damage to organ conents: prolizumab:	е	ed or repeated exposure.
Not cl STOT May c <u>Comp</u> Pemb	assified based on ava - repeated exposur cause damage to organ conents:	e ans through prolong : Immune sys	
Not cl STOT May c <u>Comp</u> Pemb Targe Asses	assified based on ava - repeated exposur cause damage to orga conents: prolizumab: t Organs	e ans through prolong : Immune sys : Causes dan	stem
Not cl STOT May c Comp Pemb Targe Asses Repe	assified based on ava - repeated exposur cause damage to orga conents: prolizumab: at Organs ssment	e ans through prolong : Immune sys : Causes dan	stem
Not cl STOT May c Comp Pemb Targe Asses Repea	assified based on ava - repeated exposur cause damage to orga conents: prolizumab: at Organs csment ated dose toxicity conents:	e ans through prolong : Immune sys : Causes dan	stem
Not cl STOT May c Comp Pemb Targe Asses Repea Comp	assified based on ava - repeated exposur cause damage to orga <u>conents:</u> prolizumab: ated dose toxicity <u>conents:</u> prolizumab: prolizumab:	e ans through prolong : Immune sys : Causes dan exposure.	stem
Not cl STOT May c Comp Pemb Asses Repea Comp Pemb Speci NOAE	assified based on ava - repeated exposur cause damage to orga <u>conents:</u> prolizumab: ated dose toxicity <u>conents:</u> prolizumab: es EL	e ans through prolong : Immune sys : Causes dan	stem
Not cl STOT May c Comp Pemb Asses Repea Comp Pemb Speci NOAE	assified based on ava - repeated exposur cause damage to orga <u>conents:</u> prolizumab: ated dose toxicity <u>conents:</u> prolizumab: es EL	e ans through prolong : Immune sys : Causes dan exposure. : Monkey : 200 mg/kg : Intravenous	stem nage to organs through prolonged or repeated
Not cl STOT May c Comr Pemb Targe Asses Repea Comr Pemb Speci NOAE Applic Expos	assified based on ava - repeated exposur cause damage to orga - rolizumab: - orolizumab: - orolizumab: - ated dose toxicity - onents: - onoents: - onoent	e ans through prolong : Immune sys : Causes dan exposure. : Monkey : 200 mg/kg : Intravenous : 180 d	stem nage to organs through prolonged or repeated
Not cl STOT May c Comp Pemb Asses Repea Comp Pemb Speci NOAE	assified based on ava - repeated exposur cause damage to orga - rolizumab: - orolizumab: - orolizumab: - ated dose toxicity - onents: - onoents: - onoent	e ans through prolong : Immune sys : Causes dan exposure. : Monkey : 200 mg/kg : Intravenous : 180 d	stem nage to organs through prolonged or repeated
Not cl STOT May c Comp Pemb Asses Repea Comp Pemb Speci NOAE Applic Expos Rema	assified based on ava - repeated exposur cause damage to orga <u>conents:</u> prolizumab: ated dose toxicity conents: prolizumab: es EL cation Route sure time trks es	e ans through prolong : Immune sys : Causes dan exposure. : Monkey : 200 mg/kg : Intravenous : 180 d : No significa : Dog	stem nage to organs through prolonged or repeated
Not cl STOT May c Comp Pemb Targe Asses Repea Comp Pemb Speci NOAE Applic Expos Rema	assified based on ava - repeated exposur cause damage to orga <u>conents:</u> prolizumab: ated dose toxicity conents: prolizumab: es EL cation Route sure time trks es EL	e ans through prolong : Immune sys : Causes dan exposure. : Monkey : 200 mg/kg : Intravenous : 180 d : No significa : Dog : 200 mg/kg	stem nage to organs through prolonged or repeated
Not cl STOT May c Comp Pemb Asses Repea Comp Pemb Speci NOAE Applic Expos Rema	assified based on ava - repeated exposur cause damage to orga <u>conents:</u> prolizumab: ated dose toxicity conents: prolizumab: es EL cation Route sure time trks es	e ans through prolong : Immune sys : Causes dan exposure. : Monkey : 200 mg/kg : Intravenous : 180 d : No significa : Dog	stem nage to organs through prolonged or repeated

Not classified based on available information.

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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, confusion, Headache, Shortness of breath, Hypofunction of thyroid gland, May cause respiratory arrest., May cause, immune-mediated pneumonitis, colitis, hepatitis, nephritis Remarks: Damage to fetus possible

12. ECOLOGICAL INFORMATION

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

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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number

: Not applicable

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Class Subs Packi Label	idiary risk ing group	 Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable no 	
UN/IE Prope Class Subs Packi Label Packi aircra Packi	er shipping name idiary risk ing group Is ing instruction (cargo	 Not applicable 	
UN n Prope Class Subs Packi Label EmS	idiary risk ing group	 Not applicable no 	

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

GB 6944/12268

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Marine pollutant	:	no

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

National regulatory information

Law on the Prevention and Control of Occupational Diseases

Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals

: This product is not listed in the cata-

according to GB/T 16483 and GB/T 17519



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Ident	ification of Major Hazard	Installations for Ha	logue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of de- termination.
1821			
Haza SAW	ardous Chemicals for Prio /S	prity Management u	nder : Not listed
Regi	ulations on Labour Pro	tection in Workpla	ces where Toxic Substances are Used
Cata	logue of Highly Toxic Ch	emicals	: Not listed
	ulation of Environment Export of Toxic Chemic		the First Import of Chemicals and the Import
	a Severely Restricted To Export	xic Chemicals for Ir	nport : Not listed
Reg	ulation on the Administ	ration of Precurso	or Chemicals
-	logue and Classification		
Van	gtze River Protection L	2.14	
	-		emicals prohibited for inland river transport.
			in the following inventories:
AICS	· · ·	: not determine	-
DSL		: not determine	d
IECS	SC	: not determine	d
16. OTHE			
Revi	sion Date	: 2024/09/28	
Furt	her information		
	ces of key data used to bile the Safety Data et		cal data, data from raw material SDSs, OECD search results and European Chemicals Agen- .europa.eu/
	s where changes have b ment by two vertical line		evious version are highlighted in the body of this
Date	format	: yyyy/mm/dd	
	text of other abbreviati		
ACG	IH	: USA. ACGIH	Threshold Limit Values (TLV)
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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

Disclaimer

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.

CN/EN