

Pembrolizumab Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.11	30.09.2023	49574-00024	Date of first issue: 23.01.2015

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	Pembrolizumab Liquid Formulation		
Manufacturer or supplier's d	eta	ils		
Company name of supplier	:	MSD		
Address	:	126 E. Lincoln Avenue		
		Rahway, New Jersey U.S.A. 07065		
Telephone	:	908-740-4000		
Emergency telephone	:	1-908-423-6000		
E-mail address	:	EHSDATASTEWARD@msd.com		
Recommended use of the chemical and restrictions on use				
Recommended use Restrictions on use	:	Pharmaceutical Not applicable		

SECTION 2. HAZARDS IDENTIFICATION

GHS	Classification
GIIS	Classification

Reproductive toxicity	:	Category 1B
Specific target organ toxicity - repeated exposure (Oral)	:	Category 1 (Immune system)

GHS label elements

GHS label elements		
Hazard pictograms	:	
Signal Word	:	Danger
Hazard Statements	:	H360D May damage the unborn child. H372 Causes damage to organs (Immune system) through pro- longed or repeated exposure if swallowed.
Precautionary Statements	:	 Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe mist or vapors. P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
		Response: P308 + P313 IF exposed or concerned: Get medical advice/ attention.
		Storage:

P405 Store locked up.





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		Disposal: P501 Dispos posal plant.	e of contents/ contai	ner to an approved waste dis-
Othe	r hazards			
None	e known.			
SECTION	3. COMPOSITION/INF	ORMATION ON I	IGREDIENTS	
Subs	stance / Mixture	: Mixture		
	ponents			
	nical name		CAS-No.	Concentration (% w/w)
Sucro			57-50-1	>= 5 -< 10
Pem	brolizumab		1374853-91-4	>= 1 -< 5
lf inh	alad	advice.	move to fresh air.	cases of doubt seek medical
	aleu	Get medical		
In ca	se of skin contact	 In case of contact, immediately flush skin with soap and plu of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. 		nd shoes.
In ca	se of eye contact	: Flush eyes v	vith water as a preca	
lf swa	allowed	: If swallowed Get medical	, DO NOT induce vor	miting.
and e delay	important symptoms effects, both acute and ved	: May damage Causes dam exposure if s	e the unborn child. age to organs throug wallowed.	h prolonged or repeated
Prote	ection of first-aiders	and use the		attention to self-protection, nal protective equipment

SECTION 5. FIRE-FIGHTING MEASURES

Notes to physician

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire	:	Exposure to combustion products may be a hazard to health.

: Treat symptomatically and supportively.

when the potential for exposure exists (see section 8).



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	fighting Hazard ucts	ous combustion prod-	:	Carbon oxides Nitrogen oxides (N	NOx)
	Specific ods	c extinguishing meth-	:	cumstances and t Use water spray to	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 fire-	l protective equipment fighters	:		e, wear self-contained breathing apparatus. ective equipment.
SEC	CTION 6	. ACCIDENTAL RELE	ASI	EMEASURES	
	tive equ	al precautions, protec- uipment and emer- procedures	:		ective equipment. ing advice (see section 7) and personal ent recommendations (see section 8).
	Enviror	nmental precautions	:	Prevent spreading oil barriers). Retain and dispos	akage or spillage if safe to do so. g over a wide area (e.g., by containment or se of contaminated wash water. should be advised if significant spillages
		ls and materials for ment and cleaning up	:	For large spills, pr containment to ke can be pumped, s container. Clean up remainir absorbent. Local or national r disposal of this ma employed in the c determine which r Sections 13 and 1	absorbent material. ovide diking or other appropriate ep material from spreading. If diked material tore recovered material in appropriate ng materials from spill with suitable egulations may apply to releases and aterial, as well as those materials and items leanup of releases. You will need to egulations are applicable. 5 of this SDS provide information regarding tional requirements.

SECTION 7. HANDLING AND STORAGE

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 vapors. 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



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Hygiene measures		 assessment 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. 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.					
Conditions for safe storage		Store locked up Keep tightly clo					
Materials to avoid		: Do not store wir Strong oxidizing	th the following product types: g agents lbstances and mixtures				

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Sucrose	57-50-1	VLE-PPT	10 mg/m ³	NOM-010- STPS-2014
		TWA	10 mg/m ³	ACGIH
Pembrolizumab	1374853-91- 4	TWA	450 μg/m3 (OEB 2)	Internal

Engineering measures	:	Minimize workplace exposure concentrations. If sufficient ventilation is unavailable, use with local exhaust ventilation.
Personal protective equipme	ent	
Respiratory protection	:	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-resistant gloves
Remarks	:	Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! 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.



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Eye protection	:		ng personal protective equipment:
Skin and body protection	:	resistance data a potential. Skin contact mus	te protective clothing based on chemical and an assessment of the local exposure at be avoided by using impervious protective aprons, boots, etc).
SECTION 9. PHYSICAL AND	CHEMI	CAL PROPERTIE	S
Appearance	:	suspension	
Color	:	Colorless to pale	e yellow
Odor	:	No data availabl	e
Odor Threshold	:	No data availabl	e
рН	:	5.5	
Melting point/freezing poir	nt :	No data availabl	е
Initial boiling point and bo range	iling :	No data availabl	e
Flash point	:	No data availabl	e
Evaporation rate	:	No data availabl	e
Flammability (solid, gas)	:	Not applicable	
Flammability (liquids)	:	No data availabl	e
Upper explosion limit / Up flammability limit	per :	No data availabl	e
Lower explosion limit / Lo	wer :	No data availabl	e
Vapor pressure	:	No data availabl	e
Relative vapor density	:	No data availabl	e
Relative density	:	No data availabl	е
Density	:	No data availabl	е
Solubility(ies) Water solubility	:	No data availabl	е
Partition coefficient: n-	:	No data availabl	e
octanol/water Autoignition temperature	:	No data availabl	е
Decomposition temperatu	re :	No data availabl	e



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Viso	ity cosity, dynamic cosity, kinematic ive properties	::	No data available No data available Not explosive	-
Oxidizing properties Molecular weight Particle size		::	The substance o No data available No data available	-

SECTION 10. STABILITY AND REACTIVITY

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

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.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.



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Not c Germ	iratory sensitization lassified based on avail cell mutagenicity lassified based on avail			
	ponents:			
Sucr				
	toxicity in vitro	:	Test Type: In vitro Result: negative	o mammalian cell gene mutation test
Carci	inogenicity			
Not c	lassified based on avail	lable	information.	
•	oductive toxicity damage the unborn chil	ld.		
Com	ponents:			
Peml	orolizumab:			
Repro sessr	oductive toxicity - As- nent	:	May damage the materials	unborn child., Based on data from similar
Not c	F-single exposure lassified based on avail	lable	information.	
		mmu	une system) throug	n prolonged or repeated exposure if swal-
Com	ponents:			
Peml	orolizumab:			
	et Organs ssment	:	Immune system Causes damage t exposure.	o organs through prolonged or repeated
Repe	ated dose toxicity			
Com	ponents:			
	prolizumab:			
Spec NOAI Appli	ies EL cation Route sure time		Monkey 200 mg/kg Intravenous 180 d No significant adv	rerse effects were reported
	EL cation Route sure time		Dog 200 mg/kg Intravenous 180 d No significant adv	rerse effects were reported



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-	ration toxicity	hla	information							
	Not classified based on available information.									
•	Experience with human exposure <u>Components:</u>									
<u>Com</u>										
Pem	brolizumab:									
Inhal	ation	:	tion, joint pain, I Fever, anemia, I confusion, Head thyroid gland, M mune-mediated	Immune system gh, Fatigue, Nausea, pruritis, Rash, constipa- Diarrhea, Pneumonia, decrease in appetite, neutropenia, musculoskeletal pain, Vomiting, lache, Shortness of breath, Hypofunction of ay cause respiratory arrest., May cause, im- pneumonitis, colitis, hepatitis, nephritis age to fetus possible						
SECTION	12. ECOLOGICAL INF	ORI	MATION							
	Ecotoxicity No data available									
	Persistence and degradability									
	ata available	ity								
	ccumulative potential									
	Components:									
	ose: tion coefficient: n- nol/water	:	Pow: < 1							
	i lity in soil ata available									
	r adverse effects ata available									
SECTION	13. DISPOSAL CONSI	DEF	ATIONS							
-	osal methods		D	· · · · ·						
Wast	e from residues	:		of waste into sewer. cordance with local regulations.						
Conta	aminated packaging	:	Empty container handling site for	rs should be taken to an approved waste recycling or disposal. specified: Dispose of as unused product.						

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG Not regulated as a dangerous good IATA-DGR



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Not r	Not regulated as a dangerous good								
	G-Code egulated as a dangero	us good							
	sport in bulk accordi	• · · ·	RPOL 73/78 and the IBC Code						
Dom	estic regulation								
	NOM-002-SCT Not regulated as a dangerous good								
Spec	Special precautions for user								
Not a	Not applicable								
SECTION	15. REGULATORY I	NFORMATION							
Safe mixt		nmental regulations	legislation specific for the substance or						

Federal Law for the control of chemical precursors, : Not applicable essential chemical products and machinery for producing capsules, tablets and pills.

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

SECTION 16. OTHER INFORMATION

Revision Date Date format	-	30.09.2023 dd.mm.yyyy
Full text of other abbreviatio	ns	
ACGIH	:	USA. ACGIH Threshold Limit Values
NOM-010-STPS-2014	:	Mexico. Norm NOM-010-STPS-2014
		the Merly Fasting and Identification

NOM-010-STPS-2014	:	Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Con- trol - Appendix 1 Occupational Exposure Limits
ACGIH / TWA NOM-010-STPS-2014 / VLE- PPT		8-hour, time-weighted average Time weighted average limit value

(TLV)

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



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- 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

Sources of key data used to : compile the Material Safety Data Sheet Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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