



Versio 2.1			S Number: 5386-00018	Date of last issue: 2023/04/04 Date of first issue: 2016/02/23
1. PRC	DUCT AND COMPANY IDE	INT	IFICATION	
Pi	oduct name	:	Pembrolizumab \$	Solid Formulation
М	anufacturer or supplier's d	etai	ls	
C	ompany	:	MSD	
A	ddress	:	126 E. Lincoln Av Rahway, New Je	venue ersey U.S.A. 07065
Te	elephone	:	908-740-4000	
Eı	mergency telephone number	:	1-908-423-6000	
E	mail address	:	EHSDATASTEW	/ARD@msd.com
R	ecommended use of the ch	em	ical and restriction	ons on use
	ecommended use estrictions on use	:		
2. HAZ	ARDS IDENTIFICATION			

GHS Classification Reproductive toxicity	:	Category 1B
Specific target organ toxicity - repeated exposure (Oral)	:	Category 1 (Immune system)
GHS label elements Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H360D May damage the unborn child. H372 Causes damage to organs (Immune system) through prolonged 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 dust. P264 Wash skin thoroughly after handling.



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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.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Sucrose	57-50-1	>= 60 -<= 100
Pembrolizumab	1374853-91-4	>= 10 -< 30

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	:	May damage the unborn child. Causes damage to organs through prolonged or repeated exposure if swallowed.



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			the skin.	ust can cause mechanical irritation or drying of
Prote	ection of first-aiders	:	First Aid respon and use the red	ith the eyes can lead to mechanical irritation. nders should pay attention to self-protection, commended personal protective equipment
Note	es to physician	:		ntial for exposure exists (see section 8). atically and supportively.
5. FIREF	IGHTING MEASURES			
Suita	able extinguishing media	:	Water spray Alcohol-resista Carbon dioxide Dry chemical	
Unsi med	uitable extinguishing ia	:	None known.	
	cific hazards during fire-	:	concentrations potential dust e	ng dust; fine dust dispersed in air in sufficient , and in the presence of an ignition source is a explosion hazard. Imbustion products may be a hazard to health
Haza ucts	ardous combustion prod-	:	Carbon oxides Nitrogen oxides	s (NOx)
Spec ods	cific extinguishing meth-	:	cumstances an Use water spra	ing measures that are appropriate to local cir- id the surrounding environment. iy to cool unopened containers. naged containers from fire area if it is safe to a
	cial protective equipment refighters	:	In the event of	fire, wear self-contained breathing apparatus. protective equipment.
6. ACCID	ENTAL RELEASE MEA	SUF	RES	
tive	onal precautions, protec- equipment and emer- cy procedures	:	Follow safe ha	protective equipment. ndling advice (see section 7) and personal pro ent recommendations (see section 8).
Envi	ronmental precautions	:	Prevent further Retain and disp	o the environment. leakage or spillage if safe to do so. cose of contaminated wash water. es should be advised if significant spillages ained.
Meth	nods and materials for	:	Sweep up or va	acuum up spillage and collect in suitable con-



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		employed in t mine which re Sections 13 a	naterial, as well as those materials and items he cleanup of releases. You will need to deter- egulations are applicable. Ind 15 of this SDS provide information regarding or national requirements.
7. HAN	IDLING AND STORAGE		
Te	echnical measures	causing an ex Provide adeq	ity may accumulate and ignite suspended dust plosion. uate precautions, such as electrical grounding or inert atmospheres.
Lo	ocal/Total ventilation		entilation is unavailable, use with local exhaust
Ac	dvice on safe handling	: Do not get on Do not breath Do not swallo Avoid contact Wash skin the Handle in acc practice, base sessment Keep contain Keep contain Keep contain Keep away fr Take precaut Do not eat, di	W.
Co	onditions for safe storage	: Keep in prope Store locked Keep tightly c	
Ma	aterials to avoid		with the following product types:

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis	
Sucrose	57-50-1	NAB	10 mg/m3	ID OEL	
	Further information: Not classified as carcinogenic to humans. No enough data to classify these materials as carcinogenic to hu- mans or animals				
		TWA	10 mg/m3	ACGIH	
Pembrolizumab	1374853-91- 4	TWA	450 μg/m3 (OEB 2)	Internal	



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Engi	neering measures	:	Apply measures to Ensure that dust- dust collectors, ve signed in a manner work area (i.e., the	ce exposure concentrations. o prevent dust explosions. handling systems (such as exhaust ducts, essels, and processing equipment) are de- er to prevent the escape of dust into the ere is no leakage from the equipment). ation is unavailable, use with local exhaust		
Pers	onal protective equipm	nent				
	Respiratory protection		If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.			
	ilter type I protection	•	Particulates type			
Μ	laterial	:	Chemical-resistar	nt gloves		
R	emarks	:	on the concentrat stance and specif determined for the applications, we r chemicals of the a	protect hands against chemicals depending ion and quantity of the hazardous sub- ic to place of work. Breakthrough time is not e product. Change gloves often! For special ecommend clarifying the resistance to aforementioned protective gloves with the er. Wash hands before breaks and at the		
Eye	protection	:		g personal protective equipment:		
Skin	and body protection	:	Select appropriate resistance data an potential. Skin contact must	e protective clothing based on chemical nd an assessment of the local exposure t be avoided by using impervious protective aprons, boots, etc).		
Hygid	ene measures	:	If exposure to che eye flushing syste ing place. When using do no	emical is likely during typical use, provide ems and safety showers close to the work- ot eat, drink or smoke. ed clothing before re-use.		

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

SAFETY DATA SHEET



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Melti	ing point/freezing point	:	No data available	
Initia rang	l boiling point and boiling e	:	No data available	9
Flasl	h point	:	Not applicable	
Evap	poration rate	:	No data available	9
Flam	nmability (solid, gas)	:	May form explosi dling or other me	ive dust-air mixture during processing, han- ans.
Flam	nmability (liquids)	:	No data available	9
	er explosion limit / Upper mability limit	:	No data available	9
	er explosion limit / Lower mability limit	:	No data available	9
Vapo	our pressure	:	No data available	9
Rela	tive vapour density	:	No data available)
Rela	tive density	:	No data available)
Dens	sity	:	No data available	9
	bility(ies) /ater solubility	:	No data available	2
	tion coefficient: n- nol/water	:	No data available	9
	-ignition temperature	:	No data available	9
Deco	omposition temperature	:	No data available	9
Visce V	osity ïscosity, dynamic	:	No data available	
V	iscosity, kinematic	:	No data available	9
Expl	osive properties	:	Not explosive	
Oxid	izing properties	:	The substance o	r mixture is not classified as oxidizing.
Mole	ecular weight	:	No data available	9
Parti	cle size	:	No data available)



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10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	: S : M d	lot classified as a reactivity hazard. table under normal conditions. lay form explosive dust-air mixture during processing, han- ling or other means. can react with strong oxidizing agents.
Conditions to avoid		leat, flames and sparks. void dust formation.
Incompatible materials	: C	Dxidizing agents
Hazardous decomposition products		lo hazardous decomposition products are known.

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.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Components:

Sucrose:

Genotoxicity in vitro

: Test Type: In vitro mammalian cell gene mutation test Result: negative



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Carcinogenicity

Not classified based on available information.

Reproductive toxicity

May damage the unborn child.

Components:

Pembrolizumab:

sessment

Reproductive toxicity - As- : 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:NOAEL:Application Route:Exposure time:Remarks:	20 In 18	lonkey 00 mg/kg ntravenous 80 d lo significant adverse effects were reported
Species:NOAEL:Application Route:Exposure time:Remarks:	20 In 18	log 00 mg/kg ntravenous 80 d lo significant adverse effects were reported

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Pembrolizumab:

Inhalation

Target Organs: Immune system :



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		tion, joint pain, Fever, anemia confusion, Hea thyroid gland, I mune-mediated	ugh, Fatigue, Nausea, pruritis, Rash, constipa- Diarrhoea, Pneumonia, decrease in appetite, neutropenia, musculoskeletal pain, Vomiting, dache, Shortness of breath, Hypofunction of May cause respiratory arrest., May cause, im- d pneumonitis, colitis, hepatitis, nephritis hage to fetus possible		
12. ECOL	OGICAL INFORMATIC	N			
	oxicity ata available				
	istence and degradab	lity			
Bioa	ccumulative potential				
<u>Com</u>	ponents:				
	ose: tion coefficient: n- nol/water	: Pow: < 1			
	i lity in soil ata available				
	r adverse effects ata available				
13. DISPO	OSAL CONSIDERATIO	NS			
Disp	osal methods				
-	e from residues		of waste into sewer.		
Conta	aminated packaging	: Empty containe dling site for re	ccordance with local regulations. ers should be taken to an approved waste han- cycling or disposal. e specified: Dispose of as unused product.		

14. TRANSPORT INFORMATION

International Regulations

UNRTDG		
UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
IATA-DGR		
UN/ID No.	:	Not applicable



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Proper shipping name Class Subsidiary risk Packing group Labels Packing instruction (cargo aircraft) Packing instruction (passen- ger aircraft)		 Not applicable 	
IMDG-Code UN number Proper shipping name Class Subsidiary risk Packing group Labels EmS Code Marine pollutant		 Not applicable 	
	sport in bulk according pplicable for product as		POL 73/78 and the IBC Code
Spec	ial precautions for use		
Not a			
5. REGU Safet ture Minis ter of	LATORY INFORMATIC	nental regulations/le tion No. 23/M-IND/P lo. 87/M-IND/PER/9/2	gislation specific for the substance or mix- ER/4/2013 concerning the Revision of Minis- 2009 concerning Globally Harmonized Sys- Is.
5. REGU Safet ture Minis ter of tem c Regu	LATORY INFORMATIC y, health and environn ster of Industry Regula i Industry Regulation N of Classification and La	nental regulations/le tion No. 23/M-IND/P lo. 87/M-IND/PER/9/3 abelling of Chemica	ER/4/2013 concerning the Revision of Minis- 2009 concerning Globally Harmonized Sys-
5. REGU Safet ture Minis ter of tem c Regu Haza	LATORY INFORMATIC by, health and environn ter of Industry Regula i Industry Regulation N of Classification and La ilation of the Minister of	nental regulations/le tion No. 23/M-IND/P lo. 87/M-IND/PER/9/ abelling of Chemica of Health No. 472 of	ER/4/2013 concerning the Revision of Minis- 2009 concerning Globally Harmonized Sys- Is.
5. REGU Safet ture Minis ter of tem c Regu Haza Haza Haza	LATORY INFORMATIC y, health and environn ter of Industry Regulation N of Classification and La lation of the Minister of rdous to Health rdous substances that m	nental regulations/le tion No. 23/M-IND/P lo. 87/M-IND/PER/9/ abelling of Chemica of Health No. 472 of nust be registered	ER/4/2013 concerning the Revision of Minis- 2009 concerning Globally Harmonized Sys- ls. 1996 on the Safeguarding of Substances
5. REGU Safet ture Minis ter of tem o Regu Haza Haza Haza Gove stano	LATORY INFORMATIC y, health and environn ter of Industry Regulation N of Classification and La lation of the Minister of rdous to Health rdous substances that m	nental regulations/le tion No. 23/M-IND/Pl lo. 87/M-IND/PER/9/2 abelling of Chemica of Health No. 472 of nust be registered . 74 of 2001 on the M	ER/4/2013 concerning the Revision of Minis- 2009 concerning Globally Harmonized Sys- ls. 1996 on the Safeguarding of Substances : Not applicable

Restricted substances : Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and : Not applicable control, Annex I





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	Type of hazardous materials subject to distribution and : Not applicable control, Annex II						
	n <mark>e components of this pro</mark> CS	oduo :	ct are reported in not determined	the following inventories:			
DS		:	not determined				
	csc						
16 OT							
			2022/00/20				
	evision Date	•	2023/09/30				
Sc	urther information ources of key data used to ompile the Safety Data neet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen cy, http://echa.europa.eu/				
Da	ate format	:	yyyy/mm/dd				
Fu	Ill text of other abbreviation	ons					
	CGIH OEL	:		eshold Limit Values (TLV) pational Exposure Limits			
	CGIH / TWA OEL / NAB	:	8-hour, time-weighted average Long term exposure limit				

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 Substanc-





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es; (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.

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