

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	530834-00022	Date of first issue: 23.02.2016

# **SECTION 1:** Identification of the substance/mixture and of the company/undertaking

1.1	Product identifier Trade name	:	Pembrolizumab Solid Formulation
1.2	Relevant identified uses of th	e s	ubstance or mixture and uses advised against
	Use of the Sub- stance/Mixture	:	Pharmaceutical
	Recommended restrictions on use	:	Not applicable
1.3	Details of the supplier of the	saf	ety data sheet
	Company	:	MSD Piercetown A86 HD21 Dunboyne, Ireland
	Telephone	:	908-740-4000
	E-mail address of person	:	EHSDATASTEWARD@msd.com

## 1.4 Emergency telephone number

responsible for the SDS

1-908-423-6000

# **SECTION 2: Hazards identification**

## 2.1 Classification of the substance or mixture

#### Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 1B
Specific target organ toxicity - repeated
exposure, Category 1

H360D: May damage the unborn child. H372: Causes damage to organs through prolonged or repeated exposure.

## 2.2 Label elements

# Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms

Signal word	:	Danger
Hazard statements	:	H360D H372

May damage the unborn child. Causes damage to organs through prolonged or



Commission Regulation (EU) 2020/878

# **Pembrolizumab Solid Formulation**

Version 4.3	Revision Date: 28.09.2024	SDS Number: 530834-00022	Date of last issue: 06.04.2024 Date of first issue: 23.02.2016
		re	epeated exposure.
Preca	autionary statements	P260 D P264 W P270 D ud P280 W	btain special instructions before use. o not breathe dust. /ash skin thoroughly after handling. o not eat, drink or smoke when using this prod- ct. /ear protective gloves/ protective clothing/ eye rotection/ face protection.
		Response:	

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

# Hazardous components which must be listed on the label:

Pembrolizumab

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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**

## 3.2 Mixtures

#### Components

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
Pembrolizumab	1374853-91-4	Repr. 1B; H360D	>= 20 - < 30
		STOT RE 1; H372	
		(Immune system)	

For explanation of abbreviations see section 16.



Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	530834-00022	Date of first issue: 23.02.2016

## **SECTION 4: First aid measures**

4.1 Description of first aid meas	ures		
General advice	<ul> <li>In the case of accident or if you feel unwell, seek medical advice immediately.</li> <li>When symptoms persist or in all cases of doubt seek medical advice.</li> </ul>		
Protection of first-aiders	: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).		
If inhaled	: If inhaled, remove to fresh air. Get medical attention.		
In case of skin contact	<ul> <li>In case of contact, immediately flush skin with soap and plenty of water.</li> <li>Remove contaminated clothing and shoes.</li> <li>Get medical attention.</li> <li>Wash clothing before reuse.</li> <li>Thoroughly clean shoes before reuse.</li> </ul>		
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.		
4.2 Most important symptoms a	nd effects, both acute and delayed		
Risks	: May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.		
	Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.		
4.3 Indication of any immediate	medical attention and special treatment needed		
Treatment	: Treat symptomatically and supportively.		
SECTION 5: Firefighting measures			

# 5.1 Extinguishing media

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



Vers 4.3	ion	Revision Date: 28.09.2024		DS Number: 0834-00022	Date of last issue: 06.04.2024 Date of first issue: 23.02.2016
	Unsuita media	able extinguishing	:	None known.	
5.2 S	Special	hazards arising from	the	e substance or mi	xture
Specific hazards during fire- fighting		:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.		
	Hazard ucts	lous combustion prod-	:	Carbon oxides Nitrogen oxides (l	NOx)
5.3 A	dvice	for firefighters			
	Special protective equipment for firefighters		:		e, wear self-contained breathing apparatus. tective equipment.
	Specifi ods	c extinguishing meth-	:	cumstances and t Use water spray t	measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to do

# **SECTION 6: Accidental release measures**

# 6.1 Personal precautions, protective equipment and emergency procedures

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

## 6.2 Environmental precautions

Environmental precautions	: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained
	cannot be contained.

# 6.3 Methods and material for containment and cleaning up

Methods for cleani	ing up :	Sweep up or vacuum up spillage and collect in suitable con- tainer for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfac- es, as these may form an explosive mixture if they are re- leased into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and dis- posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter- mine which regulations are applicable.
		mine which regulations are applicable.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Pembrolizumab Solid Formulation

Version	Revision Date: 28.09.2024	SDS Number:	Date of last issue: 06.04.2024
4.3		530834-00022	Date of first issue: 23.02.2016
			d 15 of this SDS provide information regarding national requirements.

# 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

# **SECTION 7: Handling and storage**

# 7.1 Precautions for safe handling

Technical measures	:	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding
Local/Total ventilation	:	and bonding, or inert atmospheres. 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 as- sessment 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 environment.
Hygiene measures	:	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 contami- nated clothing before re-use.
7.2 Conditions for safe storage, i	ncl	uding any incompatibilities
Requirements for storage areas and containers	:	Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Advice on common storage	:	Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases
7.3 Specific end use(s)		
Specific use(s)	:	No data available



Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	530834-00022	Date of first issue: 23.02.2016

## **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

#### **Occupational Exposure Limits**

dusts non-specific

4 mg/m3 Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable dust) Basis: IE OEL

10 mg/m3 Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable dust) Basis: IE OEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sucrose	57-50-1	OELV - 8 hrs (TWA)	10 mg/m3	IE OEL
		OELV - 15 min (STEL)	20 mg/m3	IE OEL
Pembrolizumab	1374853- 91-4	TWA	450 μg/m3 (OEB 2)	Internal

## Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health ef- fects	Value
Histidine	Workers	Inhalation	Long-term systemic effects	83.38 mg/m3
	Workers	Skin contact	Long-term systemic effects	236.45 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	20.56 mg/m3
	Consumers	Skin contact	Long-term systemic effects	118.2 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	11.8 mg/kg bw/day

## Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Histidine	Fresh water	0.1 mg/l
	Freshwater - intermittent	1 mg/l
	Marine water	0.01 mg/l
	Marine water - intermittent	1 mg/l
	Sewage treatment plant	20.5 mg/l
	Fresh water sediment	0.392 mg/kg dry weight (d.w.)
	Marine sediment	0.039 mg/kg dry weight (d.w.)
	Soil	0.02 mg/kg dry



Version 4.3	Revision Date: 28.09.2024	SDS Number: 530834-00022	Date of last issue: 06.04.2024 Date of first issue: 23.02.2016	
			weight (d.w.)	

### 8.2 Exposure controls

#### Engineering 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 designed 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.

### Personal protective equipment

Eye/face protection	:	Wear the following personal protective equipment: Safety goggles Equipment should conform to I.S. EN 166
Hand protection		Equipment should contonn to 1.0. EN 100
Material	:	Chemical-resistant gloves
Remarks	:	Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous sub- stance and 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.
Skin and body 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. Equipment should conform to I.S. EN 143
Filter type	:	Particulates type (P)

## **SECTION 9: Physical and chemical properties**

## 9.1 Information on basic physical and chemical properties

r
o off-white
a available
a available
a available
a available



Vers 4.3	ion	Revision Date: 28.09.2024		S Number: )834-00022	Date of last issue: 06.04.2024 Date of first issue: 23.02.2016
	range				
	Flamm	ability (solid, gas)	:	May form explos dling or other me	ive dust-air mixture during processing, han- ans.
	Flamm	ability (liquids)	:	No data available	9
		explosion limit / Upper ability limit	:	No data available	
		explosion limit / Lower ability limit	:	No data available	9
	Flash p	point	:	Not applicable	
	Auto-ig	gnition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	рН		:	No data available	9
	Viscos Vise	ity cosity, dynamic	:	No data available	9
	Vis	cosity, kinematic	:	No data available	9
		lity(ies) ter solubility	:	No data available	
		on coefficient: n- I/water	:	No data available	9
	Vapou	r pressure	:	No data available	9
	Relativ	e density	:	No data available	9
	Densit	У	:	No data available	9
	Relativ	ve vapour density	:	No data available	9
		e characteristics ticle size	:	No data available	9
		nformation		Not ovplosivo	
	Explos		•	Not explosive	r minture is not allocatified as suidi-ins
		ng properties	:		r mixture is not classified as oxidizing.
	∟vapo	ration rate	:	No data available	3

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Pembrolizumab Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	530834-00022	Date of first issue: 23.02.2016

Molecular weight

: No data available

# **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

## 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions		May form explosive dust-air mixture during processing, han-
		dling or other means.
		Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid

: Heat, flames and sparks. Avoid dust formation.

#### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

## **10.6 Hazardous decomposition products**

No hazardous decomposition products are known.

# **SECTION 11: Toxicological information**

## 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

## Acute toxicity

Not classified based on available information.

#### 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.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Pembrolizumab Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	530834-00022	Date of first issue: 23.02.2016

## Germ cell mutagenicity

Not classified based on available information.

#### Carcinogenicity

Not classified based on available information.

#### **Reproductive toxicity**

May damage the unborn child.

#### **Components:**

#### Pembrolizumab:

Reproductive toxicity - Assessment

: 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 through prolonged or repeated exposure.

#### **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	: : :	Monkey 200 mg/kg Intravenous 180 d No significant adverse effects were reported
Species NOAEL Application Route Exposure time Remarks		Dog 200 mg/kg Intravenous 180 d No significant adverse effects were reported

#### Aspiration toxicity

Not classified based on available information.

## 11.2 Information on other hazards

### Endocrine disrupting properties

## Product:



Version 4.3	Revision Date: 28.09.2024	SDS Number: 530834-00022	Date of last issue: 06.04.2024 Date of first issue: 23.02.2016
Assessment		ered to have REACH Artic	e/mixture does not contain components consid- endocrine disrupting properties according to le 57(f) or Commission Delegated regulation 00 or Commission Regulation (EU) 2018/605 at 6 or higher.
Expe	rience with human exp	osure	
<u>Com</u>	ponents:		
<b>Pemt</b> Inhala	<b>brolizumab:</b> ation	Symptoms: C tion, joint pair Fever, anemi confusion, He thyroid gland, mune-mediat	s: Immune system ough, Fatigue, Nausea, pruritis, Rash, constipa- n, Diarrhoea, Pneumonia, decrease in appetite, a, neutropenia, musculoskeletal pain, Vomiting, eadache, Shortness of breath, Hypofunction of May cause respiratory arrest., May cause, im- ed pneumonitis, colitis, hepatitis, nephritis mage to fetus possible
SECTION	12: Ecological infor	mation	
<b>12.1 Toxic</b> No da	c <b>ity</b> ata available		
	istence and degradabil ata available	ity	
	ccumulative potential ata available		
	<b>lity in soil</b> ata available		

## 12.5 Results of PBT and vPvB assessment

# Product:

Assessment

: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## **12.6 Endocrine disrupting properties**

### Product:

Assessment	: The substance/mixture does not contain components consid- ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation
	(EU) 2017/2100 or Commission Regulation (EU) 2018/605 at
	levels of 0.1% or higher.



Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	530834-00022	Date of first issue: 23.02.2016

# 12.7 Other adverse effects

No data available

# **SECTION 13:** Disposal considerations

13.1 Waste treatment methods	
Product	<ul> <li>Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.</li> </ul>
Contaminated packaging	<ul> <li>Empty containers should be taken to an approved waste han- dling site for recycling or disposal.</li> <li>If not otherwise specified: Dispose of as unused product.</li> </ul>

# **SECTION 14: Transport information**

## 14.1 UN number or ID number

	ADN	:	Not regulated as a dangerous good
	ADR	:	Not regulated as a dangerous good
	RID	:	Not regulated as a dangerous good
	IMDG	:	Not regulated as a dangerous good
	ΙΑΤΑ	:	Not regulated as a dangerous good
14.	2 UN proper shipping name		
	ADN	:	Not regulated as a dangerous good
	ADR	:	Not regulated as a dangerous good
	RID	:	Not regulated as a dangerous good
	IMDG	:	Not regulated as a dangerous good
	ΙΑΤΑ	:	Not regulated as a dangerous good
14.3	3 Transport hazard class(es)		
	ADN	:	Not regulated as a dangerous good
	ADR	:	Not regulated as a dangerous good
	RID	:	Not regulated as a dangerous good
	IMDG	:	Not regulated as a dangerous good
	ΙΑΤΑ	:	Not regulated as a dangerous good
14.	4 Packing group		
	ADN	:	Not regulated as a dangerous good
	ADR	:	Not regulated as a dangerous good
	RID	:	Not regulated as a dangerous good



Version 4.3	Revision Date: 28.09.2024	SDS Number: 530834-00022	Date of last issue: 06.04.2024 Date of first issue: 23.02.2016			
4.5	20.09.2024	550054-00022				
IMDG		: Not regulated as	a dangerous good			
IATA (Cargo)		: Not regulated as a dangerous good				
IATA (Passenger)		: Not regulated as a dangerous good				
14.5 Environmental hazards						
Not regulated as a dangerous good						
-	al precautions for us	er				
4 4 7 84						

# 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

# **SECTION 15: Regulatory information**

#### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	:	Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
Regulation (EC) on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollu- tants (recast)	:	Not applicable
Regulation (EU) No 649/2012 of the European Parlia- ment and the Council concerning the export and import of dangerous chemicals	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Seveso III: Directive 2012/18/EU of the European Parliar	nent	and of the Council

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

#### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

#### The components of this product are reported in the following inventories:

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

Commission Regulation (EU) 2020/878



# Pembrolizumab Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	530834-00022	Date of first issue: 23.02.2016

#### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other informatio	n	
Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
Full text of H-Statements		
H360D	:	May damage the unborn child.
H372	:	Causes damage to organs through prolonged or repeated exposure if swallowed.
Full text of other abbreviation	ns	
Repr.	:	Reproductive toxicity
STOT RE	:	Specific target organ toxicity - repeated exposure
IE OEL	:	Ireland. List of Chemical Agents and Carcinogens with Occu- pational Exposure Limit Values - Code of Practice, Schedule 1 and 2
IE OEL / OELV - 8 hrs (TWA)	:	Occupational exposure limit value (8-hour reference period)
IE OEL / OELV - 15 min (STEL)	:	Occupational exposure limit value (15-minute reference peri- od)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road: AIIC - Australian Inventory of Industrial Chemicals: ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet;



Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	530834-00022	Date of first issue: 23.02.2016

SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

#### **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/

Classification of the mixture:		Classification procedure:
Repr. 1B	H360D	Calculation method
STOT RE 1	H372	Calculation method

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.

IE / EN