According to REACH etc. (Amendment etc.) (EU Exit) Regulations 2019



MEtherm 56 No Change Service!

Version	Revision Date:	Date of last issue: 12.12.2022
02.05	04.01.2023	

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

1.1 Prod	luct identifier		
	de name que Formula Identifier I)	:	MEtherm 56 9P50-K0CS-X00H-G39C
1.2 Rele	vant identified uses of the	e si	ubstance or mixture and uses advised against
	e of the Sub- nce/Mixture	:	Decalcification agent
Rec on u	commended restrictions use	:	Restricted to professional users.
1.3 Deta	ils of the supplier of the s	safe	ety data sheet
	plier	:	MELAG Medizintechnik GmbH & Co. KG Geneststraße 6-10
			10829 Berlin Germany Telephone: +4930-7579110 Telefax: +4930-75791199 MEtherm-OEM@melag.de www.melag.com
Pro	ducer	:	Schülke & Mayr GmbH Robert-Koch-Str. 2
			22851 Norderstedt Germany Telephone: +49 (0)40/ 52100-0 Telefax: +49 (0)40/ 52100318 mail@schuelke.com www.schuelke.com
resp	nail address of person ponsible for the S/Contact person	:	ChemicalCompliance@schuelke.com
1.4 Eme	rgency telephone numbe	r	
Em ber	ergency telephone num-	:	Carechem 24 International:+44 1235 239670

According to REACH etc. (Amendment etc.) (EU Exit) Regulations 2019



MEtherm 56 No Change Service!

Version	Revision Date:	
02.05	04.01.2023	

Date of last issue: 12.12.2022

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019)

Corrosive to metals, Category 1	H290: May be corrosive to metals.
Skin corrosion, Sub-category 1B	H314: Causes severe skin burns and eye damage.
Serious eye damage, Category 1	H318: Causes serious eye damage.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019)

Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H290 May be corrosive to metals.H314 Causes severe skin burns and eye damage.
Precautionary statements	:	 Prevention: P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection. Response: P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
		Disposal: P501 Dispose of contents/ container to an approved waste disposal plant.

Hazardous components which must be listed on the label: phosphoric acid

According to REACH etc. (Amendment etc.) (EU Exit) Regulations 2019



MEtherm 56 No Change Service!

Version	Revision Date:	Date of last issue: 12.12.2022
02.05	04.01.2023	

2.3 Other hazards

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

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature

: Solution of the following substances with harmless additives.

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
phosphoric acid	7664-38-2 231-633-2 015-011-00-6 01-2119485924-24- XXXX	Met. Corr. 1; H290 Skin Corr. 1B; H314 Eye Dam. 1; H318 	>= 50 - < 70

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice	:	Take off all contaminated clothing immediately.
If inhaled	:	If symptoms persist, call a physician.
In case of skin contact	:	Wash off immediately with plenty of water for at least 15 minutes. Consult a physician.
In case of eye contact	:	In case of eye contact, remove contact lens and rinse imme- diately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical attention.
If swallowed	:	Rinse mouth with water.
Z11464_01 ZSDB_P_GB EN		Page 3/15

According to REACH etc. (Amendment etc.) (EU Exit) Regulations 2019



	<i>No Change</i> Revision Date: 04.01.2023	Se	Date of last issue: 12.12.2022
			Give small amounts of water to drink. Consult a physician if necessary.
4.2 Most importan	it symptoms an	d e	ffects, both acute and delayed
Symptoms		:	corrosive effects
Risks		:	Causes serious eye damage. Causes severe burns.
4.3 Indication of a	ny immediate n	nec	lical attention and special treatment needed
Treatment		:	For specialist advice physicians should contact the Poisons Information Service.
SECTION 5: Fire	fighting meas	ur	es
5.1 Extinguishing	media		
Suitable exting	guishing media	:	Dry powder Foam Water spray jet Carbon dioxide (CO2)
Unsuitable ext media	inguishing	:	Do NOT use water jet.
5.2 Special hazard	Is arising from	the	e substance or mixture
Specific hazar fighting	ds during fire-	:	Gives off hydrogen by reaction with metals.
Hazardous col ucts	mbustion prod-	:	No hazardous combustion products are known
5.3 Advice for fire	fighters		
Special protec for firefighters	tive equipment	:	In the event of fire, wear self-contained breathing apparatus.
Further inform	ation	:	Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
SECTION 6: Acc	idental releas	e n	neasures

6.1 Personal precautions, protective equipment and emergency procedures			
Personal precautions	:	Use personal protective equipment. Avoid contact with skin and eyes.	
6.2 Environmental precautions Environmental precautions	:	Avoid subsoil penetration. Do not flush into surface water or sanitary sewer system.	

According to REACH etc. (Amendment etc.) (EU Exit) Regulations 2019



MEtherm 56 No Change Service!

Version	Revision Date:	Date of last issue: 12.12.2022
02.05	04.01.2023	

6.3 Methods and material for containment and cleaning up

: Wipe up with absorbent material (e.g. cloth, fleece). Methods for cleaning up Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).

6.4 Reference to other sections

see Section 8 + 13

SECTION 7: Handling and storage

Advice on safe handling	:	Wear personal protective equipment. Avoid contact with skin, eyes and clothing.
Advice on protection against fire and explosion	:	The product is not flammable. Gives off hydrogen by reaction with metals.
Hygiene measures	:	Keep away from food and drink.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	:	Store at room temperature in the original container.
Further information on stor- age conditions	:	Keep container tightly closed. Keep away from heat. Recom- mended storage temperature: 5 - 25°C
Advice on common storage	:	Do not store together with alkalis.
3 Specific end use(s)		

7.3

Specific use(s) : none

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
phosphoric acid	7664-38-2	TWA	1 mg/m3	GB EH40
		STEL	2 mg/m3	GB EH40
		TWA	1 mg/m3	2000/39/EC
	Further information: Indicative			
	STEL 2 mg/m3 2000/39			
	Further inform	Further information: Indicative		

Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health ef- fects	Value
phosphoric acid	Workers	Inhalation	Long-term local ef-	2 mg/m3

According to REACH etc. (Amendment etc.) (EU Exit) Regulations 2019



MEtherm 56 No Change Service!

Version	
02.05	

Revision Date: 04.01.2023 Date of last issue: 12.12.2022

			fects	
	Workers	Inhalation	Long-term local ef- fects	1 mg/m3
	Workers	Inhalation	Long-term systemic effects	10.7 mg/m3

8.2 Exposure controls

Engineering measures

Ensure that eyewash stations and safety showers are close to the workstation location.

Personal protective equipment					
Eye/face protection :	Face-shield				
Hand protection Directive :	The selected protective gloves have to satisfy the specifica- tions of Regulation (EU) 2016/425 and the standard EN 374 derived from it.				
Remarks :	Splash protection: disposable nitrile rubber gloves e.g. Dermatril (layer thickness: 0.11 mm) made by KCL or gloves from other manufacturers offering the same protection. Pro- longed contact: Nitrile rubber gloves e.g. Camatril (>480 Min., layer thickness: 0,40 mm) or butyl rubber gloves e.g. Butoject (>480 Min., layer thickness: 0,70 mm) made by KCL or gloves from other manufacturers offering the same protec- tion.				
Skin and body protection :	Work uniform or laboratory coat. Chemical resistant apron				
Respiratory protection :	No personal respiratory protective equipment normally re- quired.				
Protective measures :	Avoid contact with skin and eyes.				

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	:	liquid
Colour	:	colourless
Odour	:	nearly odourless
Odour Threshold	:	not determined
рН	:	1.2 (20 °C) Concentration: 100 %
Melting point/freezing point	:	< -5 °C
Decomposition temperature		No data available

According to REACH etc. (Amendment etc.) (EU Exit) Regulations 2019



MEtherm 56 No Change Service!

Version 02.05	Revision Date: 04.01.2023	se	Date of last issue: 12.12.2022
Boiling po	int/boiling range	:	ca. 100 °C
Flash poir	nt	:	Not applicable
Evaporati	on rate	:	No data available
Upper exp flammabil	olosion limit / Upper ity limit	:	Not applicable
Lower exp flammabil	olosion limit / Lower ity limit	:	Not applicable
Vapour pr	ressure	:	ca. 25 hPa (20 °C)
Relative v	apour density	:	No data available
Density		:	ca. 1.43 g/cm3 (20 °C)
Solubility(Water	(ies) solubility	:	completely soluble (20 °C)
Partition c	coefficient: n- ater	:	Not applicable
Viscosity Viscos	ity, dynamic	:	No data available
Explosive	properties	:	No data available
Oxidizing	properties	:	The substance or mixture is not classified as oxidizing.
9.2 Other info	rmation		
Flammabi	ility (liquids)	:	Does not sustain combustion.
Metal con	rosion rate	:	> 6.25 mm/a Corrosive to metals Aluminium and Mild steel
Self-ignitio	on	:	No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

The product is chemically stable.

10.3 Possibility of hazardous reactions

Hazardous reactions : Reaction with alkalis(caustic liquors).

10.4 Conditions to avoid

According to REACH etc. (Amendment etc.) (EU Exit) Regulations 2019



ersion Revision Date: 2.05 04.01.2023	Date of last issue: 12.12.2022
Conditions to avoid	: Protect from frost, heat and sunlight.
0.5 Incompatible materials	
Materials to avoid	: Incompatible with strong bases and oxidizing agents.
0.6 Hazardous decomposition p None reasonably foreseeable	
ECTION 11: Toxicological in	
1.1 Information on toxicologica	leffects
Acute toxicity	
Not classified based on availa	ble information.
Components:	
phosphoric acid:	
Acute oral toxicity	: LD50: 2,600 mg/kg Method: Expert judgement
Acute dermal toxicity	: LD50 (Rabbit): 2,740 mg/kg
Skin corrosion/irritation Causes severe burns.	
Components:	
phosphoric acid:	
Species	: Rabbit
Method Result	OECD Test Guideline 404Corrosive after 3 minutes to 1 hour of exposure
Serious eye damage/eye irri	tation
Causes serious eye damage.	
Components:	
phosphoric acid:	
Species	: Rabbit
Result	: Irreversible effects on the eye
Respiratory or skin sensitis	ation
Skin sensitisation Not classified based on availa	hle information
Respiratory sensitisation Not classified based on availa	ble information.
Components:	
phosphoric acid:	

phosphoric acid:

According to REACH etc. (Amendment etc.) (EU Exit) Regulations 2019



MEtherm 56 No Change Service!

.05 04.01.2023 Result : Does not cause skin sensitisation. Remarks : largely based on human evidence Gern cell mutagenicity Not classified based on available information. Components: phosphoric acid: Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test) Test system: Salmonella typhimurium Metabolic activation: with and without metabolic activation Method: OECD Test Guideline 471 Result: negative Germ cell mutagenicity- As- : Germ cell mutagenicity As- : Not classified based on available information. Components: phosphoric acid: : In vitro tests did not show mutagenic effects sessment : No data available Carcinogenicity Assess- : No data available ment : No data available Reproductive toxicity No data available : Not classified based on available information. : Components: phosphoric acid: : : : Carcinogenicity - Assess- : No data available ment : <t< th=""><th>Etherm 5</th><th>0</th><th>e Se</th><th></th></t<>	Etherm 5	0	e Se	
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		oetal develop-	:	Application Route: Oral General Toxicity Maternal: NOAEL: >= 410 mg/kg bw/day Developmental Toxicity: NOAEL F1: >= 410 mg/kg bw/day Method: OECD Test Guideline 414
	•	ve toxicity - As-	:	Animal testing did not show any effects on fertility.

STOT - single exposure

Not classified based on available information.

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2



MEtherm 56 No Change Service!

Version	Revision Date:	Date of last issue: 12.12.2022
02.05	04.01.2023	

Components:

phosphoric acid:

Assessment

The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT - repeated exposure

Not classified based on available information.

Components:

phosphoric acid:

Assessment

The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Repeated dose toxicity

Components:

phosphoric acid:

Species	: Rat
NOAEL	: 250 mg/kg
Application Route	: Oral
Exposure time	: 90-day
Method	: OECD Test Guideline 422

Aspiration toxicity

Not classified based on available information.

Further information

Product:

Remarks

: No data is available on the product itself.

SECTION 12: Ecological information

12.1 Toxicity

<u>Components:</u>		
phosphoric acid:		
Toxicity to fish	:	LC50 (Lepomis macrochirus (Bluegill sunfish)): 3 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	(Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Test Type: static test Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201

According to REACH etc. (Amendment etc.) (EU Exit) Regulations 2019



/ersion	No Change S Revision Date:	Date of last issue: 12.12.2022
)2.05	04.01.2023	
Ecotoxicolo	gy Assessment	
Chronic aqua	atic toxicity :	This product has no known ecotoxicological effects.
2.2 Persistence	and degradability	
<u>Components</u>	<u>s:</u>	
phosphoric	acid:	
Biodegradab	ility :	Remarks: The methods for determining biodegradability are not applicable to inorganic substances.
2.3 Bioaccumul	ative potential	
<u>Component</u> :	<u>s:</u>	
phosphoric	acid:	
Bioaccumula	tion :	Remarks: Not relevant
2.4 Mobility in s	soil	
Components	<u>s:</u>	
phosphoric	acid:	
Mobility	:	Medium: Water Remarks: soluble
2.5 Results of F	PBT and vPvB ass	essment
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.
2.6 Other adver	se effects	
Product:		
Endocrine dia tial	srupting poten- :	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 a levels of 0.1% or higher.
Additional ec mation	ological infor- :	No data is available on the product itself.

According to REACH etc. (Amendment etc.) (EU Exit) Regulations 2019



MEtherm 56 No Change Service!

Version	Revision Date:
02.05	04.01.2023

Date of last issue: 12.12.2022

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	:	Disposal together with normal waste is not allowed. Special disposal required according to local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste han- dling site for recycling or disposal.

SECTION 14: Transport information

14.1 UN number

ADR	:	UN 1805
IMDG	:	UN 1805
ΙΑΤΑ	:	UN 1805
14.2 UN proper shipping name		
ADR	:	PHOSPHORIC ACID SOLUTION
IMDG	:	PHOSPHORIC ACID SOLUTION
ΙΑΤΑ	:	Phosphoric acid, solution
14.3 Transport hazard class(es)		
ADR	:	8
IMDG	:	8
ΙΑΤΑ	:	8
14.4 Packing group		
ADR Packing group Classification Code Hazard Identification Number Labels Tunnel restriction code	: : : :	III C1 80 8 (E)
IMDG Packing group Labels EmS Code	: :	III 8 F-A, S-B
IATA (Cargo) Packing instruction (cargo aircraft)	:	856
Packing instruction (LQ) Packing group Labels	:	Y841 III Corrosive
IATA (Passenger) Packing instruction (passen- ger aircraft)	:	852
Z11464_01 ZSDB_P_GB EN		Page 12/15

According to REACH etc. (Amendment etc.) (EU Exit) Regulations 2019



MEtherm 56 No Change Service!

Version 02.05	Revision Date: 04.01.2023	Date of last issue: 12.12.2022

Packing instruction (LQ)	: Y841
Packing group	: 111
Labels	: Corrosive

14.5 Environmental hazards

ADR Environmentally hazardous	:	no
IMDG Marine pollutant	:	no

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation Not applicable The Persistent Organic Pollutants Regulations (retained regulation (EU) 2019/1021 as amended for Great Britain) Not applicable Regulation (EC) No 1005/2009 on substances that deplete the ozone layer Not applicable UK REACH List of substances subject to authorisation (Annex XIV) Not applicable Volatile organic compounds Enerctive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) Not applicable Other regulations:
Regulation (EU) 2019/1021 as amended for Great Britain) Regulation (EC) No 1005/2009 on substances that de- Plete the ozone layer UK REACH List of substances subject to authorisation : Not applicable (Annex XIV) Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) Not applicable
plete the ozone layer UK REACH List of substances subject to authorisation : Not applicable (Annex XIV) Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) Not applicable
 (Annex XIV) Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) Not applicable
emissions (integrated pollution prevention and control) Not applicable
Other regulations:
The components of this product are reported in the following inventories:
TCSI : On the inventory, or in compliance with the inventory
TSCA : All substances listed as active on the TSCA inventory
AIIC : On the inventory, or in compliance with the inventory

According to REACH etc. (Amendment etc.) (EU Exit) Regulations 2019



MEtherm 56 No Change Service! Revision Date: Version Date of last issue: 12.12.2022 02.05 04.01.2023 All components of this product are on the Canadian DSL DSL 1 ENCS : On the inventory, or in compliance with the inventory **ISHL** : On the inventory, or in compliance with the inventory KECI On the inventory, or in compliance with the inventory : PICCS On the inventory, or in compliance with the inventory : **IECSC** On the inventory, or in compliance with the inventory : NZIoC Not in compliance with the inventory : TECI On the inventory, or in compliance with the inventory

15.2 Chemical safety assessment

Exempt

SECTION 16: Other information

Full text of H-Statements		
H290	:	May be corrosive to metals.
H314	:	Causes severe skin burns and eye damage.
H318	:	Causes serious eye damage.
Full text of other abbreviation	ns	
Eye Dam.	:	Serious eye damage
Met. Corr.	:	Corrosive to metals
Skin Corr.	:	Skin corrosion
2000/39/EC	:	Europe. Commission Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values
GB EH40	:	UK. EH40 WEL - Workplace Exposure Limits
2000/39/EC / TWA	:	Limit Value - eight hours
2000/39/EC / STEL	:	Short term exposure limit
GB EH40 / TWA	:	Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL	:	Short-term exposure limit (15-minute reference period)

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

According to REACH etc. (Amendment etc.) (EU Exit) Regulations 2019



MEtherm 56 No Change Service!

Version	Revision Date:	Date of last issue: 12.12.2022
02.05	04.01.2023	

- 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; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

Further information

Classification of the mixture:		Classification procedure:
Met. Corr. 1	H290	Based on product data or assessment
Skin Corr. 1B	H314	Calculation method
Eye Dam. 1	H318	Calculation method

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.