

SAFETY DATA SHEET

Pharmakaolin B 860

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	01/23/2023	100000000310	Date of first issue: 23.01.2023

SECTION 1. IDENTIFICATION

Product name : Pharmakaolin B 860

Manufacturer or supplier's details

Company name of supplier : Quarzwerke GmbH

Address : Kaskadenweg 40
Frechen 50226
Germany

Telephone : +4922341010

Emergency telephone : 911

Emergency telephone : 24-HOUR-EMERGENCY-NUMBER (INFOTRAC-CUSTOMER ID: 99125)
FROM INSIDE US/CANADA (TOLL FREE) 1 800 535 5053
FROM OUTSIDE (INTERNATIONAL)(001) 352 323 3500

Available outside office hours? : yes

Recommended use of the chemical and restrictions on use

Recommended use : Main applications - non-exhaustive list: Ceramics (sanitary-ware, floor tiles, wall tiles, roof tiles, tiles; porcelain, tableware, refractories, etc.), Paper and board, Fibreglass, Paint, Plastic & Rubber, Adhesives and Sealant, Building material & Cement, Animal nutrition, Fertilisers & Agricultural products, Cosmetics & Pharmaceuticals

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards

This product contains >0.1% crystalline silica which in the form of quartz or cristobalite dust is regarded by IARC as carcinogenic to humans (Group 1).

HazCom classification of the bulk product as "Specific Target Organ Toxicant- RE Category 1" is warranted at >1% respirable crystalline silica (quartz or cristobalite), based on the primary effect in humans of the inhalation of respirable crystalline silica dust, silicosis.

Long term exposure can cause lung injury (silicosis). IARC and NTP have determined that crystalline silica inhaled from occupational sources can cause cancer in humans. Risk of injury is dependent on the duration and level of exposure.

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SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Components

Chemical name	CAS-No.	Concentration (% w/w)
kaolin	1332-58-7	$\geq 90 - \leq 100$
Quartz fine fraction (SiO ₂)	14808-60-7	$\geq 0.1 - < 1$

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

- General advice : Do not leave the victim unattended.
- If inhaled : If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.
- In case of eye contact : Remove contact lenses.
Protect unharmed eye.
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
- Most important symptoms and effects, both acute and delayed : None known.
- Notes to physician : Treat symptomatically.

SECTION 5. FIRE-FIGHTING MEASURES

- Hazardous combustion products : No hazardous combustion products are known
- Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Avoid dust formation.
- Environmental precautions : No special environmental precautions required.

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Methods and materials for containment and cleaning up : Pick up and arrange disposal without creating dust.
Sweep up and shovel.
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling : Do not breathe dust. Do not rely on your sight to determine if dust is in the air. Silica may be in the air without a visible dust cloud. Use normal precautions against bag breakage or spills of bulk material. Avoid creation of respirable dust. Avoid creating dust when handling, using or storing. Use only with adequate ventilation or with adequate respirator to keep exposure below recommended exposure limits. Do not use as a dry abrasive blasting agent. ANSI/AIHA Z9.4:1997 recommends that silica sand be prohibited as an abrasive blasting agent for use in fixed location abrasive-blast enclosures. Use good housekeeping in storage and use areas to prevent accumulation of dust in work area.

To reduce the risk of developing silicosis, lung cancer and other adverse health effects, the ACGIH recommends that the industrial hygienist use every means available to keep exposures below the recommended TLV. NIOSH recommends reducing airborne exposure levels as low as possible below NIOSH's recommended exposure limit, substituting less hazardous materials when feasible, using appropriate respiratory protection when source controls cannot keep exposures below the recommended limit and making medical examinations available to exposed workers. Use adequate ventilation and dust collection. To minimize exposure, wear a respirator approved for silica dust when using, handling, storing or disposing of this product or bag. Refer to the most recent government and local regulations when selecting a respirator. Maintain, clean and fit test respirators in accordance with OSHA regulations. Maintain and test ventilation and dust collection equipment. Launder clothing that has become dusty. Empty containers (bags, bulk containers, storage tanks, etc.) retain silica residue and must be handled in accordance with the provisions of this Material Safety Data Sheet.

WARN and TRAIN employees in accordance with state and federal regulations. WARN YOUR EMPLOYEES (AND YOUR CUSTOMERS AND USERS IN CASE OF RESALE) BY POSTING, AND OTHER MEANS, OF THE HAZARDS AND OSHA AND ANY OTHER APPLICABLE REGULATORY PRECAUTIONS TO BE USED. PROVIDE TRAINING FOR YOUR EMPLOYEES ABOUT OSHA PRECAUTIONS.

See also American Society for Testing and Materials (ASTM)

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Standard Practice E1132-99a, "Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica".

Additional information on silica hazards and precautionary measures can be found at the following websites:
NIOSH Joint Campaign on Silicosis Prevention - <http://www.cdc.gov/niosh/topics/silica/default.html>
IOSHA Crystalline Silica Website - <https://www.osha.gov/dsg/topics/silicacrystalline/index.html>
MSHA Silicosis Prevention Website - <http://www.msha.gov/S&HINFO/SILICO/Silico.HTM>
NIOSH Hazard Review - Health Effects of Occupational Exposure to Respirable Crystalline Silica Website - <http://www.cdc.gov/niosh/docs/2002-129/>

For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.

- Conditions for safe storage : Electrical installations / working materials must comply with the technological safety standards.
- Materials to avoid : No materials to be especially mentioned.
- Further information on storage stability : Keep in a dry place.
No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
kaolin	1332-58-7	TWA (Respirable particulate matter)	2 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	10 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0
Quartz fine fraction (SiO ₂)	14808-60-7	TWA (Respirable dust)	0.05 mg/m ³	OSHA Z-1

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		TWA (respirable)	10 mg/m3 / %SiO ₂ +2	OSHA Z-3
		TWA (respirable)	250 mppcf / %SiO ₂ +5	OSHA Z-3
		TWA (respirable dust fraction)	0.1 mg/m3	OSHA P0
		TWA (Respirable particulate matter)	0.025 mg/m3 (Silica)	ACGIH
		PEL (respirable)	0.05 mg/m3	OSHA CARC
		TWA (Respirable dust)	0.05 mg/m3 (Silica)	NIOSH REL

Engineering measures : Dust formation may be relevant in the processing of this product. In addition to substance-specific OELs, general limitations of concentrations of particulates in the air at workplaces have to be considered in workplace risk assessment. Relevant limits include: OSHA PEL for Particulates Not Otherwise Regulated of 15 mg/m3 - total dust, 5 mg/m3 - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m3 - respirable particles, 10 mg/m3 - inhalable particles.

Personal protective equipment

Respiratory protection : Equipment should conform to EN 143
Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines.

Eye protection : Safety glasses

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Hygiene measures : General industrial hygiene practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : solid, powder

Color : white

Odor : odorless

Odor Threshold : Not applicable

pH : 5 - 8

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Melting point/freezing point	: > 3,092 °F / > 1,700 °C
Flash point	: Not applicable
Flammability (solid, gas)	: The product is not flammable.
Vapor pressure	: Not applicable
Density	: 2.5 - 2.7 g/cm3
Solubility(ies) Water solubility	: negligible

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: No decomposition if stored and applied as directed.
Chemical stability	: No decomposition if stored and applied as directed.
Possibility of hazardous reactions	: Stable under recommended storage conditions.
Conditions to avoid	: Not applicable
Incompatible materials	: Incompatible with strong acids and oxidizing agents.
Hazardous decomposition products	: Silica will dissolve in hydrofluoric acid producing a corrosive gas, silicon tetrafluoride.

SECTION 11. TOXICOLOGICAL INFORMATION

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 sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

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Components:

Quartz fine fraction (SiO₂):

Carcinogenicity - Assessment : The International Agency for Research on Cancer has determined that crystalline silica inhaled in the form of quartz or cristobalite from occupational sources is carcinogenic to humans (Group 1 - carcinogenic to humans). Refer to IARC Monograph 100C, A Review of Human Carcinogens: Arsenic, Fibres and Dusts (published in 2011) in conjunction with the use of these materials. The National Toxicology Program classifies respirable crystalline silica as "known to be a human carcinogen". Refer to the Twelfth Report on Carcinogens (2011). The American Conference of Governmental Industrial Hygienists (ACGIH) classifies crystalline silica, quartz, as a suspected human carcinogen (A2).

IARC	Group 1: Carcinogenic to humans Quartz fine fraction (SiO ₂) (Silica dust, crystalline)	14808-60-7
OSHA	OSHA specifically regulated carcinogen Quartz fine fraction (SiO ₂) (crystalline silica)	14808-60-7
NTP	Known to be human carcinogen Quartz fine fraction (SiO ₂) (Silica, Crystalline (Respirable Size))	14808-60-7

Reproductive toxicity

Not classified based on available information.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Components:

Quartz fine fraction (SiO₂):

Routes of exposure	: Inhalation
Target Organs	: Lungs
Assessment	: Causes damage to organs through prolonged or repeated exposure.
Remarks	: Silicosis: Excessive inhalation of respirable crystalline silica dust may cause a progressive, disabling and sometimes fatal lung disease called silicosis. Symptoms include cough, shortness of breath, wheezing, non-specific chest illness and reduced pulmonary function. This disease is exacerbated by smoking. Individuals with silicosis are predisposed to develop mycobacterial infections (tuberculous and non-tuberculous) and fungal infections. Inhalation of air with a very high concentration of respirable silica dust can cause the most serious

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forms of silicosis in a matter of months or a few years. Some epidemiologic studies have concluded that there is significant risk of developing silicosis even at airborne exposure levels that are equal to the recommended NIOSH REL, the ACGIH TLV.

Other Data with Possible Relevance to Human Health: There is some evidence that breathing respirable crystalline silica or the disease silicosis is associated with an increased incidence of significant disease endpoints such as scleroderma (an immune system disorder manifested by fibrosis of the lungs, skin and other internal organs) rheumatoid arthritis, systemic lupus, erythematosus, sarcoidosis, chronic bronchitis, chronic obstructive pulmonary disease (COPD), emphysema, chronic kidney disease and end-stage renal disease.

Aspiration toxicity

Not classified based on available information.

Further information

Product:

Remarks

: Medical Conditions Aggravated by Exposure: Individuals with respiratory disease, including but not limited to asthma and bronchitis, or subject to eye irritation, should not be exposed to respirable silica dust. Signs and Symptoms of Exposure: Exposure to dust may cause mucous membrane and respiratory irritation, cough, sore throat, nasal congestion, sneezing and shortness of breath. However, there may be no immediate signs or symptoms of exposure to hazardous concentrations of respirable crystalline silica. See "Inhalation" subsection above for symptoms of silicosis. The absence of symptoms is not necessarily indicative of safe conditions. For further information consult: "Adverse Effects of Crystalline Silica Exposure" published by the American Thoracic Society Medical Section of the American Lung Association, American Journal of Respiratory and Critical Care Medicine, Volume 155, pages 761-768, 1997 NIOSH Hazard Review - Health Effects of Occupational Exposure to Respirable Crystalline Silica, April 2002 (see Section 7 for NIOSH Hazard Review Website). "A Review of Human Carcinogens: Arsenic, Fibres and Dusts." IARC monograph, Volume 100C, 2011

Remarks

: No data available

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SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Quartz fine fraction (SiO₂):

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances

Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

Domestic regulation

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

kaolin	1332-58-7
Quartz fine fraction (SiO ₂)	14808-60-7

Pennsylvania Right To Know

kaolin	1332-58-7
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Maine Chemicals of High Concern

Quartz fine fraction (SiO ₂)	14808-60-7
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Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Prop. 65

WARNING: This product can expose you to chemicals including Quartz fine fraction (SiO₂), which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California Regulated Carcinogens

Quartz fine fraction (SiO₂)

14808-60-7

The ingredients 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
DSL	: All components of this product are on the Canadian DSL
ENCS	: On the inventory, or in compliance with the inventory
ISHL	: Not 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	: On the inventory, or in compliance with the inventory
EINECS / CH	: The mixture contains substances listed on the Swiss Inventory, On the inventory, or in compliance with the inventory
REACH	: On the inventory, or in compliance with the inventory
TECI	: On the inventory, or in compliance with the inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

Further information

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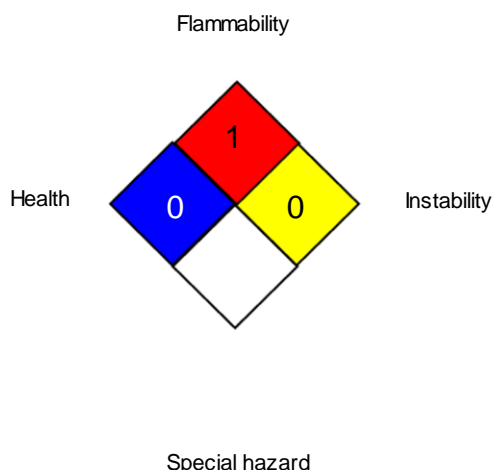
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NFPA 704:



HMIS® IV:

HEALTH	/	0
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	: USA. NIOSH Recommended Exposure Limits
OSHA CARC	: OSHA Specifically Regulated Chemicals/Carcinogens
OSHA P0	: USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
OSHA Z-1	: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
OSHA Z-3	: USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA	: 8-hour, time-weighted average
NIOSH REL / TWA	: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA CARC / PEL	: Permissible exposure limit (PEL)
OSHA P0 / TWA	: 8-hour time weighted average
OSHA Z-1 / TWA	: 8-hour time weighted average
OSHA Z-3 / TWA	: 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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

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50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECL - 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

Revision Date : 01/23/2023

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.

US / Z8