SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 as amended by Regulation (EU) No. 2020/878, and
Regulation (EC) No. 1272/2008

Issuing Date 10-Jan-2025 **Revision Date** 10-Jan-2025 **Revision Number** 1

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

1.1. Product identifier

Product Code 67-43-6

Product Name Pentetic acid

Other means of identification

A registration number is not available for this substance as the substance or its use are exempted from registration according to Article 2 REACH Regulation (EC) No 1907/2006, the annual tonnage does not require a registration, or the registration is envisaged for a later registration deadline.

EC No (EU Index No) 200-652-8

CAS Number 67-43-6

Synonyms Diethylene triamine pentaacetic acid, (Carboxymethylimino)bis(ethylenenitrilo)tetraacetic acid, N,N-Bis(2-[bis(carboxymethyl)amino]ethyl) glycine, Penta(carboxymethyl)diethylenetriamine, DTPA

Pure substance/mixture Substance

Contains Pentetic acid

Formula C14H23N3O10

Molecular Weight 393.35 g/mol

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Laboratory chemicals, Manufacture of substances, used as pharma excipients

Uses advised against Do not use where contact with food or drinking water is possible

1.3. Details of the supplier of the safety data sheet

Manufacturer
Aceto Pharma (India) Private Limited 184-186/P, Vill: Chacharwadi Vasna, Sarkhej-Bavla Highway, Tal-Sanand, Dist-Ahmedabad-382110, Gujarat, India. Web: www.actylislab.com E-Mail Address: safety.amd@actylis.com; qa.amd@actylis.com

1.4. Emergency telephone number

Emergency telephone India: 02717 616 717

Emergency telephone - §45 - (EC)1272/2008	
Europe	**112**

SECTION 2: Hazards identification

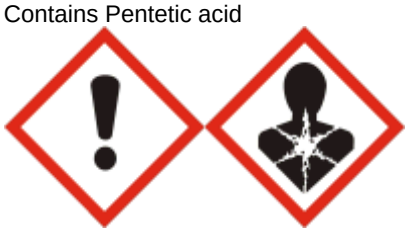
2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity - Inhalation (Dusts/Mists)	Category 4 - (H332)
Serious eye damage/eye irritation	Category 2 - (H319)
Reproductive toxicity	Category 1B - (H360)
Specific target organ toxicity (repeated exposure)	Category 2 - (H373)

2.2. Label elements

Contains Pentetic acid



Signal word
Danger

Hazard statements
H319 - Causes serious eye irritation.
H332 - Harmful if inhaled.
H360 - May damage fertility or the unborn child.
H373 - May cause damage to organs through prolonged or repeated exposure.

Precautionary Statements - EU (§28, 1272/2008)
P201 - Obtain special instructions before use.
P260 - Do not breathe dust/fume/gas/mist/vapors/spray.
P271 - Use only outdoors or in a well-ventilated area.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P312 - Call a POISON CENTER or doctor if you feel unwell.
P501 - Dispose of contents/ container to an approved waste disposal plant.
P202 - Do not handle until all safety precautions have been read and understood.
P264 - Wash face, hands and any exposed skin thoroughly after handling.
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

100 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.
100 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).
100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor).
0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.

2.3. Other hazards

No information available.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

Chemical name	EU - REACH (1907/2006) - Article 59(1) - Candidate List of Substances of Very High Concern (SVHC) for Authorisation	EU - REACH (1907/2006) - Endocrine Disruptor Assessment List of Substances
Pentetic acid	-	-

Chemical name	Endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100(3) or Commission Regulation (EU) 2018/605(4)
Pentetic acid	-

SECTION 3: Composition/information on ingredients

3.1 Substances

The product contains no substances which at their given concentration, are considered to be hazardous to health

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Pentetic acid 67-43-6	98.0% - 100.5%	No data available	200-652-8	Acute Tox. 4; Eye Irrit. 2; Repr. 1B; STOT RE 2; H332, H319, H360, H373	-	-	-

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate
No information available

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Pentetic acid 67-43-6	No data available	No data available	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

Skin contact Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician.

Ingestion Rinse mouth thoroughly with water. Drink 1 or 2 glasses of water. Do NOT induce vomiting. Get immediate medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms No information available.

Effects of Exposure See Section 11 for additional Toxicological Information.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO2, water spray or alcohol-resistant foam.

Unsuitable extinguishing media Do not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Carbon oxides. Combustible material. Most vapors are heavier than air. Vapors may spread along ground and collect in low or confined areas (sewers, basements, tanks). Containers may explode when heated.

Hazardous Combustion Products Carbon monoxide. Carbon dioxide (CO2). Ammonia.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid generation of dust. Ensure adequate ventilation. Evacuate personnel to safe areas.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling Use personal protection equipment. Ensure adequate ventilation.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store at ambient conditions. Keep out of the reach of children. Keep in properly labeled

containers.

7.3. Specific end use(s)

Risk Management Measures The information required is contained in this Safety Data Sheet.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Chemical name	European Union	Austria	Belgium	Bulgaria	Croatia
Pentetic acid 67-43-6	-	-	-	-	-

Chemical name	Cyprus	Czech Republic	Denmark	Estonia	Finland
Pentetic acid 67-43-6	-	-	-	-	-

Chemical name	France	Germany TRGS	Germany DFG	Greece	Hungary
Pentetic acid 67-43-6	-	-	-	-	-

Chemical name	Ireland	Italy MDLPS	Italy AIDII	Latvia	Lithuania
Pentetic acid 67-43-6	-	-	-	-	-

Chemical name	Luxembourg	Malta	Netherlands	Norway	Poland
Pentetic acid 67-43-6	-	-	-	-	-

Chemical name	Portugal	Romania	Slovakia	Slovenia	Spain
Pentetic acid 67-43-6	-	-	-	-	-

Chemical name	Sweden	Switzerland	United Kingdom
Pentetic acid 67-43-6	-	-	-

Biological occupational exposure limits This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Chemical name	European Union	Austria	Bulgaria	Croatia	Czech Republic
Pentetic acid 67-43-6	-	-	-	-	-

Chemical name	Denmark	Finland	France	Germany DFG	Germany TRGS
Pentetic acid 67-43-6	-	-	-	-	-

Chemical name	Hungary	Ireland	Italy MDLPS	Italy AIDII
Pentetic acid 67-43-6	-	-	-	-

Chemical name	Latvia	Luxembourg	Romania	Slovakia
Pentetic acid 67-43-6	-	-	-	-

Chemical name	Slovenia	Spain	Switzerland	United Kingdom
Pentetic acid 67-43-6	-	-	-	-

Derived No Effect Level (DNEL) - Workers No information available

Chemical name	Oral	Dermal	Inhalation
Pentetic acid 67-43-6	-	-	-

Derived No Effect Level (DNEL) - General Public No information available.

Chemical name	Oral	Dermal	Inhalation
Pentetic acid 67-43-6	-	-	-

Chemical name	Oral	Dermal	Inhalation
Pentetic acid - 67-43-6	-	-	-

Predicted No Effect Concentration (PNEC) No information available.

Chemical name	Freshwater	Freshwater (intermittent release)	Marine water	Marine water (intermittent release)	Air
Pentetic acid 67-43-6	-	-	-	-	-

Chemical name	Freshwater sediment	Marine sediment	Sewage treatment	Soil	Food chain
Pentetic acid 67-43-6	-	-	-	-	-

8.2. Exposure controls

Engineering controls Ensure adequate ventilation, especially in confined areas. Ensure that eyewash stations and safety showers are close to the workstation location. Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimize release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous material at source.

Personal Protective Equipment

Eye/face protection Safety glasses with side shields are recommended for medical or industrial exposures.

Hand protection Protective gloves. Nitrile rubber.

Skin and body protection Wear suitable protective clothing.

Respiratory protection Use appropriate respiratory protection.
Ammonia and organic ammonia derivatives filter conforming to EN 14387.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls Do not allow into any sewer, on the ground or into any body of water.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid
Color	White
Odor	Odorless.
Odor Threshold	No information available

Property	**Values**	**Remarks • Method**
Melting point / Freezing point	220°C	None known
Boiling point / boiling range	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability limit	No data available	
Lower flammability limit	No data available	
Flash Point	200 °C - closed cup	None known
Autoignition temperature °C	392 °C	None known
Decomposition temperature		None known
pH	No data available	None known
pH (as aqueous solution)	No data available	None known
Kinematic Viscosity	No data available	None known
Dynamic Viscosity	No Data Available	None known
Water solubility	Soluble in water 3.5 g/L at 20 °C	None known
Solubility in other solvents	No information available	None known
Partition coefficient: n-octanol/water	log Pow: -4.91 - (Lit.), Bioaccumulation is not expected.	None known
Vapor Pressure	No data available	None known
Relative density	1.56 g/cm3 at 20 °C	None known
Bulk density	0.625 g/cm³ @ 20 °C	
Liquid Density	No data available	
Vapor Density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

9.2. Other information

Molecular Weight	393.35 g/mol
Molecular Formula	C14H23N3O10

9.2.1. Information with regard to physical hazard classes
Not applicable

9.2.2. Other safety characteristics
No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion Data
Sensitivity to mechanical impact None.
Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid Excessive heat, Incompatible materials, dust formation.

10.5. Incompatible materials

Incompatible materials Strong oxidizing agents, strong acids, and strong bases.

10.6. Hazardous decomposition products

Hazardous Decomposition Products Nitrogen oxides (NOx), Carbon monoxide, Carbon dioxide (CO2), Ammonia.

SECTION 11: Toxicological information

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

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Acute toxicity

Numerical measures of toxicity
No information available

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral)	99,999.00	mg/kg
ATEmix (dermal)	99,999.00	mg/kg
ATEmix (inhalation-gas)	99,999.00	ppm
ATEmix (inhalation-vapor)	99,999.00	mg/l
ATEmix (inhalation-dust/mist)	1.50	mg/l

100 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.
100 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).
100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor).
0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

> 5.000 mg/kg > 2.000 mg/kg 4 h - 1,5 mg/l

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Pentetic acid	>5000 mg/kg (rat)	> 2000 mg/kg (rat)	-

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation Irritating to eyes.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Chemical name	European Union
Pentetic acid	-

Carcinogenicity No information available.

Chemical name	European Union
Pentetic acid	-

Reproductive toxicity May damage fertility or the unborn child.

Chemical name	European Union
Pentetic acid	-

STOT - single exposure No information available.

STOT - repeated exposure Causes damage to organs through prolonged or repeated exposure.

H372 - Causes damage to the following organs through prolonged or repeated exposure: Respiratory system.

Aspiration hazard No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other Adverse Effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity The environmental impact of this product has not been fully investigated.

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Pentetic acid	400 mg/l - 23 d	> 100 mg/l - 96 h	245 mg/l - 48 h	-

12.2. Persistence and degradability

Persistence/Degradability Soluble in water Persistence is unlikely based on information available.

12.3. Bioaccumulative potential

Bioaccumulation There is no data for this product.

Chemical name	Partition coefficient
Pentetic acid	-

12.4. Mobility in soil

Mobility in Soil Will likely be mobile in the environment due to its water solubility.

12.5. Results of PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
Pentetic acid	Not determined

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

IATA

14.1. UN number or ID number Not regulated
14.2. UN proper shipping name Not regulated
14.3. Transport hazard class(es) Not regulated
14.4. Packing group Not regulated
14.5. Environmental hazard Not applicable
14.6. Special precautions for user
Special Provisions None

IMDG

14.1. UN number or ID number Not regulated
14.2. UN proper shipping name Not regulated

14.3. Transport hazard class(es) Not regulated
14.4. Packing Group Not regulated
14.5. Environmental hazard Not applicable
14.6. Special precautions for user Special Provisions None
14.7 Maritime transport in bulk according to IMO instruments No information available

RID
14.1. UN number or ID number Not regulated
14.2. UN proper shipping name Not regulated
14.3. Transport hazard class(es) Not regulated
14.4. Packing Group Not regulated
14.5. Environmental hazard Not applicable
14.6. Special precautions for user Special Provisions None

ADR
14.1. UN number or ID number Not regulated
14.2. UN proper shipping name Not regulated
14.3. Transport hazard class(es) Not regulated
14.4. Packing Group Not regulated
14.5. Environmental hazard Not applicable
14.6. Special precautions for user Special Provisions None

SECTION 15: Regulatory information

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

Chemical name	French RG number
Pentetic acid - 67-43-6	-

Chemical name	Netherlands - List of Carcinogens	Netherlands - List of Mutagens	Netherlands - List of Reproductive Toxins
Pentetic acid	-	-	-

European Union
Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:
This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Pentetic acid - 67-43-6	-	-

Persistent Organic Pollutants
Not applicable

Chemical name	Persistent Organic Pollutants per (EC) 2019/1021 - Annex

	Number
Pentetic acid - 67-43-6	-

Chemical name	European Export/Import Restrictions per (EC) 649/2012 - Annex Number
Pentetic acid - 67-43-6	-

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
Pentetic acid - 67-43-6	-	-

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Chemical name	Ozone depletion potential (ODP)	Ozone-depleting substances (ODS) regulation (EC) 1005/2009
Pentetic acid - 67-43-6	-	-

Chemical name	EU - Plant Protection Products (1107/2009/EC)
Pentetic acid - 67-43-6	-

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Pentetic acid - 67-43-6	-

Chemical name	EU - Water Framework Directive (2000/60/EC)
Pentetic acid - 67-43-6	-

Chemical name	EU - Environmental Quality Standards (2008/105/EC)
Pentetic acid - 67-43-6	-

International Inventories

TSCA	Does not comply
DSL/NDSL	Does not comply
EINECS/ELINCS	Does not comply
ENCS	Does not comply
IECSC	Does not comply
KECL	Does not comply
PICCS	Does not comply
AIIC	Does not comply
NZIoC	Does not comply

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing Chemicals Inventory
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AIIC - Australian Inventory of Industrial Chemicals
NZIoC - New Zealand Inventory of Chemicals

15.2. Chemical safety assessment

Chemical Safety Report No information available

SECTION 16: Other information

Key or legend to abbreviations and acronyms

Legend
SVHC: Substances of Very High Concern for Authorization:
PBT: Persistent, Bioaccumulative, and Toxic (PBT) Substances
vPvB: Very Persistent and very Bioaccumulative (vPvB) Substances

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	Sk*	Skin designation
+	Sensitizers		

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapor	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitization	Calculation method
Skin sensitization	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

Key literature references and sources for data used to compile the SDS
Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA_RAC)
European Chemicals Agency (ECHA) (ECHA_API)
Environmental Protection Agency
Acute Exposure Guideline Level(s) (AEGL(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
National Institute of Technology and Evaluation (NITE)
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine’s PubMed database (NLM PUBMED)
U.S. National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
World Health Organization

Issuing Date 10-Jan-2025

Revision Date 10-Jan-2025

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer

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.

End of Safety Data Sheet