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Revision Number 3

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product Code 110-44-1
Product Name Sorbic 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) 203-768-7
CAS Number 110-44-1
Chemical Name Sorbic Acid
Synonyms 2,4-Hexadienoic acid
Pure substance/mixture Substance
Contains Sorbic acid
Formula C₆H₈O₂
Molecular Weight 112.13 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.comE-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]

Skin corrosion/irritation	Category 2 - (H315)
Serious eye damage/eye irritation	Category 2 - (H319)
Specific target organ toxicity (single exposure)	Category 3 - (H335)
Category 3 Respiratory irritation	

2.2. Label elements

Contains Sorbic acid

**Signal word**

Warning

Hazard statements

H315 - Causes skin irritation.

H319 - Causes serious eye irritation.

H335 + H336 - May cause respiratory irritation. May cause drowsiness or dizziness.

Precautionary Statements - EU (§28, 1272/2008)

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray.

P264 - Wash face, hands and any exposed skin thoroughly after handling.

P280 - Wear protective gloves and eye/face protection.

P312 - Call a POISON CENTER or doctor if you feel unwell.

P403 + P233 - Store in a well-ventilated place. Keep container tightly closed.

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
Sorbic 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)
Sorbic acid	-

SECTION 3: Composition/information on ingredients**3.1 Substances**

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)

Sorbic acid 110-44-1	>95%	No data available	203-768-7	Skin Irrit. 2; Eye Irrit. 2; H315, H319	-	-	-
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Full text of H- and EUH-phrases: see section 16Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

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
Sorbic acid 110-44-1	3200	2000	No data available	No data available	No data available

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

SECTION 4: First aid measures**4.1. Description of first aid measures**

General advice	Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air. IF exposed or concerned: Get medical advice/attention. Get medical attention immediately if symptoms occur.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.
Skin contact	Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
Ingestion	Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Call a physician.
Self-protection of the first aider	Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

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

Symptoms	May cause redness and tearing of the eyes. Burning sensation. Inhalation of high vapor concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting.
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.
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SECTION 5: Firefighting measures**5.1. Extinguishing media**

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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 Keep product and empty container away from heat and sources of ignition.

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

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 Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid contact with skin, eyes or clothing.

Other information Refer to protective measures listed in Sections 7 and 8.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Prevent further leakage or spillage if safe to do so.

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 Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse. Ensure adequate ventilation. Avoid breathing vapors or mists. In case of insufficient ventilation, wear suitable respiratory equipment.

General hygiene considerations Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Avoid contact with skin, eyes or clothing.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep container tightly closed in a dry and well-ventilated place.

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
Sorbic acid 110-44-1	-	-	-	-	-
Chemical name	Cyprus	Czech Republic	Denmark	Estonia	Finland
Sorbic acid 110-44-1	-	-	-	-	-
Chemical name	France	Germany TRGS	Germany DFG	Greece	Hungary
Sorbic acid 110-44-1	-	-	-	-	-
Chemical name	Ireland	Italy MDLPS	Italy AIDII	Latvia	Lithuania
Sorbic acid 110-44-1	-	-	-	-	-
Chemical name	Luxembourg	Malta	Netherlands	Norway	Poland
Sorbic acid 110-44-1	-	-	-	-	-
Chemical name	Portugal	Romania	Slovakia	Slovenia	Spain
Sorbic acid 110-44-1	-	-	-	-	-
Chemical name	Sweden		Switzerland	United Kingdom	
Sorbic acid 110-44-1	-		-	-	

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
Sorbic acid 110-44-1	-	-	-	-	-
Chemical name	Denmark	Finland	France	Germany DFG	Germany TRGS
Sorbic acid 110-44-1	-	-	-	-	-
Chemical name	Hungary	Ireland	Italy MDLPS	Italy AIDII	
Sorbic acid 110-44-1	-	-	-	-	
Chemical name	Latvia	Luxembourg	Romania	Slovakia	
Sorbic acid 110-44-1	-	-	-	-	
Chemical name	Slovenia	Spain	Switzerland	United Kingdom	
Sorbic acid 110-44-1	-	-	-	-	

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

Chemical name	Oral	Dermal	Inhalation
Sorbic acid 110-44-1	-	40 mg/kg bw/day [4] [6]	17.63 mg/m ³ [4] [6]

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

Chemical name	Oral	Dermal	Inhalation
Sorbic acid 110-44-1	2 mg/kg bw/day [4] [6]	0.17 mg/cm ² [5] [6]	52.17 mg/m ³ [4] [6] 26.08 mg/m ³ [5] [6]

Chemical name	Oral	Dermal	Inhalation
Sorbic acid - 110-44-1	-	-	-

Predicted No Effect Concentration (PNEC) No information available.

Chemical name	Freshwater	Freshwater (intermittent release)	Marine water	Marine water (intermittent release)	Air
Sorbic acid 110-44-1	0.129 mg/L	0.241 mg/L	0.01294 mg/L	-	-

Chemical name	Freshwater sediment	Marine sediment	Sewage treatment	Soil	Food chain
Sorbic acid 110-44-1	0.465 mg/kg sediment dw	0.046 mg/kg sediment dw	10 mg/L	5 mg/kg soil dw	-

8.2. Exposure controls**Engineering controls**

Ensure that eyewash stations and safety showers are close to the workstation location.
Ensure adequate ventilation, especially in confined areas.

Personal Protective Equipment**Eye/face protection**

If splashes are likely to occur, wear safety glasses with side-shields.

Hand protection

Wear suitable gloves. Impervious gloves.

Skin and body protection

Wear suitable protective clothing. Long sleeved clothing.

Respiratory protection

Use appropriate respiratory protection.
Particulates filter conforming to EN 143.

General hygiene considerations

Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this

product. Avoid contact with skin, eyes or clothing.

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

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
Melting point / Freezing point	134.1 °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	127 °C	None known
Autoignition temperature °C	415 °C	None known
Decomposition temperature	>170°C	None known
pH	ca. 3.3 at 1.6 g/l 20°C	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 - 1.6 g/l at 20 °C	None known
Solubility in other solvents	No information available	None known
Partition coefficient: n-octanol/water	log Pow: 1.32 (25°C)	None known
Vapor Pressure	0.00018 hPa at 20°C	None known
Relative density	1.2 g/cm ³ at 20 °C	None known
Bulk density	ca.650 kg/m ³	
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	112.13 g/mol
Molecular Formula	C ₆ H ₈ O ₂

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 Decomposes on exposure to light.

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** Incompatible materials. Excessive heat. Exposure to air. Avoid dust formation. Exposure to light.**10.5. Incompatible materials****Incompatible materials** Strong acids. Strong bases. Strong oxidizing agents.**10.6. Hazardous decomposition products****Hazardous Decomposition Products** Carbon monoxide. Carbon dioxide (CO₂).**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. May cause irritation of respiratory tract. May cause drowsiness or dizziness.
Eye contact	Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.
Skin contact	Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components).
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Symptoms related to the physical, chemical and toxicological characteristics**Symptoms** Redness. May cause redness and tearing of the eyes. Inhalation of high vapor concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting.**Acute toxicity****Numerical measures of toxicity****The following values are calculated based on chapter 3.1 of the GHS document**

ATEmix (oral)	3,368.40 mg/kg
ATEmix (dermal)	2,105.30 mg/kg
ATEmix (inhalation-gas)	99,999.00 ppm
ATEmix (inhalation-vapor)	99,999.00 mg/l
ATEmix (inhalation-dust/mist)	99,999.00 mg/l

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sorbic acid	= 3200 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 Classification based on data available for ingredients. Causes skin irritation.

Serious eye damage/eye irritation Classification based on data available for ingredients. Causes serious eye irritation.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Chemical name	European Union
Sorbic acid	-

Carcinogenicity No information available.

Chemical name	European Union
Sorbic acid	-

Reproductive toxicity No information available.

Chemical name	European Union
Sorbic acid	-

STOT - single exposure May cause respiratory irritation. May cause drowsiness or dizziness.

STOT - repeated exposure No information available.

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 Harmful to aquatic life with long lasting effects.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sorbic acid	-	LC50: =75mg/L (96h, Oryzias latipes)	-	EC50: =353.54mg/L (48h, Daphnia magna)

12.2. Persistence and degradability

Persistence/Degradability No information available.

12.3. Bioaccumulative potential**Bioaccumulation****Component Information**

Chemical name	Partition coefficient
Sorbic acid	1.32

12.4. Mobility in soil

Mobility in Soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment UN.

Chemical name	PBT and vPvB assessment
Sorbic acid	The substance is not PBT / vPvB

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-No	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****National regulations****France****Occupational Illnesses (R-463-3, France)**

Chemical name	French RG number
Sorbic acid - 110-44-1	RG 15bis, RG 74

Chemical name	Netherlands - List of Carcinogens	Netherlands - List of Mutagens	Netherlands - List of Reproductive Toxins
Sorbic 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

Sorbic acid - 110-44-1	-	-
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Persistent Organic Pollutants

Not applicable

Chemical name	Persistent Organic Pollutants per (EC) 2019/1021 - Annex Number
Sorbic acid - 110-44-1	-

Chemical name	European Export/Import Restrictions per (EC) 649/2012 - Annex Number
Sorbic acid - 110-44-1	-

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
Sorbic acid - 110-44-1	-	-

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

Not applicable

Chemical name	Ozone depletion potential (ODP)	Ozone-depleting substances (ODS) regulation (EC) 1005/2009
Sorbic acid - 110-44-1	-	-

Chemical name	EU - Plant Protection Products (1107/2009/EC)
Sorbic acid - 110-44-1	-

Biocidal Products Regulation (EU) No 528/2012 (BPR)

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Sorbic acid - 110-44-1	Product-type 6: Preservatives for products during storage

Chemical name	EU - Water Framework Directive (2000/60/EC)
Sorbic acid - 110-44-1	-

Chemical name	EU - Environmental Quality Standards (2008/105/EC)
Sorbic acid - 110-44-1	-

International Inventories

TSCA	Complies
DSL/NDSL	Complies
EINECS/ELINCS	Complies
Japan (ENCS)	Complies
Inventory of Existing Chemical Substances in China	Complies
Korea (KECL)	Complies
Philippines (PICCS)	Complies
AIIC	Complies
NZIoC	Complies

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 * 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
Reproductive toxicity	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

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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