

Medicines & Healthcare products Regulatory Agency

British Pharmacopoeia

Quality standards

SAFETY DATA SHEET

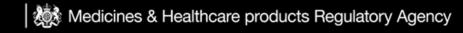
This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 11-Oct-2023

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

1.1. Product identifier	
Product Code(s)	CAT 540
Product Name	Metoprolol tartrate Assay Standard
Form	Not applicable
	nber is given for this substance because it is under the threshold in REACH Article istration requirements according to REACH Title II
EC No (EU Index No)	260-148-9
CAS No.	56392-17-7
Chemical name	Metoprolol Tartrate
Pure substance/mixture	Substance
Formula	C15H25NO3.1/2C4H6O6
Molecular weight	342.41
1.2. Relevant identified uses of the	substance or mixture and uses advised against
Recommended use	Laboratory use
Uses advised against	No information available
1.3. Details of the supplier of the sa	afety data sheet
<u>Supplier</u>	
British Pharmacopoeia Commission MHRA 10 South Colonnade Canary Wharf London E14 4PU United Kingdom	
Tel : +44 (0)20 3080 6561 eMail: bpcrs@mhra.gov.uk	





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For further information, please contact

E-mail address bpcrs@mhra.gov.uk

1.4. Emergency telephone number

Emergency Telephone

+44 (0)20 3080 6561 (Monday - Friday: 8am - 5pm)

Emergency Telephone - §45 - (EC)1272/2008			
Europe	112		
Austria	No information available		
Bulgaria			
Croatia			
Cyprus			
Czech Republic			
Denmark			
France			
Hungary			
Ireland			
Italy			
Lithuania			
Luxembourg			
Netherlands			
Norway			
Portugal			
Romania			
Slovakia			
Slovenia			
Spain			
Sweden			
Switzerland			

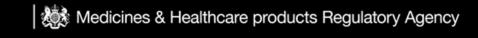
SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to

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

Serious eye damage/eye irritation	Category 2 - (H319)
Reproductive toxicity	Category 2 - (H361)





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Specific target organ toxicity — single exposure	Category 1 - (H370)
Specific larger organ toxicity — single exposure	

2.2. Label elements

Contains Metoprolol Tartrate



Signal word Danger

Hazard statements

H319 - Causes serious eye irritation H361d - Suspected of damaging the unborn child H370 - Causes damage to organs

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

P201 - Obtain special instructions before use

P260 - Do not breathe dust/fume/gas/mist/vapours/spray

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

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P308 + P311 - IF exposed or concerned: Call a POISON CENTER or doctor

P501 - Dispose of contents/ container to an approved waste disposal plant

2.3. Other hazards

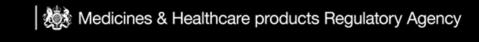
No information available.

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

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

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

SECTION 3: Composition/information on ingredients





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3.1 Substances

Chemical name	Weight-%	REACH registration number		Classification according to Regulation (EC) No. 1272/2008 [CLP]	•	M-Factor	M-Factor (long-term)
Metoprolol Tartrate 56392-17-7	90 - 100%	-	260-148-9	Eye Irrit. 2 (H319) 2 (H361d) STOT SE 1 (H370)			

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

Acute 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

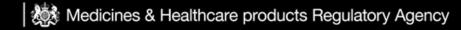
Chemical name	Oral LD50 mg/kg		Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Metoprolol Tartrate 56392-17-7	5500	No data available	No data available	No data available	No data available

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

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.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If symptoms persist, call a doctor. 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.





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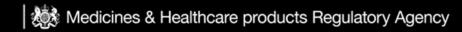
Skin contact	Wash off immediately with plenty of water for at least 15 minutes. If symptoms persist, call a doctor.	
Ingestion	Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Call a doctor.	
Self-protection of the first aider	Avoid contact with skin, eyes or 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.	
4.3. Indication of any immediate medical attention and special treatment needed		
Note to doctors	Treat symptomatically.	

SECTION 5: Firefighting m 5.1. Extinguishing media	leasures	
Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.	
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.	
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	No information available.	
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





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	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	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	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. Remove contaminated clothing and shoes.
General hygiene considerations	Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. Wash hands before breaks and immediately after handling the product.
7.2. Conditions for safe storage, inc	cluding any incompatibilities
Storage Conditions	Please refer to the manufacturer's certificate for specific storage and transport temperature conditions. Store only in the original receptacle unless other advice is given on the CoA. Store locked up. Keep containers tightly closed in a dry, cool and well-ventilated place.

7.3. Specific end use(s)





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Risk Management Methods (RMM) 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.

Biological occupational exposure limits

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

Derived No Effect Level (DNEL) No information available. Predicted No Effect Concentration (PNEC)

8.2. Exposure controls

Personal protective equipment

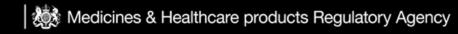
Eye/face protection Avoid contact with eyes. Wear safety glasses with side shields (or goggles). If splashes are likely to occur, wear safety glasses with side-shields.

Hand protection

The protective gloves to be used must comply with the specifications of EC Directive

89/686/EEC and the related standard EN374. Wear suitable gloves.

Gloves			
Duration of contact	PPE - Glove material	Glove thickness	Break through time
	Wear protective butyl		
	rubber gloves		
Skin and body protection	Wear suitable protective clothing.		
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.		





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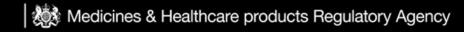
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General hygiene considerations	Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. Wash hands before breaks and immediately after handling the product.
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

9.1. Information on basic physical a		
Physical state	Solid	
Appearance	Solid	
Colour	white	
Odour	No information available.	
Odour threshold	No information available	
Property	Values	Remarks • Method
Melting point / freezing point	120 - 124 °C	None known
Initial boiling point and boiling rang		None known
Flammability	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive	No data available	
limits		
Lower flammability or explosive	No data available	
limits		
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
рН	No data available	None known
pH (as aqueous solution)	No data available	No information available
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	No data available	None known
Solubility(ies)	Methanol	
Partition coefficient	No data available	None known
Vapour pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Relative vapour density	No data available	None known





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Particle Size Particle Size Distribution	No information available No information available
9.2. Other information	
Molecular weight	342.41
Molecular formula	C15H25NO3.1/2C4H6O6

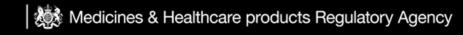
9.2.1. Information with regards to physical hazard classes Not applicable

9.2.2. Other safety characteristics No information available

SECTION 10: Stability and reactivity

10.1. Reactivity No information available. Reactivity 10.2. Chemical stability Stable under normal conditions. Stability **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 None known based on information supplied. 10.5. Incompatible materials Incompatible materials None known based on information supplied. Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information





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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.		
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. May cause irritation. Prolonged contact may cause redness and irritation.		
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea.		
Symptoms related to the physical, chemical and toxicological characteristics			
Symptoms	May cause redness and tearing of the eyes.		

Numerical measures of toxicity

Acute toxicity

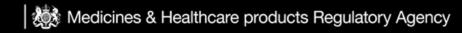
Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Metoprolol Tartrate	= 5500 mg/kg (Rat)		

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

Skin corrosion/irritation May cause skin irritation.

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





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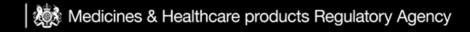
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Respiratory or skin sensitisation	No information available.		
Germ cell mutagenicity	No information available.		
Carcinogenicity	No information available.		
Reproductive toxicity	Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. Suspected of damaging fertility or the unborn child.		
STOT - single exposure	Based on the classification criteria of the Globally Harmonized System as adopted in the country or region with which this safety data sheet complies, this product has been determined to cause systemic target organ toxicity from acute exposure. (STOT SE). Causes damage to organs.		
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





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Ecotoxicity	The environmental impact of this	product has not been fully investigated.	
12.2. Persistence and degradability	_		
Persistence and degradability	No information available.		
12.3. Bioaccumulative potential			
Bioaccumulation	No information available.		
<u>12.4. Mobility in soil</u>			
Mobility in soil	No information available.		
12.5. Results of PBT and vPvB assessment			
PBT and vPvB assessment	This substance is not considered to be persistent, bioaccumulating nor toxic (PBT). This substance is not considered to be very persistent nor very bioaccumulating (vPvB).		
Chemical	name	PBT and vPvB assessment	
Metoprolol Tartrate		The substance is not PBT / vPvB	
12.6. Endocrine disrupting properties			

Endocrine disrupting properties No information available.

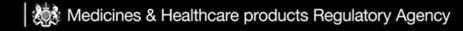
12.7. Other adverse effects

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.





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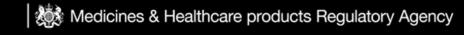
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SECTION 14: Transport information

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 hazards	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 Marine pollutant	Not applicable
14.6 Special precautions for user	
Special Provisions	None No information available
14.7 Maritime transport in bulk	No information available
according to IMO instruments	
according to into instruments	
RID	
14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.2 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.4 Facking group 14.5 Environmental hazards	Not applicable
	Not applicable
14.6 Special precautions for user	None
Special Provisions	none
ADR	
14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	None
Special Provisions	INOTIC





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SECTION 15: Regulatory information

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

slightly hazardous to water (WGK 1)

Water hazard class (WGK)

Poland

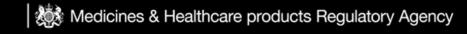
SDS created according to the following Polish regulation: Act of February 25, 2011 on chemical substances and their mixtures (Journal of Laws of 2018, item 143, as amended). Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency (EC) as amended. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, as amended. Regulation of the Minister of Health of 10 August 2012 on the criteria and method of classifying chemical substances and their mixtures (Journal of Laws of 2012, item 1018). Regulation of the Minister of Health of 20 April 2012 on labeling packaging of hazardous substances and mixtures and some mixtures (Journal of Laws of 2012, item 445). Regulation of the Minister of Family, Labor and Social Policy of 12 June 2018 on the maximum allowable concentrations and intensities of factors harmful to health in the work environment (Journal of Laws of 2018, item 1286). Announcement of the Minister of Economy, Labor and Social Policy of August 28, 2003 on the publication of the unified text of the Ordinance of the Minister of Labor and Social Policy on general health and safety at work regulations (Journal of Laws of 2003, No. 169, item 1650) . Regulation of the Minister of Health of 30 December 2004 on occupational safety and health related to the presence of chemical agents in the workplace (Journal of Laws of 2005, No. 11, item 86). Act of December 14, 2012 on waste (Journal of Laws of 2013, item 21) Regulation of the Minister of Health of December 30, 2004 on occupational health and safety related to the presence of chemical agents in the workplace (Journal U. of 2005, No. 11, item 86). Waste Act of December 14, 2012 (Journal of Laws of 2013, item 21). Act of 13 June 2013 on the management of packaging and packaging waste, Journal of Laws 2013, item 888). Government statement of September 24, 2002 - European Agreement on the International Carriage of Dangerous Goods by Road (ADR) (Journal of Laws No. 194, item 1629 and Journal of Laws of 2003, No. 207, item 2013 and 2014).

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.

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This





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product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors Not applicable

Persistent Organic Pollutants

Not applicable

Dangerous substance category per Seveso Directive (2012/18/EU) H3 - STOT SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International	Inventories
TSCA	

nt

Legend:

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

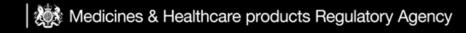
IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment





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Chemical Safety Report

A Chemical Safety Assessment has been carried out for this substance

SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

H319 - Causes serious eye irritation

H361d - Suspected of damaging the unborn child

H370 - Causes damage to organs

Legend

SVHC: Substances of Very High Concern for Authorisation:

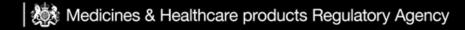
Legend Section 8: Exposure controls/personal protection

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

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 - Vapour	Calculation method		
Acute inhalation toxicity - dust/mist	Calculation method		
Skin corrosion/irritation	Calculation method		
Serious eye damage/eye irritation	Calculation method		
Respiratory sensitisation	Calculation method		
Skin sensitisation	Calculation method		
Mutagenicity	Calculation method		
Carcinogenicity	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)





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U.S. Environmental Protection Agency ChemView Database European Food Safety Authority (EFSA) EPA (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) Japan GHS Classification Australian 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) National Toxicology Program (NTP) New Zealand's Chemical Classification and Information Database (CCID) Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme Organisation for Economic Co-operation and Development Screening Information Data Set World Health Organization

Revision date

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

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