

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 01-Nov-2023

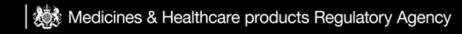
Revision Number 1

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

1.1. Product identifier	
Product Code(s)	CAT 868
Product Name	Propylene glycol Assay Standard
Form	Not applicable

NOTE [8] - No registration number is given for this substance because it is under the threshold in REACH Article 6(1) and not subject to the registration requirements according to REACH Title II

EC No (EU Index No)	200-338-0
CAS No.	57-55-6
Chemical name	Propylene Glycol
Pure substance/mixture	Substance
Formula	C 3H 8O 2
Molecular weight	76.09
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	fety data sheet
Supplier	
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] This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]





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2.2. Label elements

This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP] **Hazard statements** This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

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.

The predect deep net contain any known of edop		
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
Propylene Glycol	-	-

SECTION 3: Composition/information on ingredients

3.1 Substances

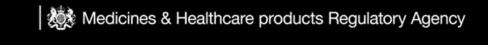
Chemical name	Weight-%	REACH registration number	· · ·	Classification according to Regulation (EC) No. 1272/2008 [CLP]	M-Factor	M-Factor (long-term)
Propylene Glycol 57-55-6	90 - 100%	-	200-338-0	-		

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	Dermal LD50	Inhalation LC50 - 4	Inhalation LC50 - 4	Inhalation LC50 - 4
		mg/kg	hour - dust/mist - mg/L	hour - vapour - mg/L	hour - gas - ppm
Propylene Glycol 57-55-6	20000	20800	No data available	No data available	No data available





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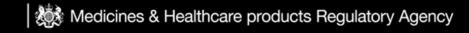
This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Remove to fresh air.			
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a doctor.			
Skin contact	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a doctor.			
Ingestion	Rinse mouth.			
4.2. Most important symptoms and	effects, both acute and delayed			
Symptoms	No information available.			
4.3. Indication of any immediate medical attention and special treatment needed				
Note to doctors	Treat symptomatically.			

SECTION 5: Firefighting measures				
5.1. Extinguishing media				
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				





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Specific hazards arising from the No information available. chemical

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.
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 conta	inment 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 Ensure adequate ventilation.





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product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection.

7.2. Conditions for safe storage, including 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.

7.3. Specific end use(s)

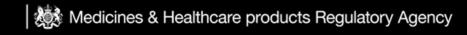
Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

Chemical name	Euro	pean Union	Austria	Belgium	Bu	Igaria	Croatia
Propylene Glycol		-	-	-		-	TWA: 150 ppm
57-55-6							TWA: 474 mg/m ³
							TWA: 10 mg/m ³
Chemical name		Ireland	Italy MDLPS	Italy AIDII	La	atvia	Lithuania
Propylene Glycol	TWA	A: 10 mg/m ³	-	-	TWA:	7 mg/m ³	TWA: 7 mg/m ³
57-55-6	TW	A: 150 ppm				-	
		.: 470 mg/m ³					
	STEL	: 1410 mg/m ³					
	STE	L: 30 mg/m ³					
	STE	L: 450 ppm					
Chemical name	Lu	xembourg	Malta	Netherlands	No	orway	Poland
Propylene Glycol		-	-	-	TWA:	25 ppm	TWA: 100 mg/m ³
57-55-6					TWA:	79 mg/m³	
						37.5 ppm	
					STEL: 1	18.5 mg/m ³	
Chemical name		SI	weden	Switzerland		Uni	ted Kingdom
Propylene Glycol			-	-		TM	/A: 150 ppm
57-55-6							A: 474 mg/m ³
						TW	A: 10 mg/m ³
							EL: 450 ppm
						STEI	_: 1422 mg/m ³





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	STEL: 30 mg/m ³

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	No information available.
(PNEC)	

8.2. Exposure controls

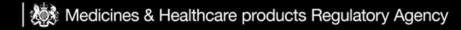
Personal protective equipment

Eye/face protection	Avoid contact with eyes. Wear safety glasses with side shields (or goggles).
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 protective nitrile 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.
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.
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	Liquid
Appearance	Oily
Colour	colourless
Odour	Slight.





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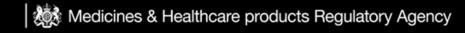
Odour threshold	No information available	
Property Making point (freezing point	<u>Values</u> -60 °C	Remarks • Method
Melting point / freezing point		None known
Initial boiling point and boiling rang	No data available	None known
Flammability	NO GAIA AVAIIADIE	None known
Flammability Limit in Air	$12.6.9(ye) + 400.0(m^3)$	None known
Upper flammability or explosive limits	12.6 %vol ; 400 g/m ³	
Lower flammability or explosive	2.6 %vol ; 80 g/m³	
limits		
Flash point	101 °C	None known
Autoignition temperature	420 °C	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	43.43 mPa s	@ 25°C
Water solubility	No data available	None known
Solubility(ies)	Chloroform, Methanol, Ethyl acetate	None known
Partition coefficient	-0.92	None known
Vapour pressure	0.11 hPa	@ 20°C
Relative density	1.04	@ 20 °C
Bulk density	No data available	
Liquid Density	No data available	
Relative vapour density	2.62	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	
9.2. Other information		
Molecular weight	76.09	
Molecular formula	C 3H 8O 2	

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





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Reactivity			
Reactivity	Doo	otivi	4.4
	Red	CLIV	ILV

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 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.

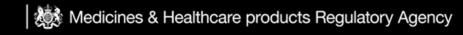
SECTION 11: Toxicological information

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			





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Symptoms

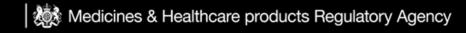
No information available.

Numerical measures of toxicity

Acute toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Propylene Glycol	= 20 g/kg (Rat)	= 20800 mg/kg (Rabbit)	
Delayed and immediate effects	as well as chronic effects fror	n short and long-term exposure	<u>e</u>
Skin corrosion/irritation	Based on available data, t	he classification criteria are not m	net.
Serious eye damage/eye irritati	on No information available.		
Respiratory or skin sensitisatio	n No information available.		
Germ cell mutagenicity	No information available.		
Carcinogenicity	No information available.		
Reproductive toxicity	No information available.		
STOT - single exposure	No information available.		
STOT - repeated exposure	No information available.		





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- 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

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Propylene Glycol	EC50: =19000mg/L (96h, Pseudokirchneriella subcapitata)	LC50: =51600mg/L (96h, Oncorhynchus mykiss) LC50: 41 - 47mL/L (96h, Oncorhynchus mykiss) LC50: =51400mg/L (96h, Pimephales promelas) LC50: =710mg/L (96h, Pimephales promelas)		EC50: >1000mg/L (48h, Daphnia magna)

12.2. Persistence and degradability

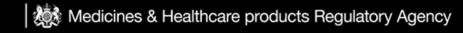
Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation There is no data for this product.

Component Information

Chemical name	Partition coefficient
Propylene Glycol	-0.92





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12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

The product does not contain any substance(s) classified as PBT or vPvB.

Chemical name	PBT and vPvB assessment	
Propylene Glycol	The substance is not PBT / vPvB PBT assessment does	
	not apply	

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

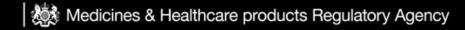
13.1. Waste treatment methods

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

ΙΑΤΑ	
14 1	I

	-	
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	
	pecial Provisions	None
	•	





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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			
<u>RID</u>			
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		
<u>ADR</u>			
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		

SECTION 15: Regulatory information

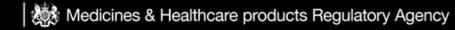
15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations

France

Occupational Illnesses (R-463-3, France)

Chemical name	French RG number	Title
Propylene Glycol	RG 84	-
57-55-6		





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Germany

Water hazard class (WGK)

non-hazardous to water (nwg)

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).

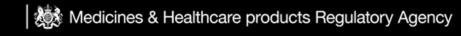
European Union

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 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





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Persistent Organic Pollutants Not applicable

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

International Inventories	
TSCA	Complies
DSL/NDSL	Contact supplier for inventory compliance status
EINECS/ELINCS	Contact supplier for inventory compliance status
ENCS	Contact supplier for inventory compliance status
IECSC	Contact supplier for inventory compliance status
KECL	Contact supplier for inventory compliance status
PICCS	Contact supplier for inventory compliance status
AIIC	Contact supplier for inventory compliance status

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

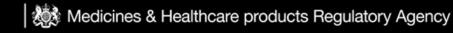
AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report A Chemical Safety Assessment is not required for this substance

SECTION 16: Other information

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





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Legend

SVHC: Substances of Very High Concern for Authorisation:

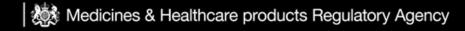
Legend Section 8: Exposure controls/personal protection

TWĂ	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		
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) 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





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Revision Number 1

CAT 868 - Propylene glycol Assay Standard

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

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