

# 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-Sep-2023

**Revision Number** 1

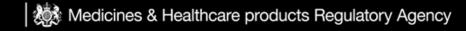
## SECTION 1: Identification of the substance/mixture and of the company/undertaking

CAT 772
Levomenthol
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)	218-690-9
CAS No	2216-51-5
Chemical name	L-menthol
Pure substance/mixture	Substance
Formula	C10H20O
Molecular weight	156.27
1.2. Relevant identified uses of the s	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 sat	fety 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)

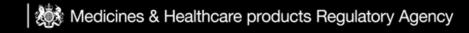
Emergency Telephone - §45 - (EC)1	272/2008
Europe	112
Austria	No information available
Bulgaria	
Croatia	
Cyprus	
Czech Republic	
Denmark	
France	
Hungary	
Ireland	
Italy	
Lithuania	
Luxembourg	
Netherlands	
Norway	
Portugal	
Romania	
Slovakia	
Slovenia	
Spain	
Sweden	
Switzerland	

## **SECTION 2: Hazards identification**

## 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008	
Skin corrosion/irritation	Category 2 - (H315)
Serious eye damage/eye irritation	Category 2 - (H319)

### 2.2. Label elements





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Warning

Hazard statements

H315 - Causes skin irritation H319 - Causes serious eye irritation

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

P264 - Wash face, hands and any exposed skin thoroughly after handling
P280 - Wear protective gloves and eye/face protection
P332 + P313 - If skin irritation occurs: Get medical advice/attention
P337 + P313 - If eye irritation persists: Get medical advice/attention
P362 + P364 - Take off contaminated clothing and wash it before reuse

### 2.3. Other hazards

Harmful to aquatic life.

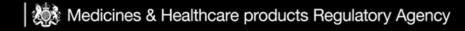
This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

Endocrine Disruptor Information	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
L-menthol	

# SECTION 3: Composition/information on ingredients

### 3.1 Substances

Chemical name	Weight-%	REACH registration	EC No (EU	Classification according	Specific	M-Factor	M-Factor
	-	number	Index No)	to Regulation (EC) No.	concentration		(long-term)
				1272/2008 [CLP]	limit (SCL)		
L-menthol	90 -	-	218-690-9	Skin Irrit. 2 (H315)			
2216-51-5	100%			Eye Irrit. 2 (H319)			





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### 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

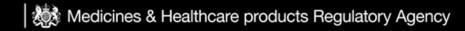
Chemical name	Oral LD50 mg/kg		Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
L-menthol 2216-51-5	3300	No data available	No data available	No data available	No data available

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. 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	Rinse mouth. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. 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			





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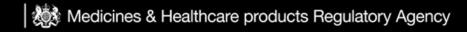
Note to doctors Treat symptomatically.

SECTION 5: Firefighting m	easures
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	e 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	Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required.
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 conta	ainment 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.





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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 it before reuse.
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.
7.2. Conditions for safe storage, inc	luding 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. Keep containers tightly closed in a dry, cool and well-ventilated place.
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

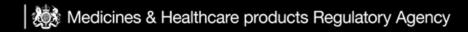
### 8.1. Control parameters

Exposure Limits

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





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

Personal protective equipment

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

Hand protectionThe protective gloves to be used must comply with the specifications of EC Directive<br/>89/686/EEC and the related standard EN374. Wear suitable gloves. Impervious gloves.

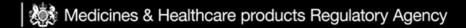
	Gloves		
Duration of contact	PPE - Glove material	Glove thickness	Break through time
	Wear protective nitrile rubber gloves		
Skin and body protection	Wear suitable protective clothing. Long sleeved clothing.		
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure 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	Solid	
Appearance	Crystalline	
Colour	white to off-white	
Odour	Characteristic.	
Odour threshold	No information available	

Property	Value	S
Melting point / freezing point	41.7	°C
Initial boiling point and boiling range	<b>2</b> 18.9	°C

Remarks • Method None known None known





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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	94 °C	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	Slightly soluble 0.397 g/L	None known
Solubility(ies)	No data available	None known
Partition coefficient	3.15	None known
Vapour pressure	0.19 hPa	None known
Relative density	0.89 g/cm3	None known
Bulk density	No data available	
Liquid Density	No data available	
Relative vapour 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	156.27	
Molecular formula	C10H20O	

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

Reactivity

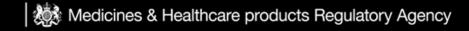
No information available.

10.2. Chemical stability

Stability

Stable under normal conditions.

**Explosion data** 





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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 Strong acids. Strong bases. Strong oxidising agents.

Hazardous decomposition products None known based on information supplied.

## **SECTION 11: Toxicological information**

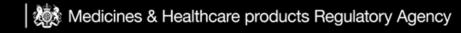
### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure

#### **Product Information**

Inhalation	Specific test data for the substance or mixture is not available. 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. 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 diarrhoea.	
Symptoms related to the physical, chemical and toxicological characteristics		
Symptoms	Redness. May cause redness and tearing of the eyes.	
Numerical measures of toxicity		

Acute toxicity





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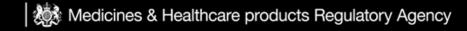
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### CAT 772 - Levomenthol

### **Component Information**

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Chemical name	Oral LD50	Dermal LD50	Inhalation LC50	
L-menthol	= 3300 mg/kg (Rat)	>5000 mg/kg (Rabbi)		
Delayed and immediate effects as well as chronic effects from short and long-term exposure				
Skin corrosion/irritation	Classification based on da irritation.	Classification based on data available for ingredients. Causes skin irritation. May cause skin irritation.		
Serious eye damage/eye irritati	on Classification based on da	ta available for ingredients. Caus	ses serious eye irritation.	
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.	No information available.		
STOT - repeated exposure	No information available.	No information available.		
Aspiration hazard	No information available.	No information available.		
11.2. Information on other hazards				
11.2.1. Endocrine disrupting properties				
Endocrine disrupting propertie	s No information available.			





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### 11.2.2. Other information

Other adverse effects

No information available.

# **SECTION 12: Ecological information**

### 12.1. Toxicity

Ecotoxicity

Harmful to aquatic life.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
			microorganisms	
L-menthol	-	LC50: =18.9mg/L (96h,	-	-
		Pimephales promelas)		

### 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
L-menthol	3.15

#### 12.4. Mobility in soil

Mobility in soil

No information available.

### 12.5. Results of PBT and vPvB assessment

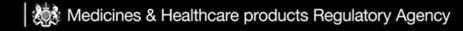
PBT and vPvB assessment

The product contains substance(s) classified as PBT or vPvB.

Chemical name	PBT and vPvB assessment
L-menthol	The substance is not PBT / vPvB

### 12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.





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### 12.7. Other adverse effects

No information available.

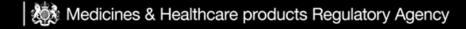
## **SECTION 13: Disposal considerations**

### 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 14.2 UN proper shipping name 14.3 Transport hazard class(es) 14.4 Packing group 14.5 Environmental hazards 14.6 Special precautions for user Special Provisions	Not regulated Not regulated Not regulated Not regulated Not applicable None
IMDG14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing group14.5Marine pollutant14.6Special precautions for user Special Provisions14.7Maritime transport in bulk according to IMO instruments	Not regulated Not regulated Not regulated Not regulated Not applicable None No information available No information available
RID14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing group14.5Environmental hazards14.6Special precautions for user Special Provisions	Not regulated Not regulated Not regulated Not regulated Not applicable None





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#### 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 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

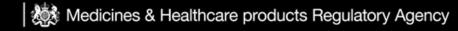
#### National regulations

### Germany

Water hazard class (WGK) slightly hazardous to water (WGK 1)

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





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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

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

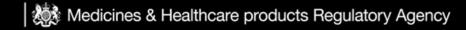
Legend:

**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





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- 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

#### Full text of H-Statements referred to under section 3

H315 - Causes skin irritation H319 - Causes serious eye irritation

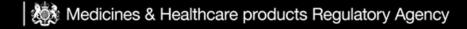
### Legend

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			





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Ozone	Calculation method
Key literature references and sources for data used to	o compile the SDS
Agency for Toxic Substances and Disease Registry (ATS	DR)
U.S. Environmental Protection Agency ChemView Databa	ase
European Food Safety Authority (EFSA)	
EPA (Environmental Protection Agency)	
Acute Exposure Guideline Level(s) (AEGL(s))	
U.S. Environmental Protection Agency Federal Insecticide	e, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production V	olume Chemicals
Food Research Journal	
Hazardous Substance Database	
International Uniform Chemical Information Database (IU	CLID)
Japan GHS Classification	
Australian National Industrial Chemicals Notification and	
NIOSH (National Institute for Occupational Safety and He	alth)
National Library of Medicine's ChemID Plus (NLM CIP)	
National Library of Medicine's PubMed database (NLM P	UBMED)
National Toxicology Program (NTP)	
New Zealand's Chemical Classification and Information D	
Organisation for Economic Co-operation and Developme	
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World Health Organization	

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

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