

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 10-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 720

Product Name Verapamil Hydrochloride

Not applicable Form

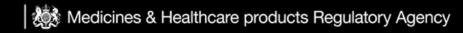
NOTE [8] - No registration number is given for this substance because it is under the threshold in REACH Article 6(1) and not subject to the registration requirements according to REACH Title II

EC No (EU Index No)	205-800-5	
CAS No.	152-11-4	
Pure substance/mixture	Substance	
Formula	C ₂₇ H ₃₉ C IN ₂ O ₄	
Molecular weight	491.06	
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 safety 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

For further information, please contact





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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

Classification according to

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

Acute toxicity - Oral	Category 3 - (H301)
Skin sensitisation	Category 1 - (H317)
Reproductive toxicity	Category 2 - (H361)
Effects on or via lactation	Yes - (H362)





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Specific target organ toxicity — single exposure	
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Category 3 - (H336)

2.2. Label elements

Contains Verapamil Hydrochloride



Signal word Danger

Hazard statements

H301 - Toxic if swallowed

H317 - May cause an allergic skin reaction

H336 - May cause drowsiness or dizziness

H361 - Suspected of damaging fertility or the unborn child

H362 - May cause harm to breast-fed children

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

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

P263 - Avoid contact during pregnancy and while nursing

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

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

P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor

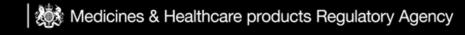
2.3. Other hazards

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
Verapamil Hydrochloride	-	_





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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)
Verapamil Hydrochloride 152-11-4	90 - 100%	-	205-800-5	Acute Tox. 3 (H301) Skin Sens. 1 (H317) Repr. 2 (H361) Lact. (H362) STOT SE 3 (H336)		

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

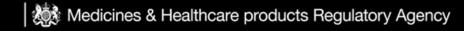
Chemical name	Oral LD50 mg/kg		Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Verapamil Hydrochloride 152-11-4	108	No data available	No data available	No data available	No data available

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 thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.





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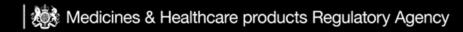
	Consult a doctor.	
Skin contact	Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a doctor.	
Ingestion	Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Get medical attention.	
4.2. Most important symptoms and effects, both acute and delayed		
Symptoms	Itching. Rashes. Hives. Inhalation of high vapour concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting.	
4.3. Indication of any immediate medical attention and special treatment needed		

Note to doctors May cause sensitisation in susceptible persons. Treat symptomatically.

SECTION 5: Firefighting m	neasures
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	ne substance or mixture
Specific hazards arising from the chemical	Product is or contains a sensitiser. May cause sensitisation by skin contact.
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





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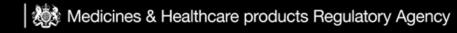
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Personal precautions	Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.	
Other information	Refer to 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 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	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash it before reuse. Remove contaminated clothing and shoes. Avoid breathing vapours or mists.
General hygiene considerations	Wash hands before breaks and immediately after handling the product. 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, including any incompatibilities	
Storage Conditions	Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach





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of children. 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

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	No information available.
(PNEC)	

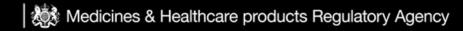
8.2. Exposure controls

Personal protective equipment

Eye/face protection Avoid contact with eyes. Wear safety glasses with side shields (or goggles).

Hand protectionWear suitable gloves. The protective gloves to be used must comply with the specifications
of EC Directive 89/686/EEC and the related standard EN374.

	Gloves		
Duration of contact	PPE - Glove material	Glove thickness	Break through time
	Wear protective butyl rubber gloves		





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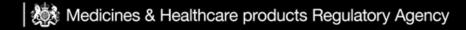
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Skin and body protection	Wear suitable protective clothing.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Wash hands before breaks and immediately after handling the product. 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

9.1. Information on basic physical a		
Physical state	Solid	
Appearance	Solid	
Colour	white to off-white	
Odour	No information available.	
Odour threshold	No information available	
Property	Values	Remarks • Method
Melting point / freezing point	138 - 140 °C	None known
Initial boiling point and boiling rang	eNo data available	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
pH	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 0.7 g/l	@ 20 °C
Solubility(ies)	Acetone, Ethanol, Ethyl acetate	None known
Partition coefficient	No data available	None known
Vapour pressure	No data available	None known
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Relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Relative vapour density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
9.2. Other information	
Molecular weight	491.06

C 27H 39C IN 2O 4

None known

None known

9.2.1. Information with regards to physical hazard classes Not applicable

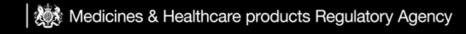
9.2.2. Other safety characteristics No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Molecular formula

Reactivity No information available. 10.2. Chemical stability Stability Stable under normal conditions. **Explosion data** Sensitivity to mechanical impact None. Sensitivity to static discharge None. 10.3. Possibility of hazardous reactions Possibility of hazardous reactions None under normal processing. 10.4. Conditions to avoid None known based on information supplied. Conditions to avoid 10.5. Incompatible materials Incompatible materials None known based on information supplied.





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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

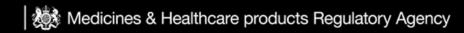
Product information	
Inhalation	May cause drowsiness or dizziness.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	May cause sensitisation by skin contact. Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components).
Ingestion	Specific test data for the substance or mixture is not available. Toxic if swallowed. (based on components).
Symptoms related to the physical, chemical and toxicological characteristics	
Symptoms	Itching. Rashes. Hives. Inhalation of high vapour concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting.
Numerical measures of toxicity	

Acute toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Verapamil Hydrochloride	= 108 mg/kg (Rat)		

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





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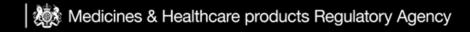
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Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	No information available.
Respiratory or skin sensitisation	May cause an allergic skin reaction.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. May cause harm to breast-fed children. Suspected of damaging fertility or the unborn child.
STOT - single exposure	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 in	formation





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

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

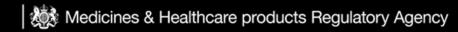
12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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





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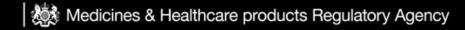
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Contaminated packaging

Do not reuse empty containers.

SECTION 14: Transport information

IATA14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing groupDescription14.5Environmental hazards14.6Special precautions for userSpecial ProvisionsERG Code	UN2811 Toxic solid, organic, n.o.s. (Verapamil Hydrochloride) 6.1 III UN2811, Toxic solid, organic, n.o.s. (Verapamil Hydrochloride), 6.1, III Not applicable A3, A5 6L
IMDG14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing groupDescription14.5Marine pollutant14.6Special precautions for userSpecial ProvisionsEmS-No.14.7Maritime transport in bulkaccording to IMO instruments	UN2811 Toxic solid, organic, n.o.s. (Verapamil Hydrochloride) 6.1 III UN2811, Toxic solid, organic, n.o.s., 6.1, III NP 223, 274 F-A, S-A No information available No information available
RID14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing group Description14.5Environmental hazards14.6Special precautions for user Special Provisions Classification code	UN2811 Toxic solid, organic, n.o.s. (Verapamil Hydrochloride) 6.1 III UN2811, Toxic solid, organic, n.o.s. (Verapamil Hydrochloride), 6.1, III Not applicable 274, 614 T2
ADR 14.1 UN number or ID number 14.2 UN proper shipping name	UN2811 Toxic solid, organic, n.o.s. (Verapamil Hydrochloride)





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14.3 Transport hazard class(es)	6.1
14.4 Packing group	
Description	UN2811, Toxic solid, organic, n.o.s. (Verapamil Hydrochloride), 6.1, III, (E)
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	
Special Provisions	274, 614
Classification code	T2
Tunnel restriction code	(E)

SECTION 15: Regulatory information

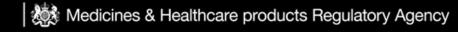
15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water hazard class (WGK)

obviously hazardous to water (WGK 2)

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





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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

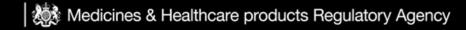
Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventories TSCA	Complies under research and development exemption or is regulated by a different government agency.
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





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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

Full text of H-Statements referred to under section 3

H301 - Toxic if swallowed

H317 - May cause an allergic skin reaction

H336 - May cause drowsiness or dizziness

H361 - Suspected of damaging fertility or the unborn child

H362 - May cause harm to breast-fed children

Legend

SVHC: Substances of Very High Concern for Authorisation:

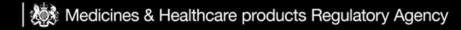
Legend Section 8: Exposure controls/personal protection

TWA	TWA (time-weighted average)	STEL
Ceiling	Maximum limit value	*

Classification procedure Classification according to Regulation (EC) No. 1272/2008 [CLP] Method Used Acute oral toxicity Calculation method Acute dermal toxicity Calculation method Calculation method Acute inhalation toxicity - gas 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 Calculation method Respiratory sensitisation Skin sensitisation Calculation method

STEL (Short Term Exposure Limit)

Skin designation





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Mutagenicity	Calculation method	
Carcinogenicity	Calculation method	
STOT - single exposure	Calculation method	
STOT - repeated exposure	Calculation method	
Acute aquatic toxicity	Calculation method	
Chronic aquatic toxicity	Calculation method	
Aspiration hazard	Calculation method	
Ozone	Calculation method	

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

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

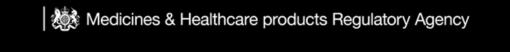
World Health Organization

Revision date

10-Nov-2023

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

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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 10-Nov-2023

Revision Number 1

CAT 720 - Verapamil Hydrochloride

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