





## Product name: Amlodipine besvlate

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Product name: Amlodipine besylate		
After swallowing Seek medical treatme	ant	(Contd. of page 1)
Information for doctor		
Indication of any immediate medical	<b>s, both acute and delayed</b> No further relevant information available. <b>attention and special treatment needed</b> No further relevant information available.	
5 Fire-fighting measures		
Extinguishing media		
Suitable extinguishing agents Carbon Special hazards arising from the subs	n dioxide, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam. stance or mixture	
Suitable extinguishing agents Carbon dioxide, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Special hazards arising from the substance or mixture If this product is involved in a fire, the following can be released: Carbon monoxide and carbon dioxide		
Sulfur oxides (SOx) Nitrogen oxides (NOx)		
Hydrogen chloride (HCl)		
Advice for firefighters Protective equipment:		
Wear self-contained respirator. Wear fully protective impervious suit.		
6 Accidental release measures		
	ipment and emergency procedures	
Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away. Ensure adequate ventilation		
Environmental precautions: Do not al	low material to be released to the environment without proper governmental permits.	
Methods and material for containmen Dispose of contaminated material as wa	aste according to section 13.	
Ensure adequate ventilation. Prevention of secondary hazards: No Reference to other sections	special measures required.	
<b>Reference to other sections</b> See Section 7 for information on safe ha	andlina	
See Section 8 for information on person See Section 13 for disposal information.	nal protection equipment.	
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7 Handling and storage Handling		
Precautions for safe handling		
Keep container tightly sealed. Store in cool, dry place in tightly closed Ensure good ventilation at the workplace	containers.	
Ensure good ventilation at the workplace Information about protection against	e. <b>explosions and fires:</b> No information known.	
Conditions for safe storage, including	•	
Storage Requirements to be met by storeroon	ns and receptacles: No special requirements.	
Information about storage in one con Further information about storage co	nmon storage facility: Store away from oxidizing agents. Inditions:	
Keep container tightly sealed. Store in cool, dry conditions in well seal		
Specific end use(s) No further relevant	t information available.	
8 Exposure controls/personal prote	ection	
	<b>of technical systems:</b> designed for hazardous chemicals and having an average face velocity of at least 100 feet per minute.	
Control parameters	designed for hazardous chemicals and having an average face velocity of at least 100 feet per minute.	
Components with limit values that re	quire monitoring at the workplace:	
Additional information: No data	ant quantities of materials with critical values that have to be monitored at the workplace.	
Exposure controls Personal protective equipment		
General protective and hygienic meas	sures	
The usual precautionary measures for handling chemicals should be followed. Keep away from foodstuffs, beverages and feed.		
Remove all soiled and contaminated clothing immediately. Wash hands before breaks and at the end of work.		
Avoid contact with the eyes and skin. Maintain an erronomically appropriate working environment		
Breathing equipment: Use suitable respirator when high concentrations are present. Protection of hands:		
Intervious gloves Check protective gloves prior to each us	no for their proper condition	
The selection of suitable gloves not only	/ depends on the material, but also on quality. Quality will vary from manufacturer to manufacturer.	
Penetration time of glove material (in Eye protection: Safety glasses		
<b>Body protection:</b> Protective work cloth	ing.	
9 Physical and chemical properties		
Information on basic physical and ch General Information		
Appearance: Form:	Solid	
Color: Odor:	Off-white Not determined	
Odor threshold:	Not determined.	
pH-value: Change in condition	Not applicable.	
Melting point/Melting range:	195-204 °C (383-399 °F) Not determined	
Boiling point/Boiling range: Sublimation temperature / start:	Not determined Not determined	
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roduct name: Amlodipine besylate		
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Flammability (solid, gaseous)	Not determined.	
Ignition temperature:	Not determined	
Decomposition temperature: Auto igniting:	Not determined Not determined.	
	Not determined.	
Danger of explosion: Explosion limits:		
Lower: Upper:	Not determined Not determined	
Vapor pressure:	Not applicable.	
Density:	Not determined	
Relative density Vapor density	Not determined. Not applicable.	
Evaporation rate	Not applicable.	
Solubility in / Miscibility with Water:	Not determined	
Partition coefficient (n-octanol/water):		
Viscosity:		
dynamic: kinematic:	Not applicable. Not applicable.	
Other information	Not applicable. No further relevant information available.	
Stability and reactivity		
Reactivity No information known. Chemical stability Stable under recomn	mended storage conditions.	
Thermal decomposition / conditions to	to be avoided: Decomposition will not occur if used and stored according to specifications.	
Possibility of hazardous reactions Rea Conditions to avoid No further relevant	t information available.	
Incompatible materials: Oxidizing agen	niomaion available. nts	
Hazardous decomposition products: Carbon monoxide and carbon dioxide		
Sulfur oxides (SOx)		
Nitrogen oxides Hydrogen chloride (HCl)		
Toxicological information		
Information on toxicological effects		
Acute toxicity: Harmful if swallowed.		
The Registry of Toxic Effects of Chemica	al Substances (RTECS) contains acute toxicity data for components in this product.	
LD/LC50 values that are relevant for c	lassification:	
Oral LD50 393 mg/kg (rat)		
Skin irritation or corrosion: Causes ski Eye irritation or corrosion: Causes sen	rious eve irritation.	
Sensitization: No sensitizing effects kno	own.	
Germ cell mutagenicity: No effects kno	own.	
Reproductive toxicity: The Registry of	on carcinogenic properties of this material is available from the EPA, IARC, NTP, OSHA or ACGIH. Toxic Effects of Chemical Substances (RTECS) contains reproductive data for this substance.	
Specific target organ system toxicity -	<ul> <li>repeated exposure: No effects known.</li> <li>single exposure: May cause respiratory irritation.</li> </ul>	
Aspiration hazard: No effects known.		
Subacute to chronic toxicity: No effect		
	To the best of our knowledge the acute and chronic toxicity of this substance is not fully known.	
Ecological information		
Toxicity		
Aquatic toxicity: No further relevant info Persistence and degradability No furth	ormation available. Der relevant information available.	
Bioaccumulative potential No further re	relevant information available.	
Mobility in soil No further relevant inforr Additional ecological information:	mation available.	
General notes:	· · ·	
Do not allow material to be released to tr	he environment without proper governmental permits. guantities to reach ground water, water course or sewage system.	
Avoid transfer into the environment.		
Results of PBT and vPvB assessment	t	
PBT: Not applicable. vPvB: Not applicable.		
Other adverse effects No further releval	Int information available.	
Disposal considerations		
Waste treatment methods		
Recommendation Consult state, local of	or national regulations to ensure proper disposal.	
Uncleaned packagings: Recommendation: Disposal must be ma	uade according to official regulations.	
Transport information UN-Number		
DOT, ADN, IMDG, IATA	Not applicable	
UN proper shipping name DOT, ADN, IMDG, IATA	Not applicable	
Transport hazard class(es)		
DOT, ADR, ADN, IMDG, IATA Class	Not applicable	
Class		(Contd. on pa
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Product name: Amlodipine besylate	
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Packing group DOT, IMDG, IATA	
	Not applicable
Environmental hazards:	Not applicable.
Special precautions for user Transport in bulk according to Annex II of MAR	Not applicable.
Transport In burk according to Annex II of MAR Transport/Additional information:	
DOT	
Marine Pollutant (DOT):	No
UN "Model Regulation":	<u> </u>
<ul> <li><b>15 Regulatory information</b> <ul> <li>Safety, health and environmental regulations/leghts label elements The product is classified and Hazard pictograms</li> <li><i>Q</i></li> <li>GHS07</li> <li>Signal word Warning Hazard statements</li> <li>H302 Harmful if swallowed.</li> <li>H315 Causes skin irritation.</li> <li>H319 Causes serious eye irritation.</li> <li>H335 May cause respiratory irritation.</li> <li>H335 May cause respiratory irritation.</li> <li>P261 Avoid breathing dust/furme/gas/</li> <li>P261 Avoid breathing dust/furme/gas/</li> <li>P280 Wear protective gloves/protecti</li> <li>P305+P351+P338 IF IN EYES: Rinse cautiously w</li> <li>P304+P340 IF INHALED: Remove person to P405 Store locked up.</li> <li>P501 Dispose of contents/container in National regulations</li> <li>This product is not listed in the U.S. Environmentator research and development only. This product must not be used for commercial purposes</li> <li>This product is not listed on the Canadian Domesti SARA Section 313 (specific toxic chemical listin California Proposition 65</li> <li>Prop 65 - Developmental toxicity, female Substate Prop 65 - Developmental toxicity, male Substate Prop 65 - Developmental toxicity, female Substate Prop 65 - Developmental toxicity, female Substate Prop 65 - Developmental toxicity, male Substate Prop 65 - Developmental toxicity.</li> <li>Matona use must be observed.</li> <li>Substance is not listed.</li> <li>Annex XIV of the REACH Regulations (requiring Chemical safety assessment: A Chemical Safety</li> </ul> </li> </ul>	Inist/vapours/spray. ve clothing/eye protection/face protection. ve clothing/eye protection/face protection. vith water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. o fresh air and keep comfortable for breathing. n accordance with local/regional/national/international regulations. I Protection Agency Toxic Substances Control Act Chemical Substance Inventory. Use of this product is restricted ust be used by or directly under the supervision of a technically qualified individual as defined by TSCA. This s or in formulations for commercial purposes. ic Substances List (DSL) or the Canadian Non-Domestic Substances List (NDSL). <b>ngs)</b> Substance is not listed. vibstance is not listed. ance is not listed. ance is not listed. ance is not listed. y by technically qualified individuals. <b>agulations</b> <b>ding to the REACH Regulations (EC) No. 1907/2006.</b> Substance is not listed. <b>icite 67 and Annex XVII of the Regulation (EC) No 1907/2006 (REACH) for the manufacturing, placing on the</b> <b>g Authorisation for use</b> ) Substance is not listed.
Department issuing SDS: Global Marketing Depa Date of preparation / last revision 11/24/2015 / -	artment
CAS: Chemical Abstracts Service (division of the American Chemic HMIS: Hazardous Materials Identification System (USA) WHMIS: Workplace Hazardous Materials Information System (Cana LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent vPyB, very Persistent and very Bioaccumulative	uses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road) cal Society) ada) ts (USA) USA
ACGIH: American Conference of Governmental Industrial Hygienist OSHA: Occupational Safety and Health Administration (USA) NTP: National Toxicology Program (USA) IARC: International Agency for Research on Cancer EPA: Environmental Protection Agency (USA)	ts (USA)