

AMRI India Pvt. Ltd. | Plot No. G-1/1, 1/2, MIDC Area, Waluj, Aurangabad - 431 136, India.

Safety Data Sheets (SDSs)

Sect	ion and Heading	Information requirements
1	Identification	IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING
		Product identifier :
	*	Substances : Substances Name: Atenolol
		Index No :NA CLP Reference No:NA
		• EC No:NA
		REACH Registration No:NA CAS No: 29122-68-7
		Mixtures Trade Name/Designation: NA
		Other means of identification : : 2-[4-[2-hydroxy-3-(propan- 2-ylamino)propoxy]phenyl]acetamide
		 Relevant identified uses of the substances or mixture and uses advised against
		· Relevant identified uses : Medicines
		 Uses advised against: Atenolol should be used with caution and in reduced dosage in patients with impaired renal function, especially when creatinine clearance is less than 35 ml/minute per 1.73 sq m Patients receiving atenolol after hemodialysis /should/ be administered the drug under close supervision in a hospital setting, since marked hypotension may occur
		Details of the supplier of the safety data sheet: Manufacturer
		o AMRI INDIA PVT LTD,G-1/1,1/2, MIDC,WALUJ,AURANGANAD,
		MAHARASHTRA,
		INDIA



	4**	Information co National conta	lephone No: +9102		
2	Hazards identification	Classific	Classification of the substances or mixture: Classification according to Regulation (EC) No		
		Hazard classes & Hazard Categories	Hazard Statements	Classification Procedure	
		Hazard class(Ch.3.9) (Category 2)	H-373	on basis of test data	
		Health class (Ch.3.8) (Category 3)	H-335	Human Experience	
		Health class(Ch.3.2) (Category 2)	H-315	Human Experience	
		R22- Han R40- Pos	tion according to 67/5 mful if swallowed. ssible risks of irrevers ating to eyes	48/EEC or 1999/45/EC	
		R- as abo			
		H-315: Causes skir	n irritation		
		H-335 : May cause	respiratory irritation		
		repeated ex through pre exposure it	olonged or repeated e	rough prolonged or ans affected, if known) exposure (state route of oven that no other routes	
		EUH401: To avoid comply with the instru		and the environment,	
				lation (EC) No 1272/2008	
		Produc Substa	t identifier: nces:		

Atenolol Index No:NA Authorization No :NA

Mixtures: Pure solid-100% W/W

· Hazard components for labeling :

Repeated or prolong exposure to the substance can produce target organ damage, May cause respiratory irritation

Authorization No:NA

· Hazard Pictograms



GHS07

(Respiratory Tract Irritation)

- Signal word(s): Warning
 - Hazard statement(s):

H-319: Causes serious eye irritation

H-335: May cause respiratory irritation

H-373: May cause damage to organs through prolonged or repeated exposure (state all organs affected, if known) through prolonged or repeated exposure (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)

Precautionary statement(s):

P-201: Obtain special instructions before use.

P-202: Do not handle until all safety precautions have been read and understood.

P-261: Avoid breathing dust/fume/gas/mist/vapors/spray.

P-264: Wash ... thoroughly after handling.

Sign / Date Juniour

P-270: Do not eat, drink or smoke when using this product.

P-271: Use only outdoors or in a well-ventilated area.

P-280: wear protective gloves/protective clothing/eye protection/face protection.

P-301+P-312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell

P-302+P-352: IF ON SKIN: Gently wash with plenty of soap and water.

P-305+P-351+P-338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P-308+P-313: IF exposed or concerned: Get medical advice/attention.

P-312: Call a POISON CENTER or doctor/physician if you feel unwell.

P-321: Specific treatment (see ... on this label).

P-330: Rinse mouth.

P-337+P-313: If eye irritation persists: Get medical advice/attention.

P-360: Rinse immediately contaminated clothing and skin with plenty of water before removing Clothes.

P-403+P-233: Store in a well-ventilated place. Keep container tightly closed.

P-405: Store locked up.

P-501: Dispose of contents/container to

- Supplemental Hazard Information (EU):
- Special rules for supplemental label elements for certain mixtures: NA
- Additional Labelling:NA
 - Other hazards: Adverse physicochemical effects: Store in cool place

Adverse Human health effect and symptoms: The substance is toxic to blood, lungs, upper respiratory tract, endocrine, skin. Repeated or prolonged exposure to



		the substance can produce target organs damage.
	y	Adverse environmental effects: Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise
		Other adverse hazards: Not specified
3	Composition /	COMPOSITION /INFORMATION ON INGREDIENTS
	information on ingredients	Substances
	3	Substances Name: Atenolol
		INDEX No:NA
	The second of th	EC No :NA
		CLP Reference No:NA
		REACH Registration No:NA
		CAS No: 29122-68-7
		•Purity :100% w/w
		Synonyms :NA
		Stabilizer:NA
		Hazard Impurities:NA
		1
		Substances Name(Impurity): 2-(4-Hydroxyphenyl)
		acetamide
		INDEX No:NA
		EC No :NA
		CLP Reference No:NA
		REACH Registration No:NA
		CAS No:NA
		Purity : <0.25 % Impurity in main product Synonyms :NA
		Stabilizer:NA
		Hazard Impurities:NA
		Substances Name(Impurity): 2-[4-[(2RS)-2,3-
		dihydroxypropoxy] phenyl] acetamide
		INDEX No:NA EC No :NA
		CLP Reference No:NA
		REACH Registration No:NA
		CAS No:NA
		•Purity: <0.25 % Impurity in main product
		Synonyms :NA
		Stabilizer:NA

Hazard Impurities:NA

Substances Name: 2-[4-(2,3-epoxypropxy) phenyl]

acetamide

INDEX No:NA EC No :NA CLP Reference No:NA REACH Registration No:NA CAS No:NA

> •Purity : <0.25 % Impurity in main product Synonyms :NA Stabilizer:NA Hazard Impurities:NA

Substances Name(Impurity): 2-[4-[(2RS)-3-chloro-2hydroxy-propoxy] phenyl] acetamide

INDEX No:NA
EC No :NA
CLP Reference No:NA
REACH Registration No:NA
CAS No:NA

 Purity: <0.25 % Impurity in main product Synonyms:NA Stabilizer:NA Hazard Impurities:NA

Substances Name(Impurity): 2,2'-[2-hydroxypropan-1,3-diylbis (oxy-4,1-phenylene)]diacetamide INDEX No:NA

EC No :NA CLP Reference No:NA REACH Registration No:NA CAS No:NA

> Purity: <0.25 % Impurity in main product Synonyms:NA Stabilizer:NA Hazard Impurities:NA

Mixtures
 Description of the mixture :
 NA

Hazardous ingredients :

 Additional information: NA

UN-CONTROLLED

CONTROLLED

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4	First-aid measures	FIRST AID MEASURES
		Description of first aid measures General information:
		 Inhalation: Allow the victim to rest in cool ventilated area, seek medical attention immediately
		 Skin Contact: wash with disinfectant soap and cover contaminated skin with anti bacterial cream, seek medical attention immediately
		 Eye Contact: Immediately the eyes with plenty of running water for at least 15 minutes, keeping eyelids open. Do not use any ointment, seek medical attention immediately
		 Ingestion: Do not induce vomiting; Loosen tight clothing color, tie belt, waistband. If victim is not breathing perform mouth to mouth resuscitation, seek medical attention immediately.
		Self-protection of the first aider:Not specific
		Notes for doctor :Not specific
		Most important symptoms and effects, both acute and delayed: Not classified
		 Indication of any immediate medical attention and special treatment needed; Not specific
5	Fire-fighting measures	FIRE FIGHTING MEASURES Extinguishing media :
		Suitable extinguishing media: Use water spray,fog,foam,
		Unsuitable extinguishing media: Do not use water Jet

	T	Small Fires: Use Dry Chemical Powder
		Large Fires : Use water spray,fog,foam,
	4	 Special hazards arising from the substances or mixture: Hazardous combustion products: Toxic fumes of CO, CO2 and nitrogen oxides.
		 Advise for Fire fighters: Fire suits can be used as an protective wear, use BA set for large fires
		Additional information: Not specific
6	Accidental release	ACCIDENTAL RELEASE MESURES
	measures	Personal precautions, protective equipment and emergency procedures (include information for emergency responders and non-emergency personnel):Avoid contact with skin, use impervious handgloves,goggles,safey shoes and dust mask for handling during emergency
		Environmental precautions :
		Methods and materials for containment and clean-up: For containment: Absorb with suitable material cleaning up: clean affected area with soap and water.
		Other information: Dispose of materials according to the applicable federal, state, or local Regulations • Reference to other sections:Ref Section 7 • Additional information: Not Specific
7	Handling and	HANDLING AND STORAGE
	storage	Precautions for safe handling: Do not ingest. Do not breathe dust. Avoid contact with Eyes. Wear suitable protective clothing. If ingested, seek medical advice immediately and show the container or the label.
		Protective measures:
		 Fire Prevention: No special storage required for hazard control. For product protection store at Controlled room temperature of 15-30°C. Keep locked up, Keep away from heat, Keep away from sources of ignition. Empty containers pose a fire risk, Evaporate the residue under a fume hood. Ground all equipment containing material.

		 Aerosol and dust generation preventions: Do not ingest. Do not breathe dust. Wear suitable protective clothing if ingested, seek medical advice immediately and show the Container or the label
		Environmental precautions:
		Advice on general occupational hygiene: shall be provided, such as: (a) not to eat, drink and smoke in work areas; (b) to wash hands after use; And (c) to remove contaminated clothing
		and protective equipment before entering eating areas • Condition for safe storage ,including any incompatibles:
		 Technical measures and storage conditions: No special storage required for hazard control. For product protection store at Controlled room temperature of 15-30°C. Keep locked up.
		Packing material : Not Specific
		 Requirement for storage rooms and vessels: No special storage required for hazard control
		 Hints on storage assembly: Not specific
	7	Storage class:
		Further information on storage conditions:NA
		Specific end uses: Recommendations; For medicines Industrial sector specific solutions: Not specific
8	Exposure controls / personal protection	EXPOSURE CONTROLS/PERSONAL PROTECTION Preventive industrial medical examination are to be carried
		Control parameters:
		Occupational exposure limits: Not established
		Biological exposure limits : Not Established
		STEL: Not Established

- Exposure limits at intended use: Not established
- DNEL/PNEC-values:
 Not established
- Risk management measures according to used control banding approach:
 Not Established

NOT ESTABLISHED

Exposure controls:

Appropriate engineering controls:

- Engineering controls are not needed during normal product use conditions in case of bulk handling Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.
- · Personal protection equipment:
 - Eye/Face protection: Eye protection is not required during expected product use conditions but may be warranted should a splash potential exist
- Skin protection: If solution contact with unprotected skin is likely, use of impervious gloves is a prudent practice
- Respiratory protection: Respiratory protection is not needed during normal product use
- Thermal Hazards:
 Not applicable
- Environmental exposure controls: Not Specific
- Consumer exposure control:
 Measures related to consumer uses of the substances (such as mixtures):Not Specific Measures related to the service life of the substances in articles: Not Specific
- Occupational exposure to Atenolol may occur through inhalation and dermal contact with this compound at workplaces where Atenolol is produced or used (SRC). Direct human exposure occurs through ingestion of the drug when dispensed in tablet form(SRC)



9	Physical and chemical properties		nt health safety	MCIAL PROPERTIES and environmental information		
	que.	Physical state Solid	colour white	odori Odori		r threshold A
			elevant Data:	T	Side Alexand	Planant
		Parameter	value	conc	Method	Remark
		PH (1% soln/water	NA			
		Melting Point	152-156°C	1		
		Boiling Point	568.72 °C			
		Decomposition Temp	NA			
		Flash point	NA			
		Auto-ignition	NA			
		temperature				
		Vapor	NA			
		Pressure				
		Vapor Density	NA			
		Density	NA			
		Bulk density	0.38 gm/ml			
		Water solubility	Very slightly soluble in cold water.			
		Partition coefficient	0.170			
		Viscosity	NA			
		Molecular weight	266.38	g/mole		
		Molecular Formula	C14H22N203			
		 Physical haz Explosive: No Flammable ga Flammable as 	on Explosive pro	oduct		
		Oxidizing gas	es:NA			



Gases under pressure:NA

Flammable solids: Non Flammable

Self reactive substances and mixtures:NA

Flammable liquids:NA

		Pyrophoric liquids: NA
		Pyrophoric solids:NA
		Self heating substances and mixtures: NA
	44.	Substances or mixtures which ,in contact with water emit flammable gases: NO
		Oxidizing liquids:NA
		Oxidizing solids:NA
		Organic peroxides:NA
		Metal corrosion:NA
		Other safety information:
		Properties of explosive atmospheres (Mixtures): Gases and vapors: NA Dusts: Not established
		Physical chemical properties of nanoparticles:NA
		Limiting oxygen concentration:NA
		Bulk density: 0.38 gms/ml
		Stability in organic solvent and identity or relevant
		degradation products: NA
		Evaporation rate:NA
		Conductivity:NA
		Surface tension:NA
		Dissociation constant in water:NA
		Oxidation -reduction Potential:NA
		Fat solubility (solvent-oil to be specified):NA
		at solubility (solvent-oil to be specified). WA
10	Stability and	STABILITY AND REACTIVITY
	reactivity	Reactivity: Reactive with oxidizing agents, metals acids.
		Chemical Stability: The product is stable for standard



use and stable under normal conditions Possibility of hazardous reaction: Not classified · Conditions to avoid: NA · Incompatible materials: NA · Hazardous decomposition products: These products are carbon oxides (CO, CO2), nitrogen oxides (NO, NO2...). TOXICOLOGICAL INFORMATION 11 **Toxicological** information · Toxicokinetics, metabolism and distribution: Information on toxicological effects: Substances: Acute toxicity: Effect Species Method Remark dose Acute oral LD50: Rat LD 50 toxicity 2000 mg/Kgs Acute LD50 NA dermal toxicity Acute LC50 NA inhalative toxicity · Skin corrosion/irritation:H-315 · Serious eye damage/irritation:NA Irritation to respiratory tract: H-335 · Respiratory or skin sensitization: NA · CMR effects (carcinogenity, mutagenicity and Toxicity for reproduction) Carcinogenicity: There is inadequate evidence for the carcinogenicity of Atenolol in humans. There is inadequate evidence for the carcinogenicity of Atenolol in experimental animals. Overall evaluation: Atenolol is not classifiable as to its carcinogenicity to humans (Group 3). Classified None. By NTP, None. by OSHA, None. By

NIOSH. 3 (Not classifiable for human.) by IARC.

Mutagenicity:

Classified POSSIBLE for human. Causes damage to the following organs: blood, lungs, upper respiratory tract, endocrine, skin.

Genotoxicity: Not classified

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans: Not available.

Special Remarks on other Toxic Effects on Humans: Not available.

Other Toxic Effects on Humans: Hazardous in case of skin contact (irritant), of ingestion, of inhalation (lung irritant).

Summarized evaluation of the CMR properties:
 STOT-Single exposure

Single exposure	Specific effect	Affected organ	Remark
Acute oral toxicity	NE	NE	NE
Acute dermal toxicity	NE	NE	NE
Acute inhalative toxicity	NE	NE	NE

STOT-Repeated exposure

Repeated exposure	Specific effect	Affected organ	Remark
Sub-acute oral	In clinical use on animals	Kidney, fetus, ears, DNA.	
Sub-acute dermal	NE	NE	
Sub-acute inhalative	NE	NE	
Sub-chronic oral	NE	NE	
Sub-chronic dermal	NE	NE	
Sub-chronic inhalative	NE	NE	

Chronic oral	NE	NE	
Chronic dermal	NE	NE	
Chronic inhalative	NE	NE	

 Route(s) of exposure: Eye contact. Inhalation. Ingestion.

Aspiration Hazard:
 Symptoms related to the physical ,chemical and toxicological characteristic:

In case of ingestion: Not classified In case of skin contact: Not classified In case of inhalation: Not classified In case of eye contact: Not classified

Mixtures:
 Not applicable

· Other information: Not specific

12	Ecological
	information

ECOLOGICAL INFORMATION

· Toxicity:

Aquatic toxicity	Effect dose	Exposure time	SPECIES	Method	Evaluation	Remark
Acute fish toxicity	LC 50	96 H	Data not available	Data not available	Data not available	Data not available
Acute daphnia toxicity	EC 50	48 H	Data not available	Data not available	Data not available	Data not available
Acute algae toxicity	IC 50	72 H	Data not available	Data not available	Data not available	Data not available

Long Term Toxicity:

	Effect dose	Exposure time	SPECIES	Method	Evaluation	Remark
Long- term fish toxicity	LC 50	Data not available	Data not available	Data not available	Data not available	Data not available

Sign / Date: Numbliou

Chronic daphnia toxicity Chronic EC Data not available	Data not available	Data not available	Data not available	Data not available
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· Persistence and degradability:

Abiotic Degradation:

Half Time		Wethod	Evaluation	Remark
Sea water	NE	NE	NE	
Fresh water	NE	NE	NE	
Air	NE	NE	NE	
Soil	NE	NE	NE	

· Physical- and photo-chemical elimination

Biodegradation:

Degradation rate (%)	Time d	Method	Evaluation	Remark
NE	NE	NE	NE	
NE	NE	NE	NE	
NE	NE	NE	NE	

· Bioaccumulative potential

Partition coefficient n-octanol /water (log Kow):

Value	Conc	PH	Deg C	Method	Evaluation	Remark
NE	NE	NE	NE	NE	NE	NE
NE	NE	NE	NE	NE	NE	NE
NE	NE	NE	NE	NE	NE	NE

Bioconcentration factor (BCF):

Values	Species	Method	Evaluation	Remark
NE	NE	NE	NE	NE
NE	NE	NE	NE	NE
NE	NE	NE	NE	NE

· Mobility in soil:

Known or predicted distribution to environmental compartments:

Surface tension:

Value	Deg C	Conc	Method	Remark
NE	NE	NE	NE	NE
NE	NE	NE	NE	NE
NE	NE	NE	NE	NE



		e Ad	sorption	Desorni	ion :			
		Transport		Log	Volatility	Method	Hysterisis	Remark
		Soil- water	NE	NE	NE	NE	NE	NE
		. Water-air	NE	NE	NE	NE	NE	NE
		Soil-air	NE	NE	NE	NE	NE	NE
13	Disposal considerations	• de	gradatio gradatio ioaccum s toxic t bility in ner adve	nal infor in produ nulative than the soil :No	mation: Possucts are not ucts may ari potential: 1 product its of Available ects: Not Available	likely. Horse The productelf. vailable	rdous short wever, long t cts of degrad	erm
		• Produconte • Produconte • Waste • Was • Oth periode	ation luct / Pacents in a codes / ste treat er disponder of commed in the code of the code	kaging of coordar waste doment of sal reconnection accordance to the coordance to the coord	disposal: Dis nce with fed esignations a ptions: Activ ommendation dance with nents	pose of co eral, state according to vated slud ons: Dispo the federa	ontainer and , and local re o EWC / AVV: ge process osal should b il, state or lo	unused egulations NA ee cal

14	Transport	TRANSPORT INFORMATION
	information	NON Hazardous for air, land, sea Transport (Not a DOT Controlled material)
		Environmental hazards: Not established
		Land transport (ADR/RID/GGVSE): UN-No: Not classified Proper shipping name:NA Class(es):Ref Section 2 Classification Code:NA Packing group:NA
		Hazard label(s): Ref Section 2
		Special provision: Not specific
		 Sea transport (IMDG-Code/GGVSee): UN No: Not classified Proper shipping name:NA Class(es): Ref Section 2 Packing group: NA Marine Pollutant: Not established Special provision(s): Not specific Air transport (ICAO-IATA/DGR): UN No: Not classified Proper shipping name: NA Class(es): Ref Section 2 Packing group: NA Special provision(s): Not specific Special precautions for user: Not Specific Additional information: Not specific
15	Regulatory information	REGULATORY INFORMATION Safety, health and environmental regulations/legislation specific for the substance or mixture: NA EU regulations Authorizations and/or restrictions on use:NA
		Authorizations:NA
		Restrictions on use:NA
		Other EU regulations:NA



Information's according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline):NA National regulations (Germany):NA Restrictions of occupation:NA Störfallverordnung (12. BlmSchV):NA Wassergefährdungsklasse (water hazard class):NA Technische Anleitung Luft (TA-Luft):NA · Chemical Safety Assessment: NA 16 Other OTHER INFORMATION information Indication of changes: First version(R-01/2010) Boiling point ,partition coefficient & Molecular formula included · Abbreviations and acronyms:NA-Not applicable,NE-Not established · Key literature references and sources for data: MSDS sheets from science lab, United states national library of medicienes-ChemIdPLUS Lite · Classification for mixtures and used evaluation method according to regulation (EC) 1207/2008 [CLP]:NA · Relevant R-, H- and EUH-phrases (number and full text):Refer section 2.0 · Training advice: Refer SDS before handling the substance · Further information: Preparation information: Prepared By:S S Shaikh-Manager EHS Date: 29-11-2010, Sign: Verified By: Vijay Kumar Suthari Date: 29-11-2010 Sign: