


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	ATENOLOL, USP
PRODUCT CODE	0262
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Pharmaceutical Manufacturing
RESTRICTIONS ON USE	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 5) Skin Irritation (Category 2) Toxic to Reproduction (Effects on or via lactation) Toxic to Reproduction (Category 2) Specific Target Organ Toxicity - Single Exposure (Category 1) - (cardiovascular system) Acute Aquatic Toxicity (Category 3)
PICTOGRAM	
SIGNAL WORD	Danger
HAZARD STATEMENT(S)	May be harmful if swallowed. Causes skin irritation. May cause harm to breast-fed children. Suspected of damaging fertility or the unborn child. Causes damage to organs (cardiovascular system). Harmful to aquatic life. Exposure may produce an allergic reaction.
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Repeated exposure may cause skin dryness or cracking.

PRECAUTIONARY STATEMENT(S)	Prevention	Wash thoroughly after handling. Obtain, read and follow all special instructions before use. Do not breathe dust, fume, gas, mist, vapors and spray. Avoid contact during pregnancy and while nursing. Do not eat, drink or smoke when using this product. Do not handle until all safety precautions have been read and understood. Wear protective gloves, protective clothing, eye and face protection and hearing protection. Avoid release to the environment.		
	Response	IF ON SKIN (HAIR): Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. IF EXPOSED: Get emergency medical help immediately. Call a poison center or doctor. IF SWALLOWED: Get medical help.		
	Storage	Store locked up.		
	Disposal	Dispose of contents and/or container in accordance with local regulations.		
HMIS CLASSIFICATION	Health Hazard	2	Flammability	1
	Reactivity	0	Personal Protection	G

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	Benzeneacetamide, 4-[2-hydroxy-3-[(1-methylethyl)amino]propoxy]-
BOTANICAL NAME	Not applicable
SYNONYM	Not available
CHEMICAL FORMULA	C ₁₄ H ₂₂ N ₂ O ₃
CHEMICAL FAMILY	Propranolamine
CAS NUMBER	29122-68-7
ALTERNATE CAS NUMBER	60966-51-0
MOLECULAR WEIGHT	266.3388

COMPOSITION	CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
	ATENOLOL	29122-68-7	249-451-7	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

NOTES Atenolol is a cardioselective beta-1 adrenergic blocker without a negative inotropic effect. It is reported to lack intrinsic sympathomimetic activity and membrane-stabilising properties.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
IF SWALLOWED	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician

**MEDICAL ATTENTION AND
SPECIAL TREATMENT**

Get emergency medical help.

**SYMPTOMS CAUSED BY
EXPOSURE**

Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES**SPECIFIC HAZARDS ARISING
FROM THE CHEMICAL**

Not applicable

FLAMMABLE PROPERTIES

May be combustible at high temperature

**HAZARDOUS COMBUSTION
PRODUCTS**

Under fire conditions, hazardous fumes will be present.

**SUITABLE & UNSUITABLE
EXTINGUISHING MEDIA**

Small fire: dry chemical, CO₂ or water spray. **Large fire:** dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

**PROTECTIVE EQUIPMENT AND
PRECAUTIONS FOR
FIREFIGHTERS**

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES**PERSONAL PRECAUTIONS**

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

**METHODS & MATERIAL FOR
CONTAINMENT**

On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

**REFERENCE TO OTHER
SECTIONS**

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE**PRECAUTIONS FOR SAFE
HANDLING**

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**CONDITIONS FOR SAFE
STORAGE**

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40 °C are acceptable.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: ATENOLOL CAS #: 29122-68-7

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³.

**PERSONAL PROTECTIVE
EQUIPMENT**

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

**SPECIFIC ENGINEERING
CONTROLS**

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

NOTES

USP: ELV: Industrial: TWA: 2 mg/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
**PHYSICAL
STATE**

Solid

DESCRIPTION

White or practically white, odorless powder.

SOLUBILITY

Freely soluble in methanol; sparingly soluble in alcohol; slightly soluble in water and in isopropanol.

ODOR

Odorless

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE	Not available	BOILING POINT	508 °C, 946.4 °F (760 mmHg)	DECOMPOSITION TEMPERATURE	Not available
EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available	FLASH POINT	261 °C, 501.8 °F
log P (OCTANOL-WATER)	0.16 (20°C)	LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	(152 - 156.5)°C, (305.6-313.7)°F
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	5.5 - 6.5
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	Not available	UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	2.92E-10 mmHg (25°C)	VISCOSITY	Not available

The physical data presented above are typical values and should not be construed as a specification.

NOTES

Melting point: (146–148)°C; (294.8-298.4)°F (Crystals from ethyl acetate).

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
CHEMICAL STABILITY	Stable under recommended storage conditions
INCOMPATIBLE MATERIALS	Strong oxidants
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
HAZARDOUS POLYMERIZATION	Will not occur
POSSIBILITY OF HAZARDOUS REACTION	Not established
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): > 2000 Dermal: Rabbit: LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Causes skin irritation. Skin irritancy test (repeated application): Rat: Moderately irritant.
SERIOUS EYE DAMAGE/EYE IRRITATION	Due to lack of data the classification is not possible.
RESPIRATORY SENSITIZATION	Due to lack of data the classification is not possible. Exposure may produce an allergic reaction.

SKIN SENSITIZATION

Based on available data, the classification criteria are not met.
Suspected skin sensitizer: CAESAR skin sensitization model in VEGA (Q)SAR platform predicts that the chemical is Sensitizer (moderate reliability)

GERM CELL MUTAGENICITY

Based on available data, the classification criteria are not met.
Mutagenicity:
Ames test in *S. typhimurium*: Negative.
Dominant lethal test in mice: Negative.
In vivo cytogenetic test in Chinese hamsters: Negative.

CARCINOGENICITY

OSHA	ATENOLOL is not listed.
NTP	ATENOLOL is not listed.
IARC	ATENOLOL is not evaluated.
California Proposition	This product contains the following chemical known to the State of California to cause birth defects or other reproductive harm: ATENOLOL.

ADDITIONAL CARCINOGENICITY INFORMATION

Based on available data, the classification criteria are not met.
Long-term carcinogenicity study: Rat: 24 months: 500 - 1500 mg/kg/day: Tumorigenic.
Long-term carcinogenicity studies: Rat: 24 months: ≤ 300 mg/kg/day: No carcinogenic potential.
Long-term carcinogenicity study: Mouse: 18 months: ≤ 300 mg/kg/day: No carcinogenic potential.

REPRODUCTIVE TOXICITY

Suspected of damaging fertility or the unborn child.
Atenolol was found to be associated with lower birth weight and ponderal index values, with a trend toward a higher prevalence of preterm (<37 weeks) delivery and small-for-gestational-age babies when compared to other antihypertensive drugs as monotherapy, or to no treatment. Placental hypoplasia associated with growth retardation and intrauterine death were common. Growth retardation was more pronounced when women received the drug early in pregnancy or for a long duration. Atenolol has not been associated with structural abnormalities in humans or in experimental animals.
Reproductivity and development study: Rabbit: 1600 mg/kg: Fetal lethality; no teratogenicity.
Reproductivity and development study: Rat: 20 - 2000 mg/kg/day: Fetal lethality at high doses; no teratogenicity.
Fertility study: Rat: 200 mg/kg/day: No adverse effects on male or female fertility.
Reproductivity and development study: Rat: ≥ 50 mg/kg/day: Dose-related increase in resorptions.
Breast feeding: Atenolol is distributed into breast milk and there has been a report of cyanosis and bradycardia in a breastfed neonate whose mother had been taking atenolol. The American Academy of Pediatrics therefore considers that it should be given with caution to breast-feeding mothers.
Suspected toxic for reproduction: The Toolbox profiler DART scheme v.1.0 gives an alert for toxicity to reproduction; CAESAR developmental toxicity model in VEGA (Q)SAR platform predicts that the chemical is Toxicant (good reliability); Developmental/Reproductive Toxicity library (PG) in VEGA (Q)SAR platform predicts that the chemical is Toxicant (EXPERIMENTAL value); DART database in the Toolbox reports that this substance as Known developmental potential

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Causes damage to organs (cardiovascular system).

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

Due to lack of data the classification is not possible.

ASPIRATION HAZARDS

Based on available data, the classification criteria are not met.

**SIGNS AND SYMPTOMS OF
EXPOSURE****ROUTES OF EXPOSURE:**

Oral, Dermal, Inhalation, Eyes

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

Beta-adrenergic blockers:

Cardiovascular effects. Hypotension. Respiratory depression or arrest. Coma.

Symptoms related to the physical, chemical, and toxicological characteristics: Beta-adrenergic blockers:

Nausea. Vomiting. Dizziness. Difficulty breathing. Headache. Mood or mental changes. Drowsiness.

Weakness. Slow heartbeat. Insomnia. Cold hands and feet. Sexual dysfunction. Stomach upset.

Nervousness. Vision disturbances. Swelling of feet or legs. Muscle, joint, or chest pain. Seizures.

Cross sensitivity: Persons sensitive to one beta-adrenergic blocker may be sensitive to this material also.

Medical conditions aggravated by exposure: Beta-adrenergic blockers: Heart disorders. Hypotension.

Peripheral vascular disease. Respiratory disorders. Psoriasis. History of allergies. Type 1 diabetes.

Hyperthyroidism. Depression. Pheochromocytoma. Impaired liver or kidney function.

POTENTIAL HEALTH EFFECTS**Inhalation** May be harmful if inhaled. May cause respiratory tract irritation.**Ingestion** May be harmful if swallowed.**Skin** May be harmful if absorbed through skin. Causes skin irritation.**Eyes** May cause eye irritation.**SECTION 12: ECOLOGICAL INFORMATION****ECOTOXICITY**

EC50: 48 Hr: Crustacea: Daphnia magna: (mg/L): 33.4

LC50: 96 Hr: Fish: (mg/L): > 100

EC50: 96 Hr: Gree Algae: (mg/L): 45.42

**PERSISTENCE AND
DEGRADABILITY**

Suspected persistent in the environment: Ready biodegradability model (IRFMN) in VEGA (Q)SAR

platform predicts that the chemical is NON Readily Biodegradable (moderate reliability);The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable.

BIOACCUMULATIVE POTENTIAL

Log Pow: 0.16 (20°C)

MOBILITY IN SOIL

Water Solubility: 1.33E+04mg/L (25°C)

Henry's Law Constant: 1.37E-18 atm-m³/mole (25°C)**OTHER ADVERSE EFFECTS**

Not available

This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS**DISPOSAL METHODS**

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION**UN PROPER SHIPPING NAME**

Not dangerous good

UN NUMBER

Not applicable

CLASS

Not applicable

PACKING GROUP Not applicable

AUSTRALIA
HAZCHEM Not applicable

EU
**TRANSPORT IN BULK ACCORDING
TO ANNEX II OF MARPOL 73/78
AND THE IBC CODE** Not listed

ENVIRONMENTAL HAZARDS Not available

**SPECIAL SHIPPING
INFORMATION** Not applicable

SECTION 15: REGULATORY INFORMATION
UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR	EPA 40 CFR Part 355		Pennsylvania	Right-to-know			California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts		
ATENOLOL 29122-68-7	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L	X

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
ATENOLOL 29122-68-7	N/L	Listed as Schedule 4	N/L	Listed	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
ATENOLOL 29122-68-7	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

**SUBJECT TO INTERNATIONAL
AGREEMENT** Not applicable

SECTION 16: OTHER INFORMATION
REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

02/2023

SUPERSEDES

04/2021

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.