



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

- **1.1 Product identifier**
- **Trade name:** atenolol
- **Article number:** 109402, 100156
- **CAS Number:**
29122-68-7
- **EC number:**
249-451-7
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Pharmaceutical intermediate
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
FAGRON a.s.
Holická 1098/31m
779 00 Olomouc
Česká republika
- **Further information obtainable from:**
Tel.: +420 585 222 590
info@fagron.cz
- **1.4 Emergency telephone number:**
Toxikologické informační středisko,
Na Bojišti 1,
128 08 Praha 2
tel.: +420 224 919 293, +420 224 915 402 (nepřetržitá lékařská služba),
e-mail:tis.cuni@cesnet.cz

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Acute Tox. 4 H302 Harmful if swallowed.
Eye Irrit. 2 H319 Causes serious eye irritation.
Carc. 2 H351 Suspected of causing cancer.
Lact. H362 May cause harm to breast-fed children.
STOT SE 3 H336 May cause drowsiness or dizziness.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The substance is classified and labelled according to the CLP regulation.
- **Hazard pictograms**

GHS07 GHS08
- **Signal word** Warning
- **Hazard statements**
H302 Harmful if swallowed.

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- H319 Causes serious eye irritation.
- H351 Suspected of causing cancer.
- H362 May cause harm to breast-fed children.
- H336 May cause drowsiness or dizziness.

· **Precautionary statements**

- P260 Do not breathe dusts or mists.
- P263 Avoid contact during pregnancy and while nursing.
- P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P405 Store locked up.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

* **SECTION 3: Composition/information on ingredients**

· **3.1 Chemical characterisation: Substances**

- **CAS No. Description**
CAS: 29122-68-7 atenolol
- **Identification number(s)**
- **EC number:** 249-451-7

* **SECTION 4: First aid measures**

· **4.1 Description of first aid measures**

· **General information:**

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

- **After inhalation:** Supply fresh air; consult doctor in case of complaints.

- **After skin contact:** Generally the product does not irritate the skin.

· **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- **After swallowing:** Call for a doctor immediately.

· **4.2 Most important symptoms and effects, both acute and delayed**

No further relevant information available.

· **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

SECTION 5: Firefighting measures

· **5.1 Extinguishing media**

· **Suitable extinguishing agents:**

Use fire extinguishing methods suitable to surrounding conditions.

· **5.2 Special hazards arising from the substance or mixture**

In case of fire, the following can be released:

Carbon monoxide (CO)

Nitrogen oxides (NOx)

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- **5.3 Advice for firefighters**
- **Protective equipment:**
Wear fully protective suit.
Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to item 13.
- **6.4 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

- **7.1 Precautions for safe handling** No special precautions are necessary if used correctly.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Additional information about design of technical facilities:** No further data; see item 7.
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes.
Avoid contact with the eyes and skin.
- **Respiratory protection:** Filter P2
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

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- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:**



Tightly sealed goggles

- **Body protection:** Protective work clothing

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Crystalline powder
Colour:	White
- **Odour:** Nearly odourless
- **Odour threshold:** Not determined.
- **pH-value:** 4
- **Change in condition**

Melting point/freezing point:	146–155°C
Initial boiling point and boiling range:	Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Product is not flammable.
- **Decomposition temperature:** Not determined.
- **Auto-ignition temperature:** Not determined.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.
- **Vapour pressure:** Not applicable.
- **Density:** Not determined.
- **Relative density** Not determined.
- **Vapour density** Not applicable.
- **Evaporation rate** Not applicable.
- **Solubility in / Miscibility with water:** Insoluble.
- **Partition coefficient: n-octanol/water:** Not determined.
- **Viscosity:**

Dynamic:	Not applicable.
Kinematic:	Not applicable.
- **9.2 Other information** No further relevant information available.

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SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:**
Carbon monoxide and carbon dioxide
Nitrogen oxides (NO_x)

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity**
Harmful if swallowed.
- **LD/LC50 values relevant for classification:**

Oral	LD50	2000 mg/kg (rat)
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- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity**
Suspected of causing cancer.
- **Reproductive toxicity**
May cause harm to breast-fed children.
- **STOT-single exposure**
May cause drowsiness or dizziness.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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- **12.6 Other adverse effects** No further relevant information available.

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SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
· **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **European waste catalogue**

HP4	Irritant - skin irritation and eye damage
HP5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity
HP6	Acute Toxicity
HP7	Carcinogenic

- **Uncleaned packaging:**
· **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

· 14.1 UN-Number · ADR, IMDG, IATA	not regulated
· 14.2 UN proper shipping name · ADR, IMDG, IATA	not regulated
· 14.3 Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class	not regulated
· 14.4 Packing group · ADR, IMDG, IATA	not regulated
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	not regulated

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **Directive 2012/18/EU**
· **Named dangerous substances - ANNEX I** Substance is not listed.
· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**
Substance is not listed.
· **REGULATION (EU) 2019/1148**
· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**
Substance is not listed.

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- **Annex II - REPORTABLE EXPLOSIVES PRECURSORS** Substance is not listed.
- **Regulation (EC) No 273/2004 on drug precursors** Substance is not listed.
- **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors** Substance is not listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing SDS:** Fagron Česká republika
- **Contact:** msds@fagron.cz
- **Abbreviations and acronyms:**
 - ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
 - IMDG: International Maritime Code for Dangerous Goods
 - IATA: International Air Transport Association
 - GHS: Globally Harmonised System of Classification and Labelling of Chemicals
 - EINECS: European Inventory of Existing Commercial Chemical Substances
 - CAS: Chemical Abstracts Service (division of the American Chemical Society)
 - LC50: Lethal concentration, 50 percent
 - LD50: Lethal dose, 50 percent
 - PBT: Persistent, Bioaccumulative and Toxic
 - vPvB: very Persistent and very Bioaccumulative
 - Acute Tox. 4: Acute toxicity – Category 4
 - Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
 - Carc. 2: Carcinogenicity – Category 2
 - Lact.: Reproductive toxicity – effects on or via lactation
 - STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
- *** Data compared to the previous version altered.**

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