

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

- **1.1 Product identifier**
- **Trade name:** Babynol – dětská mast s rybím tukem
- **Article number:** 606850
- **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**
Skin cosmetics
Additive for cosmetic or pharmaceutical preparations
- **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**
Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.
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- **2.2 Label elements**
 - **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
 - **Hazard pictograms**



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- **Signal word** Void
- **Hazard statements**
H411 Toxic to aquatic life with long lasting effects.
- **Precautionary statements**
P273 Avoid release to the environment.
P391 Collect spillage.
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.

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· vPvB: Not applicable.

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SECTION 3: Composition/information on ingredients

· 3.2 Mixtures

· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

| | | | |
|-------------------|------------|--|----------|
| CAS: 1314-13-2 | zinc oxide | Aquatic Acute 1, H400; Aquatic Chronic 1, H410 | ≥10—<25% |
| EINECS: 215-222-5 | | | |

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

· 4.1 Description of first aid measures

· **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:** If symptoms persist consult doctor.

· 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

No further relevant information available.

· 5.3 Advice for firefighters

· **Protective equipment:** 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 product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system.

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

· 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to section 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.

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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:**
Store in cool, dry conditions in well sealed receptacles.
Protect from heat and direct sunlight.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
- **Respiratory protection:**
Filter P1
Suitable respiratory protective device recommended.
- **Hand protection**
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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **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/face protection** Goggles recommended during refilling
- **Body protection:** Protective work clothing

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Fluid
- **Colour:** Yellowish
- **Odour:** Characteristic

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| | |
|--|---|
| · Odour threshold: | Not determined. |
| · Melting point/freezing point: | Undetermined. |
| · Boiling point or initial boiling point and boiling range | 100°C (CAS: 7732-18-5 Water, distilled, conductivity or of similar purity) |
| · Flammability | Not applicable. |
| · Lower and upper explosion limit | |
| · Lower: | Not determined. |
| · Upper: | Not determined. |
| · Flash point: | >150°C (CAS: 8002-74-2 Vaselinum Album Paraffinum solidum Paraffin, white soft) |
| · Auto-ignition temperature: | >290°C (CAS: 8006-54-0 HydroLano™ Lanolin anhydrous Lanolinum anhydricum) |
| · Decomposition temperature: | Not determined. |
| · pH | Not determined. |
| · Viscosity: | |
| · Kinematic viscosity | Not determined. |
| · Dynamic: | Not determined. |
| · Solubility | |
| · water: | Fully miscible. |
| · Partition coefficient n-octanol/water (log value) | Not determined. |
| · Vapour pressure: | Not determined. |
| · Density and/or relative density | |
| · Density: | Not determined. |
| · Relative density | Not determined. |
| · Vapour density | Not determined. |

| | |
|---|---|
| 9.2 Other information | |
| · Appearance: | |
| · Form: | Fluid |
| · Important information on protection of health and environment, and on safety. | |
| · Ignition temperature: | Product is not selfigniting. |
| · Explosive properties: | Product does not present an explosion hazard. |
| · Solvent content: | |
| · Water: | 6,0 % |
| · VOC (EC) | 0,00 % |
| · Solids content: | 79,0 % |
| · Change in condition | |
| · Evaporation rate | Not determined. |

| | |
|---|------|
| Information with regard to physical hazard classes | |
| · Explosives | Void |
| · Flammable gases | Void |
| · Aerosols | Void |
| · Oxidising gases | Void |
| · Gases under pressure | Void |
| · Flammable liquids | Void |
| · Flammable solids | Void |
| · Self-reactive substances and mixtures | Void |

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| | |
|---|------|
| · Pyrophoric liquids | Void |
| · Pyrophoric solids | Void |
| · Self-heating substances and mixtures | Void |
| · Substances and mixtures, which emit flammable gases in contact with water | Void |
| · Oxidising liquids | Void |
| · Oxidising solids | Void |
| · Organic peroxides | Void |
| · Corrosive to metals | Void |
| · Desensitised explosives | Void |

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:** No dangerous decomposition products known.

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

- **LD/LC50 values relevant for classification:**

CAS: 1314-13-2 zinc oxide

| | | |
|------|------|-------------------|
| Oral | LD50 | >5000 mg/kg (rat) |
|------|------|-------------------|

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **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.
- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.

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- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Remark:** Toxic for fish
- **Additional ecological information:**
- **General notes:**
Also poisonous for fish and plankton in water bodies.
Toxic for aquatic organisms
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.

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**

| | |
|------|----------|
| HP14 | Ecotoxic |
|------|----------|
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

| | |
|---|-----------------|
| · 14.1 UN number or ID 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 Maritime transport in bulk according to IMO instruments | Not applicable. |
| · UN "Model Regulation": | not regulated |

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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** None of the ingredients is listed.
- **Seveso category E2** Hazardous to the Aquatic Environment
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

- **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

- **REGULATION (EU) 2019/1148**

- **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

- **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

- **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

- **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is 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.

- **Relevant phrases**

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

- **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

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2