

Safety Data Sheet

acc. to OSHA HCS

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Printing date 03/11/2024
Reviewed on 03/11/2024

1 Identification

- **Product identifier**
- **Trade name:** Babynol – dětská mast s panthenolem
- **Article number:** 605113
- **Application of the substance / the mixture**
Additive for cosmetic or pharmaceutical preparations
Skin cosmetics
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Fagron Inc
2400 Pilot Knob Road
St. Paul, MN 55120
www.fagron.us
QA@fagron.us
- **Information department:**
Tel.: 800-423-6967
Fax: 800-339-1596
- **Emergency telephone number:**
Emergency Telephone:
US: 1-800-535-5053
International: 1-352-323-3500

2 Hazard(s) identification

- **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonized System (GHS).
- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**

HEALTH	0	Health = 0
FIRE	1	Fire = 1
REACTIVITY	0	Reactivity = 0

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

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3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with nonhazardous additions.

· Dangerous components:		
CAS: 8002-74-2	Vaselinum Album Paraffinum solidum Paraffin, white soft	10–≤25%
CAS: 8012-95-1	Paraffinum liquidum	3–≤5%

4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **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.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Particular danger of slipping on leaked/spilled product.
- **Environmental precautions:** Dilute with plenty of water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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.
- **Protective Action Criteria for Chemicals**

· PAC-1:		
CAS: 112-92-5	Stearylalkohol octadecan-1-ol	5.4 ppm

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CAS: 36653-82-4	Cetylalcohol Alcohol cetylicus	1.6 mg/m ³
· PAC-2:		
CAS: 112-92-5	Stearylalkohol octadecan-1-ol	60 ppm
CAS: 36653-82-4	Cetylalcohol Alcohol cetylicus	18 mg/m ³
· PAC-3:		
CAS: 112-92-5	Stearylalkohol octadecan-1-ol	360 ppm
CAS: 36653-82-4	Cetylalcohol Alcohol cetylicus	110 mg/m ³

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** No special measures required.
- **Information about protection against explosions and fires:** No special measures required.
- **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.
Protect from exposure to the light.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters**

· Components with limit values that require monitoring at the workplace:	
CAS: 8002-74-2 Vaselinum Album Paraffinum solidum Paraffin, white soft	
REL	Long-term value: 2 mg/m ³
TLV	Long-term value: 2 mg/m ³
CAS: 8012-95-1 Paraffinum liquidum	
PEL	Long-term value: 5 mg/m ³
REL	Short-term value: 10 mg/m ³ Long-term value: 5 mg/m ³ oil mist
TLV	L

- **Additional information:** The lists that were valid during the creation were used as basis.

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- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
- **Breathing equipment:**
Suitable respiratory protective device recommended.
Filter P1
- **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. 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 protection:** Goggles recommended during refilling.
- **Body protection:** Protective work clothing

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form: Highly viscous

Color: Yellowish

· Odor: Characteristic

· Odor threshold: Not determined.

· pH-value: Not determined.

· Change in condition

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: 100°C (212°F)

· Flash point: >150°C (>302°F)

· Flammability (solid, gaseous): Not applicable.

· Auto igniting: >290°C (>554°F)

· Decomposition temperature: Not determined.

· Ignition temperature: Product is not selfigniting.

· Danger of explosion: Product does not present an explosion hazard.

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· Explosion limits: Lower: Upper:	Not determined. Not determined.
· Vapor pressure at 20°C (68°F):	23 hPa (17.3 mm Hg)
· Density at 20°C (68°F):	~0.94849 g/cm ³ (~7.91515 lbs/gal)
· Bulk density: · Relative density · Vapor density · Evaporation rate	~948 kg/m ³ Not determined. Not determined. Not determined.
· Solubility in / Miscibility with Water:	Fully miscible.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity: Dynamic: Kinematic:	Not determined. Not determined.
· Solvent content: Water: VOC content:	34.8 % 0.00 % 0.0 g/l / 0.00 lb/gal
· Solids content:	35.3 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· LD/LC50 values that are relevant for classification:		
CAS: 8012-95-1 Paraffinum liquidum		
Oral	LD50	>5000 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (rabbit)
Inhalative	LC50/4 h	>5 mg/l (rat)

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- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
The product is not subject to classification according to internally approved calculation methods for preparations:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

- **Carcinogenic categories**

· IARC (International Agency for Research on Cancer)
None of the ingredients is listed.
· NTP (National Toxicology Program)
None of the ingredients is listed.
· OSHA-Ca (Occupational Safety & Health Administration)
None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Not hazardous for water.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:** Smaller quantities can be disposed of with household waste.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

· UN-Number	
· DOT, IMDG, IATA	not regulated
· UN proper shipping name	
· DOT, IMDG, IATA	not regulated

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· Transport hazard class(es)	
· DOT, ADN, IMDG, IATA	
· Class	not regulated
· Packing group	
· DOT, IMDG, IATA	not regulated
· Environmental hazards:	Not applicable.
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· UN "Model Regulation":	not regulated

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
No further relevant information available.

- Sara

- Section 355 (extremely hazardous substances):

None of the ingredients is listed.

- Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

- TSCA (Toxic Substances Control Act):

All components have the value ACTIVE.

- Hazardous Air Pollutants

None of the ingredients is listed.

- Proposition 65

- Chemicals known to cause cancer:

None of the ingredients is listed.

- Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

- Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

- Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

- Carcinogenic categories

- EPA (Environmental Protection Agency)

None of the ingredients is listed.

- TLV (Threshold Limit Value)

None of the ingredients is listed.

- NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

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- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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 US

Quality Assurance

- **Contact:** QA@fagron.us

- **Date of preparation / last revision** 03/11/2024

- **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

DOT: US Department of Transportation

IATA: International Air Transport Association

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

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