according to WHS Regulations

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1 Identification

- · Product identifier
- · Trade name: Babynol dětská mast s panthenolem
- · Article number: 605113
- Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- Application of the substance / the mixture
 Additive for cosmetic or pharmaceutic preparations
 Skin cosmetics
- · Details of the supplier of the safety data sheet
- Manufacturer/Supplier:

Fagron Services B.V.

Molenwerk 13, UITGEEST, 1911DB

Netherlands

Australia

Phone: +31251361400

Supplier Azelis Australia Suite 217 117 Old Pittwater Road Brookvale NSW 2100

Phone: +61 0299392188 Fax: +61 0299392799 e-mail: info@azelis.com.au

- · Further information obtainable from: info@fagron.com.au
- · Emergency telephone number:

In case of emergency, please call your local poisons:

Emergency Australia: 13 11 26

Emergency NZ: 0800 764 766 (0800 POISON)

1800 127 406 (24 h, Australia) | +64 4 917 9888 (24 h, Worldwide) CareChem 24x7 : EUROPE: +44 1235 239670 | USA: +1 202 464 2554 | CANADA - +1 800 579 7421 (Toll Free)| ASIA - +65 3158 1074 | MOROCCO - +44 1235 239671 | REST OF THE WORLD - +44 1865 407333 (English only)

2 Hazard(s) Identification

· Classification of the substance or mixture

The product is not classified, according to the Globally Harmonised System (GHS).

- · Label elements
- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Other hazards
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.

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· vPvB: Not applicable.

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3 Composition and Information on Ingredients

- · Chemical characterisation: Mixtures
- · **Description:** Mixture of substances listed below with nonhazardous additions.

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

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

4 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:
- $\boldsymbol{\cdot}$ 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

- · Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.
- · Special hazards arising from the substance or mixture No further relevant information available.
- · 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.

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7 Handling and Storage

- · Handling:
- · Precautions for safe handling No special measures required.
- Information about fire and explosion protection: No special measures required.
- · 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 and personal protection

- · Additional information about design of technical facilities: No further data; see section 7.
- · Ingredients with limit values that require monitoring at the workplace:

CAS: 8002-74-2 Vaselinum Album

Paraffinum solidum Paraffin, white soft

WES Long-term value: 2 mg/m³

CAS: 8012-95-1 Paraffinum liquidum

WES Long-term value: 5 mg/m³

- · Additional information: The lists valid during the making were used as basis.
- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Respiratory protection:

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

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· Body protection: Protective work clothing

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9 Physical and Chemical Properties

· General Information

· Appearance:

Form: Highly viscous
Colour: Yellowish
Odour: Characteristic
Odour threshold: Not determined.
pH-value: Not determined.

· Change in condition

• **Melting point/freezing point:** Undetermined.

Initial boiling point and boiling range: 100°C
 Flash point: >150°C
 Flammability (solid, gas): Not applicable.

· Auto-ignition temperature: >290°C

Decomposition temperature:Ignition temperature:Product is not selfigniting.

• Explosive properties: Product does not present an explosion hazard.

Explosion limits:

Lower: Not determined.Upper: Not determined.

· Vapour pressure at 20°C: 23 hPa

Density at 20°C: ~0.94849 g/cm³
 Bulk density: ~948 kg/m³
 Relative density Not determined.
 Vapour density Not determined.
 Evaporation rate Not determined.

· Solubility in / Miscibility with

water: Fully miscible.
 Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic: Not determined.Kinematic: Not determined.

· Solvent content:

⋅ Water: 34.8 %
 ⋅ VOC (EC) 0.00 %
 ⋅ Solids content: 35.3 %

· Other information No further relevant information available.

10 Stability and Reactivity

- · Reactivity No further relevant information available.
- 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.

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- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological Information

- · Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:	evant for classification:		
	CAS: 8012	2-95-1 Par	affinum liquidum
	Oral	LD50	>5000 mg/kg (rat)
	Dermal	LD50	>2000 mg/kg (rabbit)
	Inhalative	LC50/4 h	>5 mg/l (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.

12 Ecological Information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behaviour 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 packaging:
- · Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

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14 Transport information

· UN-Number · ADG, IMDG, IATA	not regulated	
· UN proper shipping name · ADG, IMDG, IATA	not regulated	
· Transport hazard class(es)		
· ADG, ADN, IMDG, IATA · Class	not regulated	
· Packing group · ADG, IMDG, IATA	not regulated	
· Environmental hazards:	Not applicable.	
· Special precautions for user	Not applicable.	
· Transport in bulk according to Anno Marpol and the IBC Code	ex II of Not applicable.	
· UN "Model Regulation":	not regulated	

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Australian Inventory of Industrial Chemicals

All ingredients are listed.

· Standard for the Uniform Scheduling of Medicines and Poisons

None of the ingredients is listed.

· Australia: Priority Existing Chemicals

None of the ingredients is listed.

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · National regulations:
- · Other regulations, limitations and prohibitive regulations

Therapeutic goods are listed on the Australian Register of Therapeutic Goods(ARTG)

· 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: Product Safety Department
- Contact:
- 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



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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

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