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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 pharmaceutic preparations
- 1.3 Details of the supplier of the safety data sheet
 Manufacturer/Supplier: Fagron UK Ltd
 4B Coquet St
 Newcastle upon Tyne
 England NE1 2QB
 Tel. 0845 6522525
- **Further information obtainable from:** Emergency response telephone number: +44 (0) 845 652 2525
- **1.4 Emergency telephone number:** Emergency response telephone number: +44 (0) 845 652 2525

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.

· 2.2 Label elements

- · Labelling according to Regulation (EC) No 1272/2008
- The product is classified and labelled according to the GB CLP regulation.
- Hazard pictograms



· 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.
- **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: 8002-74-2 EINECS: 232-315-6	Vaselinum Album Paraffinum solidum Paraffin, white soft substance with a Community workplace exposure limit	25–≤50%		
CAS: 1314-13-2 EINECS: 215-222-5	zinc oxide Aquatic Acute 1, H400; Aquatic Chronic 1, H410	≥10–<25%		
• 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

- \cdot 7.1 Precautions for safe handling No special precautions are necessary if used correctly.
- \cdot Information about fire and explosion protection: No special measures required.
- \cdot 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
- Ingredients with limit values that require monitoring at the workplace:
- CAS: 8002-74-2 Vaselinum Album Paraffinum solidum
 - Paraffin, white soft
- WEL Short-term value: 6 mg/m³
 - Long-term value: 2 mg/m³
- · 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



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9.1 Information on basic physical and ch General Information	emical properties		
	Fluid		
Physical state			
Colour:	Yellowish		
Odour:	Characteristic		
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.		
рН	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 haza	Ind		
classes			
• Explosives			
· Flammable gases	Void		
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· Aerosols	Void	
 Oxidising gases 	Void	
· Gases under pressure	Void	
Flammable liquids	Void	
Flammable solids	Void	
· Self-reactive substances and mixtures	Void	
· 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.
- \cdot 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.



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personalizing medicine

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.
- · **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.

- · 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 IMO instruments 	ng to Not applicable.	
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· 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 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
- · 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 UK

Quality Assurance

· Contact: quality@fagron.co.uk

· 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

* Data compared to the previous version altered.



GB