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

- · 1.1 Product identifier
- · Trade name: Ondřejova mast
- · Article number: 601354
- 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 Additive for cosmetic or pharmaceutic 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

Skin Irrit. 2 H315 Causes skin irritation.

Eye Dam. 1 H318 Causes serious eye damage.

Skin Sens. 1 H317 May cause an allergic skin reaction.

Repr. 2 H361d Suspected of damaging the unborn child.

Aquatic Chronic 3 H412 Harmful 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 CLP regulation.

· Hazard pictograms







GHS05 GHS07 GHS08

- · Signal word Danger
- · Hazard-determining components of labelling:

Salicylic acid

Lavender, Lavandula angustifolia, ext.

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· Hazard statements

H315 Causes skin irritation.

H318 Causes serious eye damage.

H317 May cause an allergic skin reaction.

H361d Suspected of damaging the unborn child.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing.

Immediately call a POISON CENTER/doctor. P310

P321 Specific treatment (see on this label).

P362+P364 Take off contaminated clothing and wash it before reuse.

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.

· Determination of endocrine-disrupting properties

CAS: 69-72-7 Salicylic acid List II; III

SECTION 3: Composition/information on ingredients

· 3.2 Mixtures

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

· Dangerous components:		
EINECS: 289-995-2	Lavender, Lavandula angustifolia, ext. Aquatic Chronic 2, H411; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	≥10-<25%
	Salicylic acid Repr. 2, H361d; Eye Dam. 1, H318; Acute Tox. 4, H302	5–≤10%

[·] 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
- General information: Immediately remove any clothing soiled by the product.
- · After inhalation:

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

After skin contact:

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

- · After eye contact: Rinse opened eye for several minutes under running water. Then 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.

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• 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:

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

• 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

Wear protective equipment. Keep unprotected persons away.

· 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).

Use neutralising agent.

Dispose contaminated material as waste according to section 13.

Ensure adequate ventilation.

· 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

Ensure good ventilation/exhaustion at the workplace.

Open and handle receptacle with care.

Prevent formation of aerosols.

- · Information about fire and explosion protection: Keep respiratory protective device available.
- · 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.

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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:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Store protective clothing separately.

Avoid contact with the eyes and skin.

· Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Filter P1

· Hand protection



Protective gloves

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.

· Eve/face protection



Tightly sealed goggles

· Body protection: Protective work clothing

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SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

Physical state
Colour:
Odour:
Odour threshold:
Melting point/freezing point:

Fluid
Yellowish
Characteristic
Not determined.
Undetermined.

· Boiling point or initial boiling point and boiling

range 211°C (CAS: 69-72-7 Salicylic acid)

· Flammability Not applicable.

Lower and upper explosion limit

Lower: 0,6 Vol % (CAS: 8012-95-1 Paraffinum liquidum)
Upper: 6,5 Vol % (CAS: 8012-95-1 Paraffinum liquidum)
Flash point: 66°C (CAS: 90063-37-9 Lavender, Lavandula

angustifolia, ext.)

• **Auto-ignition temperature:** >290°C (CAS: 8006-54-0 HydroLano™

Lanolin anhydrous Lanolinum anhydricum)

• Decomposition temperature: Not determined. • pH Not determined.

· Viscosity:

Kinematic viscosityDynamic:Not determined.Not determined.

Solubility

· water: Fully miscible.

· Partition coefficient n-octanol/water (log

value) Not determined.

· **Vapour pressure at 20°C:** >0,1 hPa (CAS: 8012-95-1 Paraffinum liquidum)

· Density and/or relative density

• **Density at 20°C:** ~0.83445~~0.9441 g/cm³

Relative density
 Bulk density:
 Vapour density
 Not determined.
 823-~933 kg/m³
 Not determined.

· 9.2 Other information

· Appearance:

· Form: Pasty

· 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:

• VOC (EC) 0,00 % • Solids content: 860.4 %

· Change in condition

• Evaporation rate Not determined.

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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	
· 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:

ATE (Acute Toxicity Estimates)

Oral LD50 8910 mg/kg (rat)

CAS: 69-72-7 Salicylic acid

Oral LD50 891 mg/kg (rat)

- · Skin corrosion/irritation Causes skin irritation.
- · Serious eye damage/irritation Causes serious eye damage.
- · Respiratory or skin sensitisation May cause an allergic skin reaction.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.

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- · Reproductive toxicity Suspected of damaging the unborn child.
- · 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

CAS: 69-72-7 Salicylic acid

List II: III

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

For information on endocrine disrupting properties see section 11.

- · 12.7 Other adverse effects
- · Remark: Harmful to fish
- · Additional ecological information:
- · General notes:

Must not reach sewage water or drainage ditch undiluted or unneutralised.

Harmful to 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.

· Europ	· European waste catalogue	
HP4	Irritant - skin irritation and eye damage	
HP10	Toxic for reproduction	
HP13	Sensitising	
HP14	Ecotoxic	

- · 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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14.1 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 accordi	ing to
IMO instruments	Not applicable.

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.
- · 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.

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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

H302 Harmful if swallowed.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H361d Suspected of damaging the unborn child.

H411 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

Acute Tox. 4: Acute toxicity - Category 4

Skin Irrit. 2: Skin corrosion/irritation - Category 2

Eye Dam. 1: Serious eye damage/eye irritation - Category 1 Eye Irrit. 2: Serious eye damage/eye irritation - Category 2

Skin Sens. 1: Skin sensitisation - Category 1

Repr. 2: Reproductive toxicity - Category 2

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

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard - Category 3

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