

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

- **1.1 Product identifier**
- **Trade name: Jelene (plasticized base)**
- **Article number:** 103158
- **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** Additional component
- **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**  
Asp. Tox. 1 H304 May be fatal if swallowed and enters airways.
- **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**



GHS08

- **Signal word** Danger
- **Hazard-determining components of labelling:**  
White mineral oil, petroleum
- **Hazard statements**  
H304 May be fatal if swallowed and enters airways.
- **Precautionary statements**  
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.  
P331 Do NOT induce vomiting.  
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.

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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: 8042-47-5	White mineral oil, petroleum	Asp. Tox. 1, H304	50–≤100%
EINECS: 232-455-8			

· **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:**

In case of irregular breathing or respiratory arrest provide artificial respiration.  
Immediately remove any clothing soiled by the product.

##### · **After inhalation:**

Supply fresh air or oxygen; call for 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:** Do not induce vomiting; call for medical help immediately.

#### · 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.

Fire-extinguishing powder

Water spray

Foam

##### · **For safety reasons unsuitable extinguishing agents:** Water with full jet

#### · 5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

In case of fire, the following can be released:

Carbon monoxide (CO)

#### · 5.3 Advice for firefighters

##### · **Protective equipment:**

Wear self-contained respiratory protective device.

Wear fully protective suit.

### SECTION 6: Accidental release measures

#### · 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

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- Mount respiratory protective device.
- **6.2 Environmental precautions:** 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 of the material collected according to regulations.  
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.

## SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** Keep ignition sources away - Do not smoke.
- **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:** Store away from oxidising agents.
- **Further information about storage conditions:**  
Keep container tightly sealed.  
Protect from heat and direct sunlight.  
Protect from exposure to the light.
- **Maximum storage temperature:** <30°C
- **Minimum storage temperature:** >4°C
- **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:**  
Keep away from foodstuffs, beverages and feed.  
Do not eat, drink, smoke or sniff while working.  
Do not inhale dust / smoke / mist.  
Wash hands before breaks and at the end of work.  
Pregnant women should strictly avoid inhalation or skin contact.  
Avoid contact with the eyes and skin.
- **Respiratory protection:** Suitable respiratory protective device recommended.
- **Hand protection**



Protective gloves

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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.

Nitrile rubber, NBR

Natural rubber, NR

· **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**



Tightly sealed goggles

Face protection

· **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:**

Whitish

· **Odour:**

Characteristic

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Undetermined.

· **Boiling point or initial boiling point and boiling range**

230°C

· **Flammability**

Not applicable.

· **Lower and upper explosion limit**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Flash point:**

115–268°C

· **Decomposition temperature:**

Not determined.

· **pH**

Not determined.

· **Viscosity:**

· **Kinematic viscosity**

Not determined.

· **Dynamic:**

Not determined.

· **Solubility**

· **water:**

Not miscible or difficult to mix.

· **Partition coefficient n-octanol/water (log value)**

Not determined.

· **Vapour pressure:**

Not determined.

· **Density and/or relative density**

· **Density at 20°C:**

≥0,852 g/cm<sup>3</sup>

· **Relative density**

Not determined.

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Fagron  
medicines

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· Bulk density:	≥852 kg/m <sup>3</sup>
· Vapour density	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 %
· 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
· 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** Reacts with strong oxidising agents.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:**  
Poisonous gases/vapours  
Carbon monoxide and carbon dioxide

## 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.
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.

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- **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** May be fatal if swallowed and enters airways.
- **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.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**  
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**  
Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water  
Do not allow product to reach ground water, water course or sewage system, even in small quantities.  
Danger to drinking water if even extremely 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.

## SECTION 14: Transport information

- |                                       |               |
|---------------------------------------|---------------|
| · <b>14.1 UN number or ID number</b>  |               |
| · <b>ADR, IMDG, IATA</b>              | not regulated |
| · <b>14.2 UN proper shipping name</b> |               |
| · <b>ADR, IMDG, IATA</b>              | not regulated |

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· 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

## 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.

## 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**  
H304 May be fatal if swallowed and enters airways.
- **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

# Safety data sheet

according to 1907/2006/EC, Article 31

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**Trade name: Jelene (plasticized base)**

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)  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
Asp. Tox. 1: Aspiration hazard – Category 1

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