

## 1 Identification

- **Product identifier**
- **Trade name: Jelene (plasticized base)**
- **Article number:** 103158
- **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
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Fagron Services B.V.  
Molenwerk 13, UITGEEST, 1911DB  
Netherlands  
Phone: +31251361400
- **Supplier**  
Azelis Australia  
Suite 217  
117 Old Pittwater Road  
Brookvale  
NSW 2100  
Australia  
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**  
Asp. Tox. 1 H304 May be fatal if swallowed and enters airways.
- **Label elements**
- **GHS label elements**  
The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Hazard pictograms**



GHS08

- **Signal word** Danger
- **Hazard-determining components of labelling:**  
White mineral oil, petroleum
- **Hazard statements**  
May be fatal if swallowed and enters airways.

Trade name: Jelene (plasticized base)

(Contd. of page 1)

- **Precautionary statements**  
IF SWALLOWED: Immediately call a POISON CENTER/ doctor.  
Do NOT induce vomiting.  
Store locked up.  
Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### 3 Composition and Information on Ingredients

- **Chemical characterisation: 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%
----------------	------------------------------	-------------------	----------

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

### 4 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.
- **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

- **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
- **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)
- **Protective equipment:**  
Wear self-contained respiratory protective device.

Trade name: Jelene (plasticized base)

Wear fully protective suit.

(Contd. of page 2)

## 6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.  
Mount respiratory protective device.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **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.
- **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.

## 7 Handling and Storage

- **Handling:**
- **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.
- **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
- **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:**  
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.
- **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.

(Contd. on page 4)

Trade name: Jelene (plasticized base)

(Contd. of page 3)

· **Protection of hands:**



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.

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 protection:**



Tightly sealed goggles

Face protection

· **Body protection:** Protective work clothing

## 9 Physical and Chemical Properties

· **General Information**

· **Appearance:**

- **Form:** Pasty
- **Colour:** Whitish
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **pH-value:** Not determined.

· **Change in condition**

- **Melting point/freezing point:** Undetermined.
- **Initial boiling point and boiling range:** 230°C
- **Flash point:** 115–268°C
- **Flammability (solid, gas):** Not applicable.
- **Decomposition temperature:** Not determined.
- **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:** Not determined.
- **Density at 20°C:**  $\geq 0.852 \text{ g/cm}^3$
- **Bulk density:**  $\geq 852 \text{ kg/m}^3$
- **Relative density:** Not determined.

**Fagron**

(Contd. on page 5)  
personalizing  
medicine

AUS

Trade name: Jelene (plasticized base)

(Contd. of page 4)

· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with water:	Not miscible or difficult to mix.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
· Dynamic:	Not determined.
· Kinematic:	Not determined.
· Solvent content:	
· VOC (EC)	0.00 %
· 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** Reacts with strong oxidising agents.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:**  
Poisonous gases/vapours  
Carbon monoxide and carbon dioxide

## 11 Toxicological Information

- **Information on toxicological effects**
- **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.
- **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.

## 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:**  
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.

Trade name: Jelene (plasticized base)

(Contd. of page 5)

- **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**  
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.

### 14 Transport information

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

### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· <b>Australian Inventory of Industrial Chemicals</b>
All ingredients are listed.
· <b>Standard for the Uniform Scheduling of Medicines and Poisons</b>
All substances have the value S5.
· <b>Australia: Priority Existing Chemicals</b>
None of the ingredients is listed.

- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.

(Contd. on page 7)

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

(Contd. of page 6)

- **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.

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

AUS