

## 1 Identification

- **Product identifier**
- **Trade name:** Formaldehydi Kutvirtti gargarisma
- **Article number:** 610773
- **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 pharmaceutical preparations
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Fagron Services B.V.  
Molenwerk 13, UITGEEEST, 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**

Flam. Liq. 2	H225 Highly flammable liquid and vapour.
Serious eye damage/irritation – Category 2A	H319 Causes serious eye irritation.
Skin Sens. 1	H317 May cause an allergic skin reaction.
Muta. 2	H341 Suspected of causing genetic defects.
Carc. 1B	H350 May cause cancer.

- **Label elements**
- **GHS label elements**  
The product is classified and labelled according to the Globally Harmonised System (GHS).

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· **Hazard pictograms**



GHS02 GHS07 GHS08

· **Signal word** Danger

· **Hazard-determining components of labelling:**

formaldehyde

· **Hazard statements**

Highly flammable liquid and vapour.  
Causes serious eye irritation.  
May cause an allergic skin reaction.  
Suspected of causing genetic defects.  
May cause cancer.

· **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. No smoking.  
Use explosion-proof electrical/ventilating/lighting equipment.  
IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.  
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
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: 64-17-5	Ethanol / Alcohol 99,5% v/v (absolute Flam. Liq. 2, H225; Serious eye damage/irritation – Category 2A, H319	50–≤100%
CAS: 50-00-0	formaldehyde Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; Muta. 2, H341; Carc. 1B, H350; Skin Corr. 1B, H314; Skin Sens. 1, H317; Flam. Liq. 4, H227	≥3–<5%
CAS: 2216-51-5	L-menthol Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319	1–≤3%

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

### 4 First Aid Measures

· **General information:**

Immediately remove any clothing soiled by the product.

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In case of irregular breathing or respiratory arrest provide artificial respiration.

Remove breathing equipment only after contaminated clothing have been completely removed.

• **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:**

Seek immediate medical advice.

Call a doctor 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:**

CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

• **Special hazards arising from the substance or mixture**

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

• **Protective equipment:**

Wear self-contained respiratory protective device.

Wear fully protective suit.

## 6 Accidental Release Measures

• **Personal precautions, protective equipment and emergency procedures**

Mount respiratory protective device.

Wear protective equipment. Keep unprotected persons away.

• **Environmental precautions:**

Dilute with plenty of water.

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 contaminated material as waste according to section 13.

Dispose of the material collected according to regulations.

Ensure adequate ventilation.

• **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**  
Ensure good ventilation/exhaustion at the workplace.  
Open and handle receptacle with care.  
Prevent formation of aerosols.
- **Information about fire - and explosion protection:**  
Keep ignition sources away - Do not smoke.  
Protect against electrostatic charges.  
Keep respiratory protective device available.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
Keep container tightly sealed.  
Store in cool, dry conditions in well sealed receptacles.
- **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.

• <b>Ingredients with limit values that require monitoring at the workplace:</b>	
<b>CAS: 64-17-5 Ethanol / Alcohol 99,5% v/v (absolute)</b>	
WES	Long-term value: 1880 mg/m <sup>3</sup> , 1000 ppm
<b>CAS: 50-00-0 formaldehyde</b>	
WES	Short-term value: 2.5 mg/m <sup>3</sup> , 2 ppm Long-term value: 1.2 mg/m <sup>3</sup> , 1 ppm Sen

- **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.  
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.  
Pregnant women should strictly avoid inhalation or skin contact.  
Do not eat, drink, smoke or sniff while working.  
Clean skin thoroughly immediately after handling the product.  
Do not inhale gases / fumes / aerosols.
- **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.

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· **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.

· **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

· **Body protection:** Protective work clothing

## 9 Physical and Chemical Properties

· **General Information**

· **Appearance:**

- |   |   |
|---|---|
| · <b>Form:</b>                                    | Liquid  |
| · <b>Colour:</b>                                  | Red-brown   |
| · <b>Odour:</b>                                   | Characteristic  |
| · <b>Odour threshold:</b>                         | Not determined.   |
| · <b>pH-value:</b>                                | Not determined.   |
| · <b>Change in condition</b>                      |   |
| · <b>Melting point/freezing point:</b>            | Undetermined.   |
| · <b>Initial boiling point and boiling range:</b> | 78°C  |
| · <b>Flash point:</b>                             | 13°C  |
| · <b>Flammability (solid, gas):</b>               | Flammable.<br>Highly flammable.   |
| · <b>Auto-ignition temperature:</b>               | 425°C   |
| · <b>Decomposition temperature:</b>               | Not determined.   |
| · <b>Ignition temperature:</b>                    | Product is not selfigniting.  |
| · <b>Explosive properties:</b>                    | Product is not explosive. However, formation of explosive air/vapour mixtures are possible. |
| · <b>Explosion limits:</b>                        |   |
| · <b>Lower:</b>                                   | 3.5 Vol %   |

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· <b>Upper:</b>	15 Vol %
· <b>Vapour pressure at 20°C:</b>	59 hPa
· <b>Vapour pressure at 50°C:</b>	280 hPa
· <b>Density at 20°C:</b>	0.87434–0.87483 g/cm <sup>3</sup>
· <b>Bulk density:</b>	866–871 kg/m <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with</b>	
· <b>water:</b>	Fully miscible.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
· <b>Dynamic:</b>	Not determined.
· <b>Kinematic:</b>	Not determined.
· <b>Solvent content:</b>	
· <b>Organic solvents:</b>	57.5–57.7 %
· <b>Water:</b>	38.3 %
· <b>VOC (EC)</b>	57.52–57.72 %
· <b>Solids content:</b>	2.0 %
· <b>Other information</b>	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.
- **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:

#### ATE (Acute Toxicity Estimates)

Oral	LD50	>5731 mg/kg (rat)
Dermal	LD50	8597 mg/kg
Inhalative	LC50/4 h	86 mg/l

#### CAS: 64-17-5 Ethanol / Alcohol 99,5% v/v (absolute)

Oral	LD50	7060 mg/kg (rat)
Inhalative	LC50/4 h	51 mg/l (rat)

#### CAS: 50-00-0 formaldehyde

Oral	LD50	>200 mg/kg (rat)
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**CAS: 2216-51-5 L-menthol**

Oral	LD50	3300 mg/kg (rat)
Dermal	LD50	>5000 mg/kg (rabbit)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **Germ cell mutagenicity** Suspected of causing genetic defects.
- **Carcinogenicity** May cause cancer.
- **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:**  
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.
- **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.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

## 14 Transport information

- **UN-Number**
- **ADG, IMDG, IATA** UN1993

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# Safety Data Sheet

according to WHS Regulations

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<ul style="list-style-type: none"> <li>· UN proper shipping name</li> <li>· ADG, IMDG</li> <li>· IATA</li> </ul>	FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHYL ALCOHOL)) Flammable liquid, n.o.s. (ETHANOL)
<ul style="list-style-type: none"> <li>· Transport hazard class(es)</li> <li>· ADG, IMDG, IATA</li> </ul> 	
<ul style="list-style-type: none"> <li>· Class</li> <li>· Label</li> </ul>	3 Flammable liquids. 3
<ul style="list-style-type: none"> <li>· Packing group</li> <li>· ADG, IMDG, IATA</li> </ul>	II
<ul style="list-style-type: none"> <li>· Environmental hazards:</li> </ul>	Not applicable.
<ul style="list-style-type: none"> <li>· Special precautions for user</li> <li>· Hazard identification number (Kemler code):</li> <li>· EmS Number:</li> <li>· Stowage Category</li> </ul>	Warning: Flammable liquids. 33 F-E, S-E B
<ul style="list-style-type: none"> <li>· Transport in bulk according to Annex II of Marpol and the IBC Code</li> </ul>	Not applicable.
<ul style="list-style-type: none"> <li>· Transport/Additional information:</li> </ul>	
<ul style="list-style-type: none"> <li>· ADG</li> <li>· Limited quantities (LQ)</li> <li>· Excepted quantities (EQ)</li> </ul>	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
<ul style="list-style-type: none"> <li>· Transport category</li> <li>· Tunnel restriction code</li> </ul>	2 D/E
<ul style="list-style-type: none"> <li>· IMDG</li> <li>· Limited quantities (LQ)</li> <li>· Excepted quantities (EQ)</li> </ul>	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
<ul style="list-style-type: none"> <li>· UN "Model Regulation":</li> </ul>	UN 1993 FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHYL ALCOHOL)), 3, II

## 15 Regulatory information

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

· Australian Inventory of Industrial Chemicals

All ingredients are listed.

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· Standard for the Uniform Scheduling of Medicines and Poisons		
CAS: 64-17-5	Ethanol / Alcohol 99,5% v/v (absolute)	Not scheduled
CAS: 50-00-0	formaldehyde	S2, S6, S10
CAS: 67-56-1	methanol	S5, S6, S10
· Australia: Priority Existing Chemicals		
CAS: 50-00-0	formaldehyde	

- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Seveso category P5c** FLAMMABLE LIQUIDS
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5000 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50000 t
- **National regulations:**
- **Information about limitation of use:**  
Workers are not allowed to be exposed to the hazardous carcinogenic materials contained in this preparation. Exceptions can be made by the authorities in certain cases.
- **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**  
H225 Highly flammable liquid and vapour.  
H227 Combustible liquid.  
H301 Toxic if swallowed.  
H311 Toxic in contact with skin.  
H314 Causes severe skin burns and eye damage.  
H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H331 Toxic if inhaled.  
H341 Suspected of causing genetic defects.  
H350 May cause cancer.
- **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)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic

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vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2

Flam. Liq. 4: Flammable liquids – Category 4

Acute Tox. 3: Acute toxicity – Category 3

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

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

Serious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A

Skin Sens. 1: Skin sensitisation – Category 1

Muta. 2: Germ cell mutagenicity – Category 2

Carc. 1B: Carcinogenicity – Category 1B

· \* **Data compared to the previous version altered.**

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