


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

- **1.1 Product identifier**
- **Trade name:** Formaldehydi Kutvirtí gargarisma
- **Article number:** 610773
- **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 pharmaceutical 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**
Flam. Liq. 2 H225 Highly flammable liquid and vapour.
Eye Irrit. 2 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.
- **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**

GHS02 GHS07 GHS08
- **Signal word** Danger
- **Hazard-determining components of labelling:**
formaldehyde
- **Hazard statements**
H225 Highly flammable liquid and vapour.

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H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H341 Suspected of causing genetic defects.
H350 May cause cancer.

• **Precautionary statements**

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P241 Use explosion-proof [electrical/ventilating/lighting] equipment.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
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.

SECTION 3: Composition/information on ingredients

• **3.2 Mixtures**

• **Description:** Mixture of substances listed below with nonhazardous additions.

• **Dangerous components:**

CAS: 64-17-5 EINECS: 200-578-6	Ethanol / Alcohol 99,5% v/v (absolute Flam. Liq. 2, H225; Eye Irrit. 2, H319	50–≤100%
CAS: 50-00-0 EINECS: 200-001-8	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 Specific concentration limits: Skin Corr. 1B; H314: C ≥ 25 % Skin Irrit. 2; H315: 5 % ≤ C < 25 % Eye Irrit. 2; H319: 5 % ≤ C < 25 % Skin Sens. 1; H317: C ≥ 0,2 % STOT SE 3; H335: C ≥ 5 %	≥3–<5%
CAS: 2216-51-5 EINECS: 218-690-9	L-menthol Skin Irrit. 2, H315; Eye Irrit. 2, H319 Specific concentration limits: Skin Irrit. 2; H315: C ≥ 25 % Eye Irrit. 2; H319: C ≥ 25 %	1–≤3%
CAS: 67-56-1 EINECS: 200-659-6	methanol Flam. Liq. 2, H225; Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; STOT SE 1, H370 Specific concentration limits: STOT SE 1; H370: C ≥ 10 % STOT SE 2; H371: 3 % ≤ C < 10 %	0,1–≤1%

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

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SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

Immediately remove any clothing soiled by the product.
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.

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:

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

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

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

Mount respiratory protective device.
Wear protective equipment. Keep unprotected persons away.

6.2 Environmental precautions:

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.
Dispose of the material collected according to regulations.
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.

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See Section 13 for disposal information.

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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 ignition sources away - Do not smoke.
Protect against electrostatic charges.
Keep respiratory protective device available.

7.2 Conditions for safe storage, including any incompatibilities

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.

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:

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

NPK (Czechia)	Short-term value: 3000 mg/m ³ Long-term value: 1000 mg/m ³
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CAS: 50-00-0 formaldehyde

NPK (Czechia)	Short-term value: 0,74 0,74* mg/m ³ Long-term value: 0,37 0,5* mg/m ³ I, K, S, *Balzamování
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CAS: 67-56-1 methanol

NPK (Czechia)	Short-term value: 1000 mg/m ³ Long-term value: 250 mg/m ³ D, B
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Ingredients with biological limit values:

CAS: 67-56-1 methanol

BEH (Czechia)	15 mg/l Biologického materiálu: moči Doba odběru: Konec směny Ukazatel: Methanol
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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.

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· **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.
- 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.

· **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.

· **Eye/face protection**



Tightly sealed goggles

· **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:**

Red-brown

· **Odour:**

Characteristic

· **Odour threshold:**

Not determined.

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· Melting point/freezing point:	Undetermined.
· Boiling point or initial boiling point and boiling range	78°C (CAS: 64-17-5 Ethanol / Alcohol 99,5% v/v (absolute))
· Flammability	Flammable. Highly flammable.
· Lower and upper explosion limit	
· Lower:	3,5 Vol % (CAS: 64-17-5 Ethanol / Alcohol 99,5% v/v (absolute))
· Upper:	15 Vol % (CAS: 64-17-5 Ethanol / Alcohol 99,5% v/v (absolute))
· Flash point:	13°C
· Auto-ignition temperature:	425°C (CAS: 64-17-5 Ethanol / Alcohol 99,5% v/v (absolute))
· Decomposition temperature:	Not determined.
· pH	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 at 20°C:	59 hPa (CAS: 64-17-5 Ethanol / Alcohol 99,5% v/v (absolute))
· Vapour pressure at 50°C:	280 hPa
· Density and/or relative density	
· Density at 20°C:	0,87434–0,87483 g/cm ³
· Relative density	Not determined.
· Bulk density:	866–871 kg/m ³
· Vapour density	Not determined.

· 9.2 Other information	
· Appearance:	
· Form:	Liquid
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· Solvent content:	
· Organic solvents:	57,5–57,7 %
· Water:	38,3 %
· VOC (EC)	57,52–57,72 %
· Solids content:	2,0 %
· 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	Highly flammable liquid and vapour.
· 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	>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)

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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)

CAS: 67-56-1 methanol

Oral	LD50	5628 mg/kg (rat)
Dermal	LD50	15800 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.
- **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.

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· European waste catalogue	
HP3	Flammable
HP4	Irritant - skin irritation and eye damage
HP6	Acute Toxicity
HP7	Carcinogenic
HP11	Mutagenic

- **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	UN1993
· 14.2 UN proper shipping name · ADR, IMDG · IATA	FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHYL ALCOHOL)) Flammable liquid, n.o.s. (ETHANOL)
· 14.3 Transport hazard class(es) · ADR, IMDG, IATA	
	
· Class · Label	3 Flammable liquids. 3
· 14.4 Packing group · ADR, IMDG, IATA	II
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user · Hazard identification number (Kemler code): · EmS Number: · Stowage Category	Warning: Flammable liquids. 33 F-E, S-E B
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	
· ADR · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· Transport category	2

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· Tunnel restriction code	D/E
· IMDG	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1993 FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHYL ALCOHOL)), 3, II

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 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
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3, 28, 69, 72

· 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.

· 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.

- 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.

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· **Relevant phrases**

H225 Highly flammable liquid and vapour.
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.
H370 Causes damage to organs.

· **Department issuing SDS:** Fagron Česká republika

· **Contact:** msds@fagron.cz

· **Date of previous version:** 27.02.2024

· **Version number of previous version:** 1.1

· **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

Flam. Liq. 2: Flammable liquids – Category 2

Acute Tox. 3: Acute toxicity – Category 3

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

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

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Muta. 2: Germ cell mutagenicity – Category 2

Carc. 1B: Carcinogenicity – Category 1B

STOT SE 1: Specific target organ toxicity (single exposure) – Category 1

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

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