

Safety Data Sheet

according to UK REACH Regulation

Formaldehyd 37 % für Gassterilisatoren

Revision date: 13.02.2025

Product code: FO_3740

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

1.1. Product identifier

Formaldehyd 37 % für Gassterilisatoren

UFI: CUQR-8GJ4-W5FX-3RYE

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

These formaldehyde sterilization solutions are specifically designed to sterilize medical devices in a medical environment together with Getinge gas sterilizers. Follow the instructions for use of the gas sterilizer! The sterilization solution can only be used by trained specialist personnel.

1.3. Details of the supplier of the safety data sheet

Company name: SAV Liquid Production GmbH
Street: Hochriesstr. 2
Place: D-83126 Flintsbach am Inn
Telephone: +49 8034 90980-0
E-mail: info@sav-lp.de
Contact person: Chemischer Sicherheitsbeauftragter
E-mail: info@sav-lp.de
Internet: www-sav-lp.de

Supplier Australia: Getinge Australia Pty Ltd
Suite 701, Level 7, 11 Help Street
Chatswood, NSW 2067 Australia
Phone: 1800 438 464

Supplier New Zealand: Getinge Australia (NZ Branch)
600 Great South Road, Bldg A, Ground Floor, Unit D
Ellersie, Auckland 1051, New Zealand
Phone: 0800 1 438 464

Emergency Contacts: Australia +61 280 144 558
New Zealand +64 9 929 1484

1.4. Emergency telephone number:

Deutschland: Giftinformationszentrum Göttingen, Tel: +49 (0) 551-19240
Österreich: Vergiftungsinformationszentrale, Tel: +43 1 406 43 43

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GB CLP Regulation

Carc. 1B; H350
Muta. 2; H341
Acute Tox. 2; H330
Acute Tox. 3; H311
Acute Tox. 3; H301
Skin Corr. 1B; H314
Eye Dam. 1; H318
Skin Sens. 1; H317
STOT SE 1; H370 H335

Full text of hazard statements: see SECTION 16.

2.2. Label elements

GB CLP Regulation

Hazard components for labelling

formaldehyde %
methanol

Signal word: Danger

Pictograms:



Hazard statements

H301+H311 Toxic if swallowed or in contact with skin.

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H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H330	Fatal if inhaled.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects (inhalation, skin contact).
H350	May cause cancer.
H370	Causes damage to organs (central nervous system).

Precautionary statements

P201	Obtain special instructions before use.
P280	Wear protective gloves/protective clothing and eye protection/face protection.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor.
P308+P311	IF exposed or concerned: Call a POISON CENTER/doctor.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.

Special labelling of certain mixtures

Restricted to professional users.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Relevant ingredients

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
50-00-0	formaldehyde %			25 - 50 %
	200-001-8	605-001-00-5		
	Carc. 1B, Muta. 2, Acute Tox. 3, Acute Tox. 3, Acute Tox. 3, Skin Corr. 1B, Skin Sens. 1; H350 H341 H331 H311 H301 H314 H317			
67-56-1	methanol			>10 - < 20 %
	200-659-6	603-001-00-X		
	Flam. Liq. 2, Acute Tox. 3, Acute Tox. 3, Acute Tox. 3, STOT SE 1; H225 H331 H311 H301 H370			

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
50-00-0	200-001-8	formaldehyde %	25 - 50 %
	inhalation: ATE = 3 mg/l (vapours); inhalation: ATE = 0,5 mg/l (dusts or mists); dermal: ATE = 300 mg/kg; oral: ATE = 100 mg/kg Skin Corr. 1B; H314: >= 25 - 100 Skin Irrit. 2; H315: >= 5 - < 25 Eye Irrit. 2; H319: >= 5 - < 25 Skin Sens. 1; H317: >= 0,2 - 100 STOT SE 3; H335: >= 5 - 100		
67-56-1	200-659-6	methanol	>10 - < 20 %
	inhalation: ATE = 3 mg/l (vapours); inhalation: ATE = 0,5 mg/l (dusts or mists); dermal: ATE = 300 mg/kg; oral: ATE = 100 mg/kg STOT SE 1; H370: >= 10 - 100 STOT SE 2; H371: >= 3 - < 10		

Further Information

This preparation does not contain any substances of very high concern (SVHC) at a concentration of = 0.1% according to Regulation (EC) 1907/2006, Article 57.

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SECTION 4: First aid measures**4.1. Description of first aid measures****General information**

Remove contaminated, saturated clothing immediately.
Atenschutz erst nach Entfernung verunreinigter Kleidungsstücke abnehmen.
If breathing is irregular or stopped, administer artificial respiration.
In case of unconsciousness place and transport in stable sideways position.
If the problems are persistent, consult a doctor.

After inhalation

Remove casualty to fresh air and keep warm and at rest.
Call a physician immediately.
Provide fresh air. If unconscious but breathing normally, place in recovery position and seek medical advice. If the problems are persistent, consult a doctor.

After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. Call a physician immediately.

After contact with eyes

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.
Possibly existing contact lenses remove if possible.

After ingestion

Rinse mouth immediately and drink 1 glass of water. Do NOT induce vomiting. Adverse human health effects and symptoms: Gastric perforation. Call a physician immediately.

4.2. Most important symptoms and effects, both acute and delayed

Symptomatic treatment. If splashes get into the eyes, rinse immediately and consult an ophthalmologist.
Codeine for dry cough. If respiratory tract irritation occurs, allow dexamethasone spray (Auxiloson) to be inhaled. If taken orally: gastric lavage (addition of 60 - 70 g of urea and activated carbon). Then add 100 ml of 2% ammonium carbonate solution together with 20 g of urea. Add urea solution (20 - 30 g in water) tablespoon by tablespoon. Pay attention to alkali reserves. Pain control. Cave shock. Infection prophylaxis. Additional measures against methanol poisoning. Coughing fits, severe watering of the eyes, severe irritation of the nasal and throat mucous membranes, nausea, visual disturbances

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically. No further relevant information available.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Foam, Extinguishing powder.
Water spray jet,

Unsuitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

Highly flammable. Vapours can form explosive mixtures with air.
In case of fire may be liberated: Formaldehyde Carbon dioxide (CO₂)

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

Additional information

Use water spray jet to protect personnel and to cool endangered containers. Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or

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surface water.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures****General advice**

Remove all sources of ignition. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment. Provide adequate ventilation. Take precautionary measures against static discharges.

6.2. Environmental precautions

Do not allow uncontrolled discharge of product into the environment. Explosion risk.

Dilute with plenty of water.

Inform the relevant authorities if larger quantities are released.

6.3. Methods and material for containment and cleaning up**For cleaning up**

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage**7.1. Precautions for safe handling****Advice on safe handling**

Keep container tightly closed. Store cool and dry in well sealed containers. Handle and open container with care. Measures to prevent aerosol and dust generation Avoid contact with skin, eyes and clothes.

Advice on protection against fire and explosion

Keep away from sources of ignition - No smoking. Take precautionary measures against static discharges.

Vapours can form explosive mixtures with air.

Advice on general occupational hygiene

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme.

Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat, drink, smoke, sniff.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaust at critical locations. Keep in a cool, well-ventilated place. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Store between 10° and 40°. Store away from light.

Hints on joint storage

Do not store together with: Oxidizing agent., Food and feedingstuffs

7.3. Specific end use(s)

Basic material with a use not specifically defined

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

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Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
50-00-0	Formaldehyde	2	2.5		TWA (8 h)	WEL
		2	2.5		STEL (15 min)	WEL
67-56-1	Methanol	200	266		TWA (8 h)	WEL
		250	333		STEL (15 min)	WEL

8.2. Exposure controls



Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Keep away from drinks, food and animal feedingstuffs. Remove contaminated, saturated clothing immediately.

Wash hands before breaks and after work. Avoid contact with eyes and skin. Do not breathe mist/vapours/spray.

Individual protection measures, such as personal protective equipment

Eye/face protection

Suitable eye protection: goggles.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. Chemical resistant protective gloves (EN 374)

Suitable gloves type

NBR (Nitrile rubber)

Butyl caoutchouc (butyl rubber)

The selection of a suitable glove is not only based on the material, but also on others. Dependent on quality features and varies from manufacturer to manufacturer.

Permeation time (maximum wear duration):

Our recommendation refers to a one-time short-term use as protection against liquid splashes. For other applications please contact a glove manufacturer.

Skin protection

Use of protective clothing.

Standard protective clothing. Chemical resistant safety shoes or boots. If skin contact can occur, wear protective clothing impervious to this solution.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Filtering device with filter or ventilator filtering device of type: A

Thermal hazards

Flame-retardant protective clothing. Wear anti-static footwear and clothing

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:

Liquid

Colour:

colourless

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Odour: Aldehyde

Test method

Melting point/freezing point:	0 °C
Boiling point or initial boiling point and boiling range:	97 °C
Flammability:	not determined
Lower explosion limits:	5,5 vol. %
Upper explosion limits:	72 vol. %
Flash point:	66 - 73 °C
Auto-ignition temperature:	380 °C
Decomposition temperature:	not determined
pH-Value (at 20 °C):	3 - 5
Viscosity / kinematic:	not determined
Water solubility:	easily soluble
Solubility in other solvents:	not determined
Partition coefficient n-octanol/water:	not determined
Vapour pressure:	128 hPa
(at 20 °C)	
Density (at 20 °C):	1,08 - 1,1 g/cm³
Relative vapour density:	not determined
Particle characteristics:	not applicable

DIN 51757

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

The product is not: Explosive.

Oxidizing properties

The product is not: oxidising.

Further Information

Odour threshold: Formaldehyde 0,05 - 1 ppm

SECTION 10: Stability and reactivity

10.1. Reactivity

No further relevant information available.

10.2. Chemical stability

No known hazardous decomposition products.

10.3. Possibility of hazardous reactions

Formation of flammable or explosive vapor-air mixtures possible.

10.4. Conditions to avoid

Keep away from sources of heat (e.g. hot surfaces), sparks and open flames.

10.5. Incompatible materials

Oxidising agent, strong

Alkali (lye)

10.6. Hazardous decomposition products

In case of fire formation of carbon monoxide CO and carbon dioxide CO₂.

Further information

The aqueous formaldehyde solution is flammable when it reaches its flash point. Above the Flash point creates so much water vapor that ignition is not possible.

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SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in GB CLP Regulation

Acute toxicity

Fatal if inhaled.
Toxic in contact with skin.
Toxic if swallowed.

ATEmix tested

	Dose	Species	Source
LD50, oral	>200 - 1000 mg/kg	Rat	
LD50, dermal	270 mg/kg	Rabbit	

ATEmix calculated

ATE (inhalation vapour) 5,770 mg/l; ATE (inhalation dust/mist) 0,9620 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
50-00-0	formaldehyde %				
	oral	ATE 100 mg/kg			
	dermal	ATE 300 mg/kg			
	inhalation vapour	ATE 3 mg/l			
	inhalation dust/mist	ATE 0,5 mg/l			
67-56-1	methanol				
	oral	ATE 100 mg/kg			
	dermal	ATE 300 mg/kg			
	inhalation vapour	ATE 3 mg/l			
	inhalation dust/mist	ATE 0,5 mg/l			

Irritation and corrosivity

Skin corrosion/irritation: Causes severe skin burns and eye damage.
Serious eye damage/eye irritation: Causes serious eye damage.

Sensitising effects

May cause an allergic skin reaction. (formaldehyde %)

Carcinogenic/mutagenic/toxic effects for reproduction

May cause cancer. (formaldehyde %)
Suspected of causing genetic defects. (formaldehyde %)
Reproductive toxicity: Based on available data, the classification criteria are not met.

STOT-single exposure

Causes damage to organs. (methanol)
May cause respiratory irritation. (formaldehyde %)

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.

Additional information on tests

If swallowed, severe caustic effect on the mouth and throat and risk of perforation esophagus and stomach .
Oral intake of the component methanol leads to blindness and can also be fatal.

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11.2. Information on other hazards

Endocrine disrupting properties

None of the ingredients are included

SECTION 12: Ecological information

12.1. Toxicity

Based on available data, the classification criteria are not met.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
67-56-1	methanol					
	Acute fish toxicity	LC50 mg/l	15400	96 h (Sunfish (Lepomis macrochirus))		
	Acute algae toxicity	ErC50 mg/l	22000	96 h Pseudokirchneriella subcapitata	OECD 201	
	Acute crustacea toxicity	EC50 mg/l	24500	48 h Daphnia magna (Big water flea)		
	Fish toxicity	NOEC mg/l	7900	Oryzias latipes (Ricefish)		

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.

The product has not been tested.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation. Must not be disposed together with household garbage.

Contaminated packaging

Hazardous waste according to Directive 2008/98/EC (waste framework directive). Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number:

UN 2209

14.2. UN proper shipping name:

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14.3. Transport hazard class(es):

8

14.4. Packing group:

III

Hazard label:

8



Classification code:

C9

Special Provisions:

533

Limited quantity:

5 L

Excepted quantity:

E1

Transport category:

3

Hazard No:

80

Tunnel restriction code:

E

Inland waterways transport (ADN)

14.1. UN number or ID number:

UN 2209

14.2. UN proper shipping name:

FORMALDEHYDE SOLUTION

14.3. Transport hazard class(es):

8

14.4. Packing group:

III

Hazard label:

8



Classification code:

C9

Special Provisions:

533

Limited quantity:

5 L

Excepted quantity:

E1

Marine transport (IMDG)

14.1. UN number or ID number:

UN 2209

14.2. UN proper shipping name:

FORMALDEHYDE SOLUTION

14.3. Transport hazard class(es):

8

14.4. Packing group:

III

Hazard label:

8



Special Provisions:

-

Limited quantity:

5 L

Excepted quantity:

E1

EmS:

F-A, S-B

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:

UN 2209

14.2. UN proper shipping name:

FORMALDEHYDE SOLUTION

14.3. Transport hazard class(es):

8

14.4. Packing group:

III

Hazard label:

8



Special Provisions:

A803

Limited quantity Passenger:

1 L

Passenger LQ:

Y841

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Excepted quantity:	E1	
IATA-packing instructions - Passenger:		852
IATA-max. quantity - Passenger:		5 L
IATA-packing instructions - Cargo:		856
IATA-max. quantity - Cargo:		60 L

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

Warning: Combustible liquid. strongly corrosive. No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

Other applicable information

Hazchem code: •2X

SECTION 15: Regulatory information

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

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 40, Entry 72, Entry 75

Directive 2004/42/EC on VOC in
paints and varnishes: 86,4 - 132 g/l

Information according to Directive
2012/18/EU (SEVESO III): H2 ACUTE TOXIC

Additional information: P5c

National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

Water hazard class (D): 3 - highly hazardous to water

Skin resorption/Sensitization: Permeates easily through outer skin and causes poisoning. Causes allergic hypersensitivity reactions.

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

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Abbreviations and acronyms

Flam. Liq: Flammable liquids
Acute Tox: Acute toxicity
Skin Corr: Skin corrosion
Eye Dam: Eye damage
Skin Sens: Skin sensitisation
Muta: Germ cell mutagenicity
Carc: Carcinogenicity
STOT SE: Specific target organ toxicity - single exposure
CLP: Classification, labelling and Packaging
REACH: Registration, Evaluation and Authorization of Chemicals
GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals
UN: United Nations
CAS: Chemical Abstracts Service
DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration
ATE: Acute toxicity estimate
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
LL50: Lethal loading, 50%
EL50: Effect loading, 50%
EC50: Effective Concentration 50%
ErC50: Effective Concentration 50%, growth rate
NOEC: No Observed Effect Concentration
BCF: Bio-concentration factor
PBT: persistent, bioaccumulative, toxic
vPvB: very persistent, very bioaccumulative
ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
RID: Regulations concerning the international carriage of dangerous goods by rail
MARPOL: International Convention for the Prevention of Marine Pollution from Ships
IBC: Intermediate Bulk Container
VOC: Volatile Organic Compounds
SVHC: Substance of Very High Concern
For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
(Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)
IMDG: International Maritime Code for Dangerous Goods
EmS: Emergency Schedules
MFAG: Medical First Aid Guide
IATA: International Air Transport Association
ICAO: International Civil Aviation Organization

Relevant H and EUH statements (number and full text)

H225	Highly flammable liquid and vapour.
H301	Toxic if swallowed.
H301+H311	Toxic if swallowed or in contact with skin.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H331	Toxic if inhaled.

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H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H341	Suspected of causing genetic defects (inhalation, skin contact).
H350	May cause cancer.
H370	Causes damage to organs (central nervous system).
H370	Causes damage to organs.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the relevant ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)