



KALTEK srl

F1609SS

Revision n. 4
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FORMALDEHYDE 4%

Safety data sheet

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

1.1. Product identifier

Product name **FORMALDEHYDE 4% (w/w)**
Chemical name and synonym **10% (v/v) LILLIE'S BUFFERED FORMALIN SOLUTION**

1.2. Relevant identified uses of the substance or mixture and uses advised against
Intended use **FIXATIVE FOR HISTOLOGY**

1.3. Details of the supplier of the safety data sheet

Name **KALTEK srl**
Full address **Via del Progresso, 2**
District and Country **35127 Padova (PD)**
Italia
Tel. +390498703410
Fax +390498703383

e-mail address of the competent person
responsible for the Safety Data Sheet **qualit@kaltek.it**

1.4. Emergency telephone number

For urgent inquiries refer to **+390498703410**

SECTION 2. Hazards identification.

2.1. Classification of the substance or mixture.

The product is classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of EC Regulation 1907/2006 and subsequent amendments. Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Carcinogenicity, category 1A	H350	May cause cancer.
Germ cell mutagenicity, category 2	H341	Suspected of causing genetic defects.
Acute toxicity, category 4	H332	Harmful if inhaled.
Skin sensitization, category 1	H317	May cause an allergic skin reaction.

2.2. Label elements.

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.



Signal words:



Danger

Hazard statements:

H350	May cause cancer.
H341	Suspected of causing genetic defects.
H332	Harmful if inhaled.
H317	May cause an allergic skin reaction. Restricted to professional users.



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Precautionary statements:

P201	Obtain special instructions before use.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves / clothing and eye / face protection.
P302+P352	IF ON SKIN: wash with plenty of water and soap.
P308+P313	IF exposed or concerned: Get medical advice / attention.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.

Contains: FORMALDEHYDE

2.3. Other hazards.

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

SECTION 3. Composition/information on ingredients.

3.1. Substances.

Information not relevant.

3.2. Mixtures.

Contains:

Identification.	Conc. %.	Classification 1272/2008 (CLP).
FORMALDEHYDE CAS. 50-00-0 EC. 200-001-8 INDEX. 605-001-00-5	1 - 5	Carc. 1B H350, Muta. 2 H341, Acute Tox. 3 H301, Acute Tox. 3 H311, Acute Tox. 3 H331, Skin Corr. 1B H314, STOT SE 3 H335, Skin Sens. 1 H317, Note B D
METHANOL CAS. 67-56-1 EC. 200-659-6 INDEX. 603-001-00-X	0.1 – 0.5	Flam. Liq. 2 H225, Acute Tox. 3 H301, Acute Tox. 3 H311, Acute Tox. 3 H331, STOT SE 1 H370

Note: Upper limit is not included into the range.

The full wording of hazard (H) phrases is given in section 16 of the sheet.

SECTION 4. First aid measures.

4.1. Description of first aid measures.

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 30-60 minutes, opening the eyelids fully. Get medical advice/attention.

SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention.

INGESTION: Have the subject drink as much water as possible. Get medical advice/attention. Do not induce vomiting unless explicitly authorised by a doctor.

INHALATION: Get medical advice/attention immediately. Remove victim to fresh air, away from the accident scene. If the subject stops breathing, administer artificial respiration. Take suitable precautions for rescue workers.

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

For symptoms and effects caused by the contained substances, see chap. 11.

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

Information not available.



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SECTION 5. Firefighting measures.

5.1. Extinguishing media.

SUITABLE EXTINGUISHING EQUIPMENT

Extinguishing substances are: carbon dioxide, foam, chemical powder. For product loss or leakage that has not caught fire, water spray can be used to disperse flammable vapours and protect those trying to stem the leak.

UNSUITABLE EXTINGUISHING EQUIPMENT

Do not use jets of water. Water is not effective for putting out fires but can be used to cool containers exposed to flames to prevent explosions.

5.2. Special hazards arising from the substance or mixture.

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Excess pressure may form in containers exposed to fire at a risk of explosion. Do not breathe combustion products.

5.3. Advice for firefighters.

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures.

6.1. Personal precautions, protective equipment and emergency procedures.

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions.

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up.

Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. Check incompatibility for container material in section 7. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections.

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage.

7.1. Precautions for safe handling.

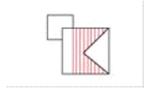
Keep away from heat, sparks and naked flames; do not smoke or use matches or lighters. Vapours may catch fire and an explosion may occur; vapour accumulation is therefore to be avoided by leaving windows and doors open and ensuring good cross ventilation. Without adequate ventilation, vapours may accumulate at ground level and, if ignited, catch fire even at a distance, with the danger of backfire. Avoid bunching of electrostatic charges. When performing transfer operations involving large containers, connect to an earthing system and wear antistatic footwear. Vigorous stirring and flow through the tubes and equipment may cause the formation and accumulation of electrostatic charges. In order to avoid the risk of fires and explosions, never use compressed air when handling. Open containers with caution as they may be pressurised. Do not eat, drink or smoke during use. Avoid leakage of the product into the environment.

7.2. Conditions for safe storage, including any incompatibilities.

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Store in a well ventilated place, keep far away from sources of heat, naked flames and sparks and other sources of ignition. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s).

Information not available.



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

Regulatory References:

CYP	Κύπρος	Κ.Δ.Π. 268/2001; Κ.Δ.Π. 55/2004; Κ.Δ.Π. 295/2007; Κ.Δ.Π. 70/2012
ESP	España	INSHT - Límites de exposición profesional para agentes químicos en España 2015
EST	Eesti	Töökeskkonna keemiliste ohutegurite piirnormid 1. Vastu võetud 18.09.2001 nr 293 RT I 2001, 77, 460 - Redaktsiooni jõustumise kp: 01.01.2008
GRB	United Kingdom	EH40/2005 Workplace exposure limits
GRC	Ελλάδα	ΕΦΗΜΕΡΙΣ ΤΗΣ ΚΥΒΕΡΝΗΣΕΩΣ - ΤΕΥΧΟΣ ΠΡΩΤΟ Αρ. Φύλλου 19 - 9 Φεβρουαρίου 2012
ITA	Italia	Decreto Legislativo 9 Aprile 2008, n.81
LTU	Lietuva	DĒL LIETUVOS HIGIENOS NORMOS HN 23:2007 CHEMINIŲ MEDŽIAGŲ 2007 m. spalio 15 d. Nr. V-827/A1-287
LVA	Latvija	Κίτμisko vielu aroda ekspozīcijas robežvērtības (AER) darba vides gaisā 2012
EU	OEL EU TLV-ACGIH	Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC. ACGIH 2014

FORMALDEHYDE**Threshold Limit Value.**

Type	Country	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
VLA	ESP			0,7	0,3
TLV	EST	0,6	0,5	1,2 (C)	1 (C)
WEL	GRB	2,5	2	2,5	2
TLV	GRC	2,5	2	2,5	2
RD	LTU	0,6	0,5	1 (C)	1,2 (C)
RV	LVA	0,5			
TLV-ACGIH				0,37 (C)	0,3 (C)

METHANOL**Threshold Limit Value.**

Type	Country	TWA/8h		STEL/15min		
		mg/m3	ppm	mg/m3	ppm	
TLV	CYP	260	200			SKIN.
VLA	ESP	266	200			SKIN.
WEL	GRB	266	200	333	250	SKIN.
TLV	GRC	260	200	325	250	
OEL	IRL	260	200			SKIN.
TLV	ITA	260	200			SKIN.
OEL	EU	260	200			SKIN.
TLV-ACGIH		262	200	328	250	

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

8.2. Exposure controls.

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration. Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Provide an emergency shower with face and eye wash station.

The product must be used inside a closed circuit, in a well-ventilated environment and with strong localised aspiration systems in place.

HAND PROTECTION

Protect hands with category III work gloves (see standard EN 374).

The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.



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The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

SKIN PROTECTION

Wear category II professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type A filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS.

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties.

9.1. Information on basic physical and chemical properties.

Appearance	liquid
Colour	colourless
Odour	pungent
pH.	7±1
Flash point.	> 60 °C.
Boiling point	100 °C
Density	1,010 Kg/l
Solubility	soluble in water

9.2. Other information.

Information not available.

SECTION 10. Stability and reactivity.

10.1. Reactivity.

There are no particular risks of reaction with other substances in normal conditions of use.

FORMALDEHYDE: aqueous solutions are stabilised with methanol but tend to polymerise over time. Storage temperature varies according to concentration. Solutions >25% are also corrosive. Decomposes under the effect of heat.

10.2. Chemical stability.

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions.

No hazardous reactions are foreseeable in normal conditions of use and storage.

FORMALDEHYDE: risk of explosion on contact with: nitromethane, nitrogen dioxide (at 180°C/356°F), hydrogen peroxide, phenol, performic acid, nitric acid. It may also polymerise on contact with: strong oxidising agents, alkalis. Can react dangerously with: hydrochloric acid, magnesium carbonate, sodium hydroxide, perchloric acid and aniline. Forms explosive mixtures with the air.

10.4. Conditions to avoid.

None in particular. However the usual precautions used for chemical products should be respected.

FORMALDEHYDE: avoid exposure to light, sources of heat and naked flames.



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10.5. Incompatible materials.

FORMALDEHYDE: acids, alkalies, ammonia, tannin, strong oxidising agents, phenols and copper, silver and iron salts.

10.6. Hazardous decomposition products.

FORMALDEHYDE: carbon oxides.

SECTION 11. Toxicological information.

11.1. Information on toxicological effects.

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification. It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

This product has a carcinogenic effect on human beings. Currently available data suggest a cause-effect relationship between human exposure to the substance contained in this product and cancer development.

This product must be handled carefully because of its possible mutagenic effects. Anyway, currently available data are insufficient to definitively prove hereditary gene alterations.

Acute effects: inhalation of this product is harmful. Exposure symptoms may include: stinging and irritated eyes, mouth, nose, throat; cough, respiratory disorders, dizziness, headache, nausea and sickness. In the most serious cases, inhalation of this product may cause larynx and bronchial tube edema and irritation, chemical pneumonia and pulmonary edema.

Upon contact with skin, this product causes sensitization (dermatitis). Dermatitis derives from skin irritation on the areas which repeatedly come into contact with the sensitizing agent. Cutaneous lesions may include: erythemas, edemas, papules, vesicles, pustules, scurries, ulcerations and exudative phenomena, whose intensity varies according to illness seriousness and affected areas. Erythemas, edemas and exudative phenomena prevail during the acute phase. Scurry skin, dryness, ulcerations and skin thickening prevail during the chronic phase.

FORMALDEHYDE

LD50 (Oral).100 mg/kg Rat

LD50 (Dermal).270 mg/kg Rabbit

LC50 (Inhalation).0,588 mg/l/4h Rat

SECTION 12. Ecological information.

12.1. Toxicity.

Information not available.

12.2. Persistence and degradability.

FORMALDEHYDE

Solubility in water. 55000 mg/l

Rapidly biodegradable.

12.3. Bioaccumulative potential.

FORMALDEHYDE

Partition coefficient: n-octanol/water. 0,35

BCF. < 1

12.4. Mobility in soil.

FORMALDEHYDE

Partition coefficient: soil/water. 1,202

12.5. Results of PBT and vPvB assessment.

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects.

Information not available.



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SECTION 13. Disposal considerations.

13.1. Waste treatment methods.

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information.

14.1. UN number.

Not applicable.

14.2. UN proper shipping name.

Not applicable.

14.3. Transport hazard class(es).

Not applicable.

14.4. Packing group.

Not applicable.

14.5. Environmental hazards.

Not applicable.

14.6. Special precautions for user.

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code.

Information not relevant.

SECTION 15. Regulatory information.

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

Seveso category. 2

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.

Product.

Point. 3

Substances in Candidate List (Art. 59 REACH).None.

Substances subject to authorisation (Annex XIV REACH).None.

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:none.

Substances subject to the Rotterdam Convention:None.

Substances subject to the Stockholm Convention:None.

Healthcare controls.

Workers exposed to this health-dangerous chemical agent must undergo sanitary checks carried out in compliance with 2004/37/EC directive.

15.2. Chemical safety assessment.

No chemical safety assessment has been processed for the mixture and the substances it contains.

SECTION 16. Other information.

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Flam. Liq. 2	Flammable liquid, category 2
Carc. 1B	Carcinogenicity, category 1B
Muta. 2	Germ cell mutagenicity, category 2
Acute Tox. 3	Acute toxicity, category 3
STOT SE 1	Specific target organ toxicity - single exposure, category 1
Skin Corr. 1B	Skin corrosion, category 1B



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STOT SE 3	Specific target organ toxicity - single exposure, category 3
Skin Sens. 1	Skin sensitization, category 1
H225	Highly flammable liquid and vapour.
H350	May cause cancer.
H341	Suspected of causing genetic defects.
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H331	Toxic if inhaled.
H370	Causes damage to organs.
H314	Causes severe skin burns and eye damage.
H335	May cause respiratory irritation.
H317	May cause an allergic skin reaction.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EU) 1907/2006 (REACH) of the European Parliament
 2. Regulation (EU) 1272/2008 (CLP) of the European Parliament
 3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
 4. Regulation (EU) 2015/830 of the European Parliament
 5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
 6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
 7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
 9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
- The Merck Index. - 10th Edition
 - Handling Chemical Safety
 - INRS - Fiche Toxicologique (toxicological sheet)
 - Patty - Industrial Hygiene and Toxicology
 - N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
 - ECHA website

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.
Provide appointed staff with adequate training on how to use chemical products.

Changes to previous review:

The following sections were modified: 01 / 08 / 09 / 11 / 12.