Material Safety Data Sheet

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

1.1. Product identifier.

Code:	**TC45600**
Product name.	**BUFFERED FORMALDEHYDE 10% v/v(4%w/v)**

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

Intended use.	**Laboratory reagent and for process control**

1.3. Details of the supplier of the safety data sheet.

Name.	**TITOLCHIMICA SPA**
Full address.	**VIA S.PIETRO MARTIRE 1054**
District and Country.	**45030 PONTECCHIO POLESINE (RO)** **ITALIA**
	Tel. +39425492644
	Fax. +39425492909
e-mail address of the competent person.	
responsible for the Safety Data Sheet.	**utecnico@titolchimica.it**

1.4. Emergency telephone number.

For urgent inquiries refer to.

Antipoison center (24/24h):
Pavia - 0382/24444;
Milano - 02/66101029;
Bergamo - 800/83300;
Firenze - 055/7947819;
Roma - Gemelli 06/3054343;
Roma - Umberto I 06/49978000;
Roma - Bambino Gesù 06/68593726;
Napoli - 081/7472870;
Foggia - 0881/732326.

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 1B	H350	May cause cancer.
Germ cell mutagenicity, category 2	H341	Suspected of causing genetic defects.
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.

Hazard pictograms:

Signal words: Danger

Hazard statements:

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

Precautionary statements:

P201	Obtain special instructions before use.
P261	Avoid breathing dust / fume / gas / mist / vapours / spray.
P280	Wear protective gloves / clothing and eye / face protection.
P302+P352	IF ON SKIN: Wash with plenty of water / . . .
P308+P313	IF exposed or concerned: Get medical advice / attention.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.

Contains: Formaldehyde

2.3. Other dangers.

On the basis of available data, the product does not contain any PBT or vPvB in percentage upper 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).**	**Specific concentration limits**
Formaldehyde %			
CAS. 50-00-0	1 - 5	Carc. 1B H350, Mutag. 2 H341, Acute Tox. 3 H301, Acute Tox. 3 H311, Acute Tox. 3 H331, Skin Corr. 1B H314, Skin Sens. 1 H317, Note B D	Skin Irrit. 2; H315: 5% ≤ C < 25% Skin Sens. 1; H317: C ≥ 0,2% Eye Irrit. 2; H319: 5% ≤ C < 25% STOT SE 3; H335: C ≥ 5% Skin Corr. 1B; H314: C ≥ 25%
EC. 200-001-8			
INDEX. 605-001-00-5			
Reg. no. 01-2119488953-20-XXXX			
METHYL ALCOHOL			
CAS. 67-56-1	0 - 0,5	Flam. Liq. 2 H225, Acute Tox. 3 H301, Acute Tox. 3 H311, Acute Tox. 3 H331, STOT SE 1 H370	STOT SE 1; H370: C ≥ 10% STOT SE 2; H371: 3% ≤ C < 10%
EC. 200-659-6			
INDEX. 603-001-00-X			
Reg. no. 01-2119433307-44-XXXX			

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.

AFTER EYES CONTACT: 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.
AFTER SKIN CONTACT: Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention.
AFTER SWALLOWING: Consult immediately a doctor. Do not induce vomiting unless explicitly authorised by a doctor.
AFTER INHALATION: Get medical advice/attention immediately. Remove victim to fresh air, away from the accident scene. If breathing is difficult, administer artificial respiration. Take suitable precautions for rescue workers.

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

METHYL ALCOHOL
Acute effects dose-dependant
Skin: irritation, delipidization.
Nervous system: if swallowed or inhaled at high doses: depression, headache, intoxication, vertigo, coma.
Eyes: irritation, if swallowed campimetric alteration even serious.
First aerial ways: irritation
Lungs: irritation
Digestive apparatus: if swallowed abdominal colic, vomit
Urogenital apparatus: kidney damage

Chronic effects
Skin: irritation, desquamation
Nervous system: headache, insomnia, vertigo.
Eyes: irritation, ocular sequelae (campimetric alteration even serious)

FORMALDEHYDE

Acute effects dose dependant
Skin: irritation, sensitisation, burns, necrosis.
Eyes: irritation, keratitis, conjunctivitis.
Nose: irritation, rhinitis
First aerial way: irritation
Lungs: irritation, sensitisation, pneumonia, asthma
Digestive apparatus: if swallowed, abdominal colics, diarrhea, vomit.

Chronic effects
Skin: allergic dermatitis, eczema
First aerial way: irritation, rhinitis
Lungs: chronic bronchitis

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

Provide an emergency shower with visocular bowl.

SECTION 5. Firefighting measures.

5.1. Extinguishing media.

SUITABLE EXTINGUISHING MEDIA
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 MEDIA
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
The product is not classified as flammable, by the way, in case of thermal decomposition due to high temperature, there can be the development of

potentially harmful substances for human health, mainly carbon monoxide and carbon dioxide.

METHYL ALCOHOL
Turn away if possible the containers of the substance from the fire place or cool it, as if it is exposed to thermic irradiation or if directly involved it can give origin to toxic fumes. The vapours can cause vertigo, faint or suffocation. The firefighting operations must take into account of the risk of explosion; the addicted staff to shut down the fire must act by protected position. Containers can exploded if exposed to fire.

FORMALDEHYDE
Turn away if possible the containers of the substance by the fire place or cool it, as if it is exposed to thermic irradiation or if directly involved it can give origin to toxic fumes. Turn away if possible the containers of the substance by the fire place or cool it, as if it is heat up, it can cause polymerization.

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 dangerous for health. Always wear complete fireproof clothes. Collect extinguishing water to prevent it from draining into the sewer system. Dispose the contaminated water used for extinction and the remains of the fire according to applicable regulations.

EQUIPMENT
Normal fire fighting clothes as a self respirator compressed air open circuit (EN 137), anti flame complete (EN469), anti flame gloves (EN 659) and firework boots (HOA29 or A30).

SECTION 6. Accidental release measures.

6.1. Personal precautions, protective equipment and emergency procedures.

For non-emergency personnel
Alert the personnel addicted to the management of such emergencies. Turn away by the damaged area if not in possession of personal protection devices listed at section 8.

For emergency personnel
turn away the staff not suitably equipped to fight the emergency.
Wear suitable protection device (included the individual protection devices as at section 8 of the safety data sheet) to prevent skin, eyes personal clothes contamination. Block the leakage if there is no danger.
Let the damaged area accessible to the workers only after a suitable drainage. Provider fresh air to the places interested by the incident.

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.

Suck the released product into a suitable container. Evaluate the compatibility of the container to be used with the product, and verify section 10. Absorb the rest of the material with inert absorbent material.
Provide to a sufficient aeration of the place interested by the leakage. Verify the eventual incompatibility for the material of the containers in section7. The disposal of the contaminated material shall be done according to the disposition as point 13.

6.4. Reference to other sections.

Any information on personal protection and disposal are reported in sections 8 and 13.

SECTION 7. Handling and storage.

7.1. Precautions for safe handling.

Avoid the contact with wyes and skin. Do not inhale vapours or fogs. Do not eat, nor drink or smoke during use. Wash hands after use. Avoid the release of the product into the environment.

7.2. Conditions for safe storage, including any incompatibilities.

Store only in its original container. Store the containers tightly closed, in a well ventilated place. Keep the product in containers clearly labelled. Avoid overheating. Avoid violent shocks. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s).

Information not available.

SECTION 8. Exposure controls/personal protection.

8.1. Control parameters.

Regulatory References:

GRB	United Kingdom	EH40/2005 Workplace exposure limits
ITA	Italy	Regulation 9th April 2008, n.81
EU	OEL EU	Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC.
	TLV-ACGIH	ACGIH 2016

Formaldehyde...%

Threshold Limit Value.

Type	Country	TWA/8h		STEL/15min		Note	
		mg/m3	ppm	mg/m3	ppm	annotations	Critic effects
WEL	GRB	2,5	2	2,5	2		
TLV-ACGIH				0,37 (C)	0,3 (C)	Sen, A2	Irrit rspr and oc

Predicted no-effect concentration - PNEC.

Normal value in fresh water	0,47	mg/l
Normal value in marine water	0,47	mg/l
Normal value for fresh water sediment	2,44	mg/l
Normal value for marine water sediment	2,44	mg/kg
Normal value for water, intermittent release	4,7	mg/l
Normal value of STP microorganisms	0,19	mg/l
Normal value for the terrestrial compartment	0,21	mg/kg

Health - Derived no-effect level - DNEL / DMEL

Exposition way	Effects on consumers. Acute local	Acute systemic	Chronic local	Chronic systemic	Effects on workers Acute local	Acute systemic	Chronic local	Chronic systemic
Oral.			VND	4,1 mg/kg				
Inhalation.			0,1 mg/m3	3,2 mg/m3	1 mg/m3	VND	0,5 mg/m3	9 mg/m3
Skin.			12 mg/kg	102 mg/kg			37 mg/kg	240 mg/kg

METHYL ALCOHOL

Threshold Limit Value.

Type	Country	TWA/8h		STEL/15min		Note	
		mg/m3	ppm	mg/m3	ppm	annotations	Critic effects
WEL	GRB		200		250		
TLV	ITA	260	200			SKIN.	
OEL	EU	260	200				
TLV-ACGIH		262	200	328	250	Cute, IBE	Oclr, cfl

Predicted no-effect concentration - PNEC.

Normal value in fresh water	154	mg/l
Normal value in marine water	15,4	mg/l
Normal value for fresh water sediment	570,4	mg/kg
Normal value for the terrestrial compartment	23,5	mg/kg

Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers. Acute local	Acute systemic	Chronic local	Chronic systemic	Effects on workers Acute local	Acute systemic	Chronic local	Chronic systemic
Oral.	VND	8 mg/kg	VND	8 mg/kg				
Inhalation.	50 mg/m3	50 mg/m3	50 mg/m3	50 mg/m3	260 mg/m3	260 mg/m3	260 mg/m3	260 mg/m3
Skin.	VND	8 mg/kg	VND	8 mg/kg	VND	40 mg/kg	VND	40 mg/kg

Legend:

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

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.
Irrit= irritation
Rspr= respiratory
Oclr=ocular
Cfl=headache
IBE= biologic indicator of exposition
Sen= sensitization
A2=carcinogenic suspected on human being

IBE METHYL ALCOHOL: methanol in urins, end of the shift, 15 mg/L.

Sample methods

METHYL ALCOHOL : http://amcaw.ifa.dguv.de/substance/methoden/065-L-Methanol.pdf
FORMALDEHYDE: http://amcaw.ifa.dguv.de/substance/methoden/057-L-Formaldehyde.pdf.

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 they comply with the current regulations.
The product shall be used in a closed circuit, in strong aerated areas and at the presence of strong local suction

HAND PROTECTION
Protect hands with work gloves category III, permeation resistant, class A/J, for example polychloroprene (see standard EN 374).
The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.
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 category III(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
Odour threshold.	Not available.
pH.	7
Melting point / freezing point.	Not available.

Initial boiling point.	100 °C.
Boiling range.	Not available.
Flash point.	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	not applicable
Lower flammability limit.	Not available.
Upper flammability limit.	Not available.
Lower explosive limit.	Not available.
Upper explosive limit.	Not available.
Vapour pressure.	Not available.
Vapour density	Not available.
Relative density.	1,010 Kg/l
Solubility	partially soluble in water
Partition coefficient: n-octanol/water	Not available.
Auto-ignition temperature.	Not available.
Decomposition temperature.	Not available.
Viscosity	Not available.
Explosive properties	Not applicable (absence of chemical groups associated to explosive properties according to the dispositions of the Annex I, Part 2, chap. 2.1.4.3 of the reg. (EC) 1272/2008 - CLP).
Oxidant properties	Not applicable (absence of the requirements related to the presence of atoms and(or chemical bonds associated with oxidant properties in the molecules of components according the dispositions of the Annex I, Part 2, 2.13.4 of the reg. (EC) 1272/2008 – CLP).

9.2. Other information.

Danger of explosion	No
Solvent solubility	Insoluble

SECTION 10. Stability and reactivity.

10.1. Reactivity.

MEHTYL ALCOHOL
Vapours create explosive mixtures with air.

FORMALDEHYDE
The aqueous solutions are stabilised with methanol, but they polymerize during the time. The store temperature vary in function of the concentration. The solutions > 25 % are also corrosive. It decompose by heat effect.

10.2. Chemical stability.

METHYL ALCOHOL.
In the combustion it develops formaldehyde.

10.3. Possibility of dangerous reactions.

METHYL ALCOHOL
It polymerizes only if heated.

FORMALDEHYDE
Risk of explosion by contact with nitromethane, nitrogen dioxide (at 180°C), hydrogen peroxide, phenol, performic acid, nitric acid. It can polymerise by contact with : strong oxidant agents, alkalis. It can react dangerously with: chloride acid, magnesium carbonate, sodium hydroxide, perchloric acid and aniline. It creates explosive mixtures with the air.

10.4. Conditions to avoid.

Avoid overheating.

METHYL ALCOHOL
Avoid overheating and free flames.

FORMALDEHYDE
Avoid the exposition to light, to heat sources and free flames.

10.5. Incompatible materials.

METHYL ALCOHOL
Oxidant substances.

FORMALDEHYDE
Acids, alkalis, ammonia, tannin, strong oxidant, phenols and copper salts, silver and iron.

10.6. Hazardous decomposition products.

For thermic decomposition or in case of fire there can be the release of gas and vapours potentially harmful for health.

METHYL ALCOHOL
Heated at decomposition, it develops fumes and vapours acrid and irritating.

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 the 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.

Acute toxicity
Based on the evaluation of the classification of the component and to the dispositions of classification Annex I, Part 3 of the reg. (EC) 1272/2008 and following adjustments and integrations.

METHYL ALCOHOL
LD50 (Oral).> 1187 mg/kg rat
LD50 (Dermal).17100 mg/kg rabbit
LC50 (Inhalation).128,2 g/m3/4h rat

FORMALDEHYDE..%
LD50 (Oral).100 mg/kg Rat
LD50 (Dermal).270 mg/kg Rabbit
LC50 (Inhalation).0,588 mg/l/4h Rat

Skin corrosion/ irritation
Based on the evaluation of the classification of the components and to the disposition of the classification of the Annex I, Part 3 of the reg. (EC) 1272/2008 and following adjustments and integrations, the mixture is not classified for this class of danger.
The product is corrosive and produce severe burns and vescicles on skin, that can also compare also after the exposition. The burns cause strong pain and stings.
Skin injuries can include erythema, oedemas, papules, vescicles, scales, fissures and exudative phenomena, that vary according to the phase of the illness and of the damaged areas. In the acute phase predominate erythema, oedemas and sudoration. In the chronic phases predominate scales, dryness, fissuring and thickening of the skin.

METHYL ALCOHOL
The repeated contact or prolonged ones with the substance in liquid form can pause skin irritation: dermatosis, erythema and scales.

FORMALDEHYDE
It can cause injuries for irritation and caustic according to the concentration. The formaldehyde is irritating for the human skin. Experimental studies confirm the irritating action observed by man. Aqueous solution of formaldehyde (0,1% to 20%) are irritating for rabbit skin. (OECD, 2002)

Serious eye damage/ irritation
Based on the evaluation of the classification of the components and of the dispositions of classification of the Annex I, Part 3 of the Reg. (EC) 1272/2008 and following adjustments and integrations the mixture is not classified for this dangerous class.
Contact with eyes it cause severe injuries and can cause corneal opacity, iris injury, irreversible coloration of the eye.

METHYL ALCOHOL
The substance for inhalator way is irritant. Liquid form can causes conjunctivitis, superficial injuries of the cornea and chemosis.

Respiratory or skin sensitization.
Based on the evaluation of the classification of the component and to the dispositions of classification of the Annex I, Part 3 of the Reg. (EC) 1272/2008 and following adjustments and integrations, the mixture is classified as Skin Sens.1 H317.
The contact of the product with the skin cause a sensitization (contact dermatitis). The dermatitis is originated after a inflammation of the skin, that starts from the skin areas which come at repeated contact with the sensitizing agent.

FORMALDEHYDE
Skin sensitization
The substance has a sensitising power. In several studies on different models (Buehler essay on the rat and maximisation on cavy) indicate that the formaldehyde is a skin sensitizing into animals where it induce an answer from moderate to strong at not irritating concentration (INRS, 2011)

RESPIRATORY SENSITIZATION
The exposition, even short, at an atmospheric concentration of 50ppm of formaldehyde can be responsible of severe bronchospasm and severe caustic lesions of the respiratory ways (pulmonary acute oedema, tracheal laceration and bronchial). The exposition of healthy volunteers, no smokers, at 2 ppm for 40 minutes, at rest or during a moderate physical exercise (10 minutes over 40), has not altered the respiratory rate during the following 24 hours and not induced bronchial hyper reactivity (INRS, 2011).
Studies expressively projected (test IgE, secretion profiles of cytokines of lymph node cells) and did not reveal the evidence of sensitization of the respiratory ways on rats. (OECD, 2002).

Germ cell mutagenicity
Based on the evaluation of the classification of the components and the disposition of classification Annex I, Part 3 of the Reg. (EC) 1272/2008 and following adjustments and integrations the mixture is classified as Mutag. 2 H341.
The product is considered with suspect because of possible mutagenic effects. Sufficient information aren't available to demonstrate in definitive way hereditary genetic alterations.

METHYL ALCOHOL
Data on human are not available. Methanol gives negative results in the essay of Ames, with or without methabolic activation. In the culture induced point mutations on cells of lymphoma of rat. In vivo it increases the frequency of the chromosomic aberrations in rat and in locusts. In rat the answer is dose-dependent and it is accompanied by the increase of the frequency of exchanges between chromatid brothers and of micronucleus in the cells of bone marrow.

FORMALDEHYDE
The formaldehyde is a directed genotoxic agent which provide positive results in the most part of the essays on bacteria, yeast, fungus, insects, nematodes and mammal cells. In vivo is genotoxic in man and in the experimental animals.

Carcinogenicity.
Bases on the evaluation of the classification of the components and to the disposition of the classification of the Annex I, Part 3 of the Reg. (EC) 1272/2008 and following adjustments and integrations, the mixture is classified carcinogenic on man. There are sufficient elements to retain probable that the exposition on man to the contained substance can cause the development of tumours.

FORMALDEHYDE
Several epidemiological studies and meta-analysis showed a causal relationship between exposition to formaldehyde and cancer on human. There is a strong increase of the incidence of nasopharyngeal, cancer of nasal sinus and cancer of lympho hematopoietic, in particular myelogenus leukemia (the substance, after the exposition for inhalatory way, causes genetic damage in nasal tissues both in humans and in experimental animals). The International Agency for Research on Cancer (IARC) allocates the formaldehyde in group 1 (carcinogenic assessed on man), based on the evidence of carcinogenicity sufficient on human (nasopharynx tumour and leukemia and exists furthermore positive association for the tumours nasal sinus) and on animals (IARC,2012). The US National Toxicology Program (NTP) lists the Formaldehyde in the Thirteenth Report on Carcinogens and allocates it in the category of carcinogenic recognized for humans (US DHHS, 2014). The US Environmental Protection Agency (EPA) revises the evaluation of the formaldehyde (USEPA file online 2014).

Reproductive toxicity
Based on the evaluation of the classification of the components and to the dispositions of the classification of the Annex I, Parte 3 of the Reg. (CE) 1272/2008 and following adjustments and integrations, the mixture is not classified for this dangerous class.

METHYL ALCOHOL
- Adverse effects on the sexual function and fertility: date not available.
- Adverse effects on the development: in pregnant rats exposed at 20000 ppm of substance, 7/hours a day for all the length of the gestation or even only from the 7^{th} to the 15^{th} day of gestation, the substance caused a slow maternal toxicity and strong incidence of congenital malformation (supernumerary ribs or rudimental, malformations of urinary system or cardiovascular).
- Effects on breastfeeding or through it: data not available.

FORMALDEHYDE

- Adverse effects on the sexual function and fertility: data not available on the reproductive toxicity.
- Adverse effects on the development: the epidemiologic studies available indicate an increasing of spontaneous abortion and a decrease of the weight at the birth.
  These results are misunderstandings as it can't be excluded the role of other risk factors.
- Effects on breastfeeding or through it: there are no data available about the effects on breastfeeding or through it.

Specific toxicity for target organs (STOT) – Single exposure.
Based on the evaluation of the classification of the components and to the dispositions of classifications of the Annex I, Part 3 of the Reg. (CE) 1272/2008 and following adjustments and integrations, the mixture is not classified for this dangerous class.

METHYL ALCOHOL
The substance has its action on the SNC where it causes initially syndrome of intoxication, then consciousness disorders more or less deep accompanied sometimes by convulsions, respiratory depression, and cardiovascular collapse.

FORMALDEHYDE
Its action it's from irritating to caustic for the respiratory apparatus. After an acute exposition for inhalation, it is observes irritation on eyes, nose, throat and lungs, so as cells alterations, as eye damage and swelling cell of the upper respiratory ways. In human, after swallowing have been observed severe ulceration of the gastrointestinal tract. (OCSE, 2002)

Specific toxicity for target organs (STOT) - Repeated exposure.
Based on the evaluation of the classification of the components and to the disposition of classification of the Annex I, Part 3 of the Reg. (EC) 1272/2008 and following adjustments and integrations, the mixture is not classified for this dangerous class.

METHYL ALCOHOL
Epidemiologic studies on workers exposed to the vapours of substances in a prolonged way, highlighted the presence of visual disorder, regarding the optical nerve and the retina, headaches strong and recidivists. The repeated or prolonged contact with the substance in liquid form can cause cutaneous irritation: dermatosis, erythema and scales.

FORMALDEHYDE
In the exposition long length there can be irritation of the ocular and respiratory mucous, symptoms of a chronic bronchitis, alteration of the functional respiratory proofs, respiratory epithelium injuries. Epidemiologic studies indicate also events of psycho-organic syndrome. A chronic cutaneous irritation has been also observed.

Aspiration hazard
Based on the evaluation of the classification of the components and on the disposition of classification of the Annex I, Part 3 of the Reg.(EC) 1272/2008 and following adjustments and integrations, the mixture is not classified for this dangerous class.

Metabolism, kinetics, mechanism of action and other information
METHYL ALCOHOL
The substance can be absorbed after swallowing, inhalation or skin contact. It is rapidly distributed in the total organism water. The half life is about 24 hours. The metabolism is on liver. The first step regards the oxidation of the methanol to formaldehyde by the hepatic alcohol dehydrogenase, enzyme not specific that has an affinity also for ethanol and butanol. The affinity regarding alcohol dehydrogenase for ethanol and methanol is approximatively 20:1; that means that this step is limited because it is bounded to a saturation process. In the 2nd step the formaldehyde is oxidised by the aldehyde dehydrogenase in formic acid or format in relation with pH. The 3rd step that bring to the formation of carbon dioxide is controlled by the metabolic way of the compounds to a carbon atom (system under the dependence of a derived by folic acid); is the limited step of the bio transformation. That explain the accumulation of formats in the organism in case of massive administration or repeated of methanol. The elimination of methanol and of its metabolites occurs with expired air (methanol and carbon dioxide) and with urines (methanol and formats). This process is slow, in particular if compared with ethanol. In the primates the metabolic process is about 50% slower than the rodents. The urinary concentration of the methanol, well related to the blood concentration, is a good indicator of the spreading of the substance. The existence of a latency phase previous to the appearance of the specific toxic effects suggests that these are not due to the substance itself, but for its metabolites. It has not been cleared the mechanism of the ocular toxicity, even if is probable that's due to the presence of formic acid and not of formic aldehyde. The accumulation of formic acid coincides with the metabolic acidosis and with the toxic effects on the central nervous system.

FORMALDEHYDE
The formaldehyde is an intermediate metabolic in al the cells. It is reproduced during the metabolism of the serine, glycine and choline and also for demethylation of the compounds N-, S-, and O-methyls. It is rapidly absorbed by the respiratory tract and gastro intestinal and rarely absorbed after skin application. It is methabolized to fomate by the enzyme formaldehyde dehydrogenase and after the carbon atom is oxidized into carbon dioxide or incorporate into purines, thymidines and aminoacids. Both formaldehyde and the formate don't accumulate in tissues. It spreads in the organs richly vascolarised, in tissues with rapid cells exchange (organs emathopoietics, gastrointestinal mucous) and in those with high protein synthesis (exocrine pancreas, salivary glands). After the absorbance the formaldehyde creates bounds with the proteins and the nucleic acids in the site of contact. The most part is excreted with the expired air as carbon dioxide, another amount is eliminated with urins.

Information on the probable exposure ways
The main potential exposure ways are inhalation, skin contact and ingestion. The exposition of the workers comes by skin contact and for inhalation.

Symptoms related to the physical, chemical and toxicological features

Acute effects: the product is toxic, causes poisoning for inhalation, skin absorption, and for ingestion. By inhalation of the product the poisoning can man take place, according to cases, with different symptoms that can include: burning and irritation to eyes, mouth, nose and throat, cough, respiratory difficult, vertigo, headache, sickness and vomiting. In the most severe cases the inhalation of the product can provoke: inflammation and oedema of the larynx and of bronchus, chemical pneumonia and pulmonary oedema, increasing or reduction of the cardiac frequency, plentiful salivation or bloody sputum, loss of consciousness, behaviour disorders (depression or euphoria). By skin contact the poisoning can take place with symptoms that can include: increase of the skin temperature, swelling, itch, headache, respiratory disorders and sometimes burnings or acid burns.
Also the ingestion of minimum quantities can provoke several disorders to health, that can include the following symptoms: burnings or mouth an throat damages, sickness, abdominal pain, vomit, diarrhea, excessive sweating, convulsions, state of unconsciousness.
The vapours and/or the powders are caustic for the respiratory apparatus and can cause pulmonary oedema, which symptoms are manifested, sometimes, only after some hour. The exposition symptoms can include: sensation of burning, cough, asthmatic respiration, laryngitis, short breath, headache, sickness and vomit. The ingestion can provoke mouth burnings, throat and esophagus: vomit, diarrhea, oedema, larynx swelling and consequent suffocation. There can be also perforation of gastrointestinal tract. The product can produce irreversible damages, not lethal, after a single exposure for inhalation, skin absorption and for ingestion.

Immediate, delayed and chronic effects derived from expositions at short and long term.
METHYL ALCOHOL
In case of severe intoxications, both digestive and inhalatory, the latency time for the comparison of the symptoms varies, from 10 to 48 hours, also

according to the swallowed dose. You have: -no specific symptoms as depression of the SNC with thrill syndrome, then conscious disorders more or less deep accompanied sometimes by convulsions, respiratory depression and cardio vascular collapse. Symptoms characteristic of methanol: metabolic acidosis marked with a wide and rapid respiration Kussumaul's type. You can arrive to an arterial Ph, lower than 7, important reduction of bicarbonates and increase of lactates; - visual disorders that can arrive lately, from the 2nd to 4th day and that are the manifestation of a neuritis bulbar optics. You have bilateral mydriasis with abolition of the fotomotor reflex, reduction of the visual acuity that can change in complete blindness and concentric shrinkage of the visual field. There is a big variability among the individuals for the resistance to methanol. In the most severe cases, death can arrive for respiratory insufficiency, or, even, after sever intoxications, you can recuperate totally but the ocular sequelae are frequents (reduction of visual field, complete blindness) epidemiologic studies on workers exposed to the substance vapours in a prolonged way with the substance in liquid form can cause skin irritation: dermatosis, erythema, scale. The substance for inhalatory way is irritating for eyes and respiratory apparatus.

FORMALDEHYDE
The olfactory perception and the sensitization to irritant effects vary from an individual to another. After swallowing the exposition to high concentrations of substance can cause bronchospasm with severe caustic injuries of the respiratory tree, acute pulmonary oedema, tracheitis and bronchitis ulcers. After swallowing big amounts, at high concentrations, cause caustic injuries. Those risk to be underrated because the mucous is stored whole. The systemic intoxication is responsible of a poly visceral damage that manifest itself with convulsion, coma, hepatic cytolysis and cardio circulatory disorders, moderate hemolysis, and tubular nephropathy. In more severe cases you have metabolic acidosis intense and coagulopathy of consume. In short term complications are perforations and bleeding associated to respiratory damages for larynx oedema, pneumopathy for inhalation or fistulas eso tracheal. Further evolution can be a digestive stenosis. The substance has an high allergenic powder and can cause of anaphylactic shock. In the expositions of long term you can irritation of ocular and respiratory mucous, symptoms of a chronic bronchitis, alteration in the functional respiratory proofs, injuries at the respiratory epithelium. Epidemiologic studies indicate also manifestations of organic psycho-syndrome.

SECTION 12. Ecological information.

12.1. Toxicity.

METHYL ALCOHOL

LC50 - for Fish.	15,4 g/l Lepomis macrochirus
EC50 - for Crustacea.	> 10 g/l Daphnia magna
Chronic NOEC for Fish.	7,9 g/l Oryzias latipes

FORMALDEHYDE...%

EC50 - for Crustacea.	5,8 mg/l/48h
EC50 - for Algae / Aquatic Plants.	> 3,48 mg/l/72h
Chronic NOEC for Fish.	> 48 mg/l

12.2. Persistence and degradability.

METHYL ALCOHOL

It expected to biodegrade.

FORMALDEHYDE
Released in atmosphere the gaseous formaldehyde degrade for reaction with radical oxyhydrogen products fotochemically (half life of reaction of about 41 hour).
It suffers direct photolysis as it absorbs in the environmental UV spectrum (half life of reaction of about 6 hours) (HSDB, 2014).
It polymerises rapidly in water.
It is biodegradable both in aerobic conditions and anaerobic in water and soil.
Because of slow oxidation it forms with formic acid; the complete oxidation conduces to carbon dioxide and water.
Rapidly biodegradable.

12.3. Bio accumulative potential.

METHYL ALCOHOL
Based on the log Kow it has been rated a BCF of 0,2. Based on the values of BCF rated and reported it is not foreseeable that the substance is bio concentrate in aquatic organisms.

Partition coefficient: n-octanol/water.	< 1
BCF.	< 10

FORMALDEHYDE
The bio concentration is not relevant. Experimental data with a variety of fishes and invertebrates animals show that it does not bio concentrates (HSDB, 2014) BCF 3.

12.4. Mobility in soil.

METHYL ALCOHOL

The volatilization from the water and from the soil should be relevant in normal environmental conditions.
Partition coefficient: soil/water. > 0,13

FORMALDEHYDE
It is foreseeable high mobility in soil based on a Koc rated of 37 (HSDB, 2014).
It is essentially volatile.
It is not foreseeable the volatilization from surfaces of wet soil (based on Henry laws).
The formaldehyde volatilizes from surfaces of dry soil.
In water, it does not absorb to suspended sediments and solids.

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.

METHYL ALCOHOL
Some plants exposed to air contain methanol (conc. Between 0,4 and 2,5 mg/m3) for 14 days, suffered delays on growth.

FORMALDEHYDE
The bean and barley plants can absorb formaldehyde through leafs.

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.

UNLCEANED 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.(s)

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. None.

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.

Product not intended for uses provided for by Dir. 2004/42/CE.

15.2. Chemical safety assessment.

A chemical safety assessment has been performed for the following contained substances.

FORMALDEHYDE...%

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
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.
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 labelling 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 bio accumulative 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 Bio accumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY
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2. Regulation (EU) 1272/2008 (CLP) of the European Parliament
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5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
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9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
- The Merck Index. - 10th Edition
- Handling Chemical Safety
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- 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: complete revision.