

AB Achema
Safety Data Sheet



according to Regulation No. 1907/2006/EC (REACH), annex No. II, with all subsequent amendments and additions and the Commission Regulation (EU) No. 2020/878

Formaldehyde solution (formalin)

Revision date: 2026.02.28
Version No: 12.0
Revision No: 0
Issuing date: 2026.02.28

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Mixture trade name: Formaldehyde solution (formalin).

Mixture components: formaldehyde, methanol, water.

Components identification

Chemical name of the substance: Formaldehyde.

Index number in accordance with the Regulation (EC) No. 1272/2008: 605-001-00-5.

EC No. 200-001-8.

CAS No. 50-00-0.

REACH registration No. 01-2119488953-20-XXXX.

Chemical name of the substance: Methanol.

Index number in accordance with Regulation (EC) No. 1272/2008: 603-001-00-X

EC No. 200-659-6

CAS No. 67-56-1

REACH registration No. 01-2119433307-44-XXXX.

Other means of identification: Unique formula identifier of the product according to the Regulation EU 2017/542 – **UFI:** R00F-KG2M-CJFJ-FUEA.

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

1.2.1. Identified uses

Industrial use:

- Industrial use [SU3, SU8, SU9, SU10, SU12]: Production of formaldehyde and aqueous formaldehyde (PC excluded);

- Industrial use [SU3, SU10]: production of mixtures (30 to 60%) (PC excluded).

Professional use: Not available.

Further consumer use: Not available.

1.2.2. Uses advised against: Not available.

1.3. Details of the supplier of the safety data sheet

Manufacturer: AB Achema

Address: Jonalaukio k. 1, Jonavos sen., Jonavos raj. LT55296

Country: Republic of Lithuania

Phone: +370 (349) 56736

Manufacturer's/supplier's website: www.achema.lt

Person in charge of the Safety Data Sheet: Dainius Šlepetis, d.slepetis@achema.com

1.4. Emergency telephone number

Please contact: Poison Information and Control Office in the Republic of Lithuania by phone +370 52362052, cell phone +370 687 53378, on site <http://www.apsinuodijau.lt/information-in-english/> or by the Common

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emergency Center by 112.

Helpdesk services work: 24 hours a day, 365 days a year.

Other remarks (language in which assistance is provided): assistance is provided in Lithuanian.

Poison Control Centers in Europe are available on site <http://www.who.int/pcs/poisons/centre/directory/euro/en/>.

Telephone numbers of poison control centers in the European Economic Area: **IRELAND** (Dublin) +353 1 8379964; **AUSTRIA** (Vienna) +43 1 406 43 43; **BELGIUM** (Brussels) +32 70 245 245; **BULGARIA** (Sofia) +359 2 9154 409; **CZECH REPUBLIC** (Praha) +420 224 919 293; **DENMARK** (Copenhagen) 82 12 12 12; **ESTONIA** (Tallinn) 112; **GREECE** (Athens) +30 10 779 3777; **ICELAND** (Reykjavik) +354 525 111, +354 543 2222; **ITALY** (Rome) +39 06 305 4343; **LATVIA** (Ryga) +371 704 2468; **MALTA** (Valletta) 2425 0000; **NORWAY** (Oslo) 22 591300; **NETHERLANDS** (Bilthoven) +31 30 274 88 88; **FRANCE** (Paris) +33 1 40 0548 48; **FINLAND** (Helsinki) +358 9 471 977; **SWEDEN** emergency cases 112; in less acute cases +46 040 456 6700; **HUNGARY** (Budapest) 06 80 20 11 99; **GERMANY** (Berlin) +49 30 19240.

SECTION 2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

2.1.1. Classification according to Regulation (EC) No. 1272/2008 [CLP]

In English

Carc. 1B, H350.

Muta. 2, H341.

Acute Tox. 3, H301.

Acute Tox. 3, H311.

Acute Tox. 3, H331.

Eye Dam. 1, H318.

Skin Corr. 1B, H314.

Skin Sens. 1, H317.

STOT SE 2, H371.

STOT SE 3, H335.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms:



GHS08



GHS06



GHS05

Signal word: DANGER

Hazard statements:

H350: May cause cancer.

H341: Suspected of causing genetic defects.

H371: May cause damage to organs.

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- H301: Toxic if swallowed.
- H311: Toxic in contact with skin.
- H331: Toxic if inhaled.
- H318: Causes serious eye damage.
- H314: Causes severe skin burns and eye damage.
- H317: May cause an allergic skin reaction.

Precautionary statements:

- P260: Do not breathe dust/fume/gas/mist/vapours/spray.
- P280: Wear protective gloves/ protective clothing/ eye (face) protection.
- P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
- P302 + P352: IF ON SKIN: Wash with plenty of soap and water.
- P304 + P340: IF INHALED: Remove to fresh air and keep at rest in a position 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.
- P401: Store at a temperature not below 15 °C and not higher than 25 °C.
- P403 + P233: Store in a well-ventilated place. Keep container tightly closed.

Additional information about the hazard (EUH): Not applicable.

2.3. Other hazards

The product does not meet the PBT or vPvB criteria under Regulation (EC) No. 1907/2006 Annex XIII. Has a sharp irritating odour. Especially flammable. Formaldehyde mixtures are explosive when in contact with air. Easily soluble in water. Formaldehyde solutions have a high vapour pressure at room temperature. Formaldehyde tends to generate polymers. May cause acute and long-lasting health damage. Has toxic effect when inside human body. Hazardous for the environment.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Formalin is treated as a mixture in accordance with Regulation (EC) No. 1907/2006 requirements.

3.2. Mixtures

Identity of the components of the mixture.

CAS No.	EC No.	Index number in accordance with Regulation (EC) No. 1272/2008	REACH registration No.	Mass fraction, %	Name	Classification according to Regulation (EC) No. 1272/2008
50-00-0	200-001-8	605-001-00-5	01-2119488953-20-XXXX	37.2±0.3 (only for formalin 37); 42.0±0.5 (only for formaline 42);	Formaldehyde	Carc. 1B, H350, Muta. 2, H341, Acute Tox. 3, H301, Acute Tox. 3, H311, Acute Tox. 3, H331, Skin Corr. 1B, H314, Eye Dam 1, H318, Skin Sens. 1, H317.

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						Specific concentration limits: Skin Corr. 1B, H314: $C \geq 25\%$; Skin Irrit. 2, H315: $5\% \leq C < 25\%$; Eye Irrit. 2, H319: $5\% \leq C < 25\%$; STOT SE 3, H335: $C \geq 5\%$; Skin Sens. 1, H317: $C \geq 0,2\%$.
67-56-1	200-659-6	603-001-00-X	01-2119433307-44-XXXX	4-8 (only for formaline 37); 0.2-1.5 (only for formaline 42);	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: $C \geq 10\%$; STOT SE 2, H371: $3\% \leq C < 10\%$

SECTION 4. FIRST-AID MEASURES

4.1. Description of first aid measures

4.1.1. General information

The substance may enter the organism through: respiratory tract, contact with skin, eyes, if swallowed.

4.1.2. If inhaled: call emergency medical assistance immediately. Remove the affected person to fresh air, calm them down, cover with something warm. Ensure the affected person immediately inhales a set standard dose of corticosteroid from an inhalation device. If such a device is unavailable, give a breath of water steam with a few drops of ammonium chloride. In the event of respiratory failure or the disappearance of vital functions, perform artificial respiration. If breathing and/or vital functions do not recover, perform artificial respiration until the ambulance arrives.

4.1.3. If on skin: If a small amount of the product contacts the skin, remove the contaminated clothing immediately, wash the affected area with plenty of water. Put on clean clothes. Apply a sterile bandage on the affected area. Seek medical attention immediately.

If a greater amount of the product contacts the body and it is difficult to remove working clothes fast, wash the affected area together with clothing with plenty of water. Remove contaminated clothing. Continue washing the affected area with plenty of water. Wrap the areas affected by the product with a sterile bandage. Put on clean clothes. Seek medical attention immediately.

4.1.4. If in eyes: Start washing the affected eyes instantly, keeping them open, in running water. Wash your eyes for at least 15 minutes. Seek medical attention immediately.

4.1.5. If swallowed: do not induce vomiting! Wash your mouth well with water immediately. Then drink about 200 to 300 ml of clean water. Seek medical attention immediately.

4.1.6. Individual protection measures recommended for use by first aid-providing persons. The product is toxic if inhaled, if in contact with skin, if swallowed, it is skin corrosive and sensitising; therefore, persons who provide first aid must first take care of their own safety, i.e. use protective clothing, gloves, respiratory protective devices.

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

Acute effects:

4.2.1. Inhalation: Symptoms of acute toxicity. Irritation of nasal and pharyngeal mucosa (burning sensation, sneezing, colds), possible asthma attacks / asthma complaints. High concentrations can cause severe respiratory

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problems, cough attacks, chest pressure, and circulatory reactions. There is a risk of bronchospasm, bronchiolitis, pulmonary edema.

4.2.2. After skin contact: Symptoms of acute toxicity. Depending on the concentration and duration of contact, skin corrosion, superficial coagulation necrosis with hardening and darkening of the skin, allergic skin reactions (edema, urticaria, delayed eczema formation).

4.2.3. Eye contact: Causes long-term damage to the cornea. Product gas / vapor corrosive to the eyes.

4.2.4. Ingestion: Depending on the concentration, mucosal corrosion, abdominal pain, stomach cramps, blood vomiting, cyanosis, respiratory failure. Blood systemic absorption of formaldehyde, anxiety / fear, dyspnea, albuminuria, hematuria, oliguria to anuria, acidosis, somnolence, vertigo, spasms, cardiovascular reactions. In severe cases, there may be rapid loss of consciousness, coma and death.

Delayed effects: The product may cause delayed symptoms, ie. symptoms may occur some time after exposure. Repeated exposure may cause kidney disease. May cause damage to organs. May cause cancer. Suspected of causing genetic defects.

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

Remove contaminated clothing immediately.

Measures that can be assumed only by a doctor: stomach washing, giving 100 ml of the solution containing 2 % ammonium carbonate and 20 % urea to drink. Apply measures to prevent pulmonary oedema.

If there is a chance that the patient may lose consciousness, hold him/her well fixed and transport while holding in a recovery position.

SECTION 5. FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media: finely sprayed water, foam, carbon dioxide, powder and foam fire extinguishers.

Unsuitable extinguishing media: Strong water current.

5.2. Special hazards arising from the substance or mixture

Combustion may release formaldehyde, carbon monoxide, carbon dioxide and methanol gas.

5.3. Advice for firefighters

Use self-contained breathing apparatus. In the event of a fire, use all possible ways to avoid the substance spreading in the environment; do not allow to enter sewage as it can lead to potential explosion.

Firefighters should wear personal protective equipment (safety boots, protective work clothing, protective gloves, eye, face protection, respiratory protection) according to LST EN 469.

Other information: Dispose firebrands and contaminated water used for extinguishing in accordance with the European Union and national legislation requirements.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel: Use personal protective equipment referred to in Section 8.2 of this Safety Data Sheet. Avoid any contact with the product. In case the product contacts clothes, remove them, wash the affected areas with plenty of running water.

6.1.2. For emergency responders: emergency personnel must ensure their own safety before providing assistance. Use personal protective equipment referred to in Section 8.2 of this Safety Data Sheet. Firefighters

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must wear fire resistant suits, fire suits, rubber vulcanized fire boots, fire resistant gloves, acid resistant gloves, protective helmets according to LST EN 469. In case of an emergency, evacuate people from dangerous areas. Collect as much as possible of spilled product using dry sand or another absorptive agent. Avoid any contact with the product. If the product contacts clothes, remove them, wash the affected areas with plenty of running water.

6.2. Environmental precautions

Avoid any product release into the environment. Collect as much as possible of the spilled product in a sealed container. Do not discharge onto the ground, into drains, surface or groundwater.

6.3. Methods and material for containment and cleaning up

Collect as much as possible of spilled product in sealed containers, remove the residues with suitable absorbent material (sand or a universal absorbent), scoop the material up into waste container and store until destruction. Protective barriers shall be installed and sewage system shall be closed in case of a spill.

6.4. Reference to other sections

See Section 8.2 on personal protective equipment and Section 13 on waste management.

SECTION 7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Production and storage rooms and laboratories must be equipped with input and exhaust ventilation, and workplaces must be equipped with local exhaust ventilation. Avoid any product dispersion in the environment. Use personal protective equipment referred to in Section 8.2 of this Safety Data Sheet. Handle the product in accordance with good industrial hygiene and safety requirements. In the working environment, where the product is used and stored, eating, smoking, drinking is strictly prohibited. After finishing working with the product or before going into the eating room, take off contaminated clothing and contaminated protective measures and wash yourself thoroughly.

7.2. Conditions for safe storage, including any incompatibilities

Avoid product vapour/aerosol formation. The product vapour may form an explosive mixture with air. Take precautions to prevent electrostatic charge. Electrical equipment must have explosion protection. Store away from sources of inflammation and heat. Do not smoke! The product packaging must be leak-proof, resistant to corrosion. Store the product in heated hermetic containers protected from direct sunlight in well-ventilated premises at +15 °C to +25 °C (for 37 % formaldehyde solution). Transport and storage of formaldehyde solution may result in turbidity or a white precipitate (paraformaldehyde). In this case, the product shall be heated not exceeding the temperature of 40 °C, without the use of an open flame.

The maintenance of stationary containers of the product in Lithuania is performed in accordance with the amendment of the Order No. A1-178 of the Republic of Lithuania of 30 May 2008 “On approval of the rules for maintenance of stationary non-pressurized containers of hazardous substances and mixtures”, Order No. A1-1132 of the Ministry of Social Security and Labour of the Republic of Lithuania of 20th of November 2020.

When storing the product in Lithuania in stationary containers with a volume of more than 50 m³, these containers must be registered with the state register management institution in accordance with the Chief State Labour Inspector of the Republic of Lithuania of 1st August 2006 Order No. 1-178 “On the Approval of the List-Classification of Potentially Dangerous Equipment to be Registered in the State Register, Indicating Their Parameters”. When storing the product in other countries, the storage requirements in force in those countries must be complied with.

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Incompatible materials: chemical substances that are unsuitable (incompatible) for combined storage are strong oxidising agents, aniline, phenol, isocyanates, anhydrides, strong acids, strong bases, amines, peroxides.

Suitable materials of containers: stainless steel 1.4301 (V2), high density polyethylene (HDPE), low density polyethylene (LDPE), stainless steel 1.4401, aluminium.

Unsuitable materials of containers: paper/chipboard, cardboard, glass.

It is allowed to store no more than 50 t of formalin in the storage at a time. Higher formalin quantities may be stored in facilities which met the requirements applicable to dangerous objects under Resolution No. 966 of the Government of the Republic of Lithuania of 17 August 2004 “On the Approval of the Provisions of the Prevention, Liquidation and Investigation of Industrial Accidents and of the List and the Description of Qualification Criteria for the Substances, Mixtures or Preparations Classified as Dangerous Substances in Dangerous Objects” (Official Gazette, 2004, No. 130-4649) with subsequent amendments and additions or the Directive 2012/18/EU.

7.3. Specific end use(s)

Formaldehyde solution is used in the production of urea formaldehyde resins, melamine-urea formaldehyde resins.

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control parameters

The limit value of the component of the chemical substance and the preparation in the ambient air:

Long-term exposure limit value (LTELV): 0.6 mg/m³ or 0.5 ppm (by formaldehyde) (applicable in Lithuania pursuant to the Hygiene Norm HN 23); 0,37 mg/m³ or 0,3 ppm (by formaldehyde) in accordance with Directive (EU) 2019/983.

Maximum allowable value for short-term exposure (MAVSTE): 0,74 mg/m³ or 0,6 ppm (by formaldehyde) in accordance with Directive (ES) 2019/983.

Limit value (LV): not applicable (by formaldehyde) (applicable in Lithuania pursuant to the Hygiene Norm HN 23).

Formaldehyde - in - air measurements and monitoring must be carried out in the production, storage and use areas of formalin. Formal and professional use of formalin shall be subject to compliance by the Minister of Social Security and Labor and the Minister of Health of 2001. July 24 Approval of Ordinance No 97/406 on the approval of provisions for the protection of workers from chemical agents at work and on the protection of workers from the effects of carcinogens and mutagens at work (Official Gazette, 2001, No. 65-2396, TAR identification code 1012230ISAK0097 / 406) and additions to the requirements.

Derived no-effect level(s) (DNEL). The values of formaldehyde registration according to REACH documentation DNEL values are provided below.

For employees

The route of exposure	The type of exposure	Hazard	Physical and chemical property that could cause the largest adverse effects
If inhaled	Systemic exposure – long-term	DNEL: 9 mg/m ³	Specific target organ toxicity (repeated exposure)
If inhaled	Systemic exposure – acute		
If inhaled	Local exposure – long-term	DNEL: 0.375 mg/m ³	
If inhaled	Local exposure – acute	DNEL: 0.75 mg/m ³	
Through	Systemic exposure – long-term	DNEL: 240 mg/kg bw/day	Specific target organ toxicity (repeated

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the skin			exposure)
Through the skin	Systemic exposure – acute		
Through the skin	Local exposure – long-term	DNEL: 37 µg/cm ²	
Through the skin	Local exposure – acute		
Through contact with the eyes	Local exposure		

Explanation of DNEL derivation for employees

The type of exposure	DNEL derivation	The assessment factor used in the DNEL derivation
If inhaled Systemic exposure – long-term	DNEL reference point: NOAEC	
Through the skin Systemic exposure – long-term	DNEL reference point: NOAEL	Overall assessment factor: 12
Through the skin Local exposure – long-term		

The general public

The route of exposure	The type of exposure	Hazard	Physical and chemical property that could cause the largest adverse effects
If inhaled	Systemic exposure – long-term	DNEL: 32 mg/m ³	Specific target organ toxicity (repeated exposure)
If inhaled	Systemic exposure – acute		
If inhaled	Local exposure – long-term	DNEL: 0,1 mg/m ³	
If inhaled	Local exposure – acute		
Through the skin	Systemic exposure – long-term	DNEL: 102 mg/kg bw/day	Specific target organ toxicity (repeated exposure)
Through the skin	Systemic exposure – acute		
Through the skin	Local exposure – long-term	DNEL: 12 µg/cm ²	
Through the skin	Local exposure – acute		
Through the mouth	Systemic exposure – long-term	DNEL: 4.1 mg/kg bw/day	Specific target organ toxicity (repeated exposure)
Through the mouth	Systemic exposure – acute		
Through	Local exposure		

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contact with the eyes			
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Explanation of DNEL derivation for the general public

The type of exposure	DNEL derivation	The assessment factor used in the DNEL derivation
If inhaled Systemic exposure – Long-term		
If on skin Systemic exposure – Long-term	DNEL reference point: NOAEL	Overall assessment factor: 20
If on skin Local exposure – Long-term		Overall assessment factor: 3
Oral Systemic exposure – Long-term	DNEL reference point: NOAEL	Overall assessment factor: 20

Predicted no-effect concentration(s) (PNEC). The values of formaldehyde registration according to REACH documentation PNEC values are provided below.

Task in the field of environmental protection	The PNEC value
Fresh water	0.44 mg/l
Fresh water sediment	2.3 mg/kg sediment dw
Sea water	0.44 mg/l
Interrupted release to water	4.44 mg/l
Sea-water sediment	2.3 mg/kg sediment dw
Food chain	
Micro-organisms in sewage treatment plants	0.19 mg/l
Soil (agricultural purpose)	0.2 mg/kg soil dw
Air	Since formaldehyde is characterised by a low log Pow, secondary poisoning is not a likely route of exposure.

8.2. Exposure controls

8.2.1. Appropriate engineering controls: input/exhaust ventilation.

8.2.2. Individual protection measures, such as personal protective equipment:

8.2.2.1. Eye/face protection: well attached chemically resistant hermetic goggles that protect the eyes from splash of the product or face protection shield in accordance to LST EN ISO 16321-1 and LST EN ISO 16321-3. It is recommended to use full face protection measures.

8.2.2.2. Skin protection

Hand protection: wear protective gloves that comply with the requirements under LST EN 420, LST EN 21420 for protection against chemical hazards, LST EN 388 for protection against mechanical risks. Protective gloves must be manufactured from one of the materials specified in the table below and have thickness and resistance to penetration at least as specified.

Gloves material	Glove thickness, mm	Penetration through the glove material time, min*

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Butyl rubber	0.35	> 480
Viton butyl	0.70	> 480
Two-layer neoprene	0.75	480
Neoprene	0.13	240 to 480
Nitrile synthetic rubber	0.40	480
Nitrile	0.12	> 480
Nitrile rubber/Nitrile latex	0.35	> 480
Nitrile/Neoprene	0.19	> 480
Fluorocarbon rubber	0.40	> 480
LLDPE	0.062	> 480
Polychloroprene	0.50	240

* penetration through the glove material time is the time during which the product in contact with the glove penetrates fully through it. The shorter the penetration time is, the less product-resistant glove material is.

The product user should select the gloves material suitable for his/her situation out of the following possible choices having regard to the nature of the work, the likelihood of the gloves' contact with the product and the duration of potential exposure. In the event of continuous work with the product, it is recommended to use glove materials with the penetration time of at least 480 minutes. When working with the product, gloves cannot be used longer than the penetration time.

Gloves made from polyvinyl chloride, natural rubber/natural latex, PVA, textile, leather are not suitable for working with the product.

Skin protective creams do not ensure sufficient protection from the product.

Please note that the penetration through the glove material time specified here was determined at 22 °C using a 37 % formaldehyde aqueous solution. Using the product mixtures with other materials at normal temperature or using the product at an elevated temperature, the material resistance may be significantly lower; therefore, in such cases the permitted period of using the gloves must be shortened. When introducing a new type of gloves or gloves of another manufacturer, we recommend first of all to make sure that these gloves are sufficiently chemically and mechanically resistant to work under the existing working conditions. Should you have any questions regarding the suitability of specific gloves, please address the glove manufacturers/suppliers.

Inside, the gloves cannot contain powder that can cause hand skin allergies.

Before putting on the gloves, always make sure the gloves are free from any tears, cracks or other defects. After finishing the work, gloves must be well cleaned and washed before taking them off. After finishing the work, hand skin care must receive sufficient attention.

Other protection: chemically resistant working clothes in accordance with LST EN ISO 13688 and LST EN 13034, work boots in accordance with LST EN ISO 20345.

8.2.2.3. Respiratory protection: Appropriate respiratory protection, in case of low product vapour / aerosol concentrations in the air (slightly exceeding the permitted limit values for the working environment air according to the Hygiene Norm HN 23), is a filtering gas-mask with A and E brand filters in accordance with LST EN 14387. In case of higher formaldehyde concentration in the air or in case of a prolonged exposure to the contaminated environment, use hose gas-masks, compressed air breathing devices according to LST EN 402.

Other protection: take off product-contaminated clothing immediately. It is prohibited to eat, drink, and smoke while handling the product. Wash hands before eating, smoking or using the toilet.

8.2.3. Environmental exposure controls: do not allow to enter into the sewage and the environment.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

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- a) Physical state:** 30 to 60 % formaldehyde aqueous solution is clear colourless liquid at 20 °C and 1013 hPa. During storage, the turbidity or white precipitate dissolving at a temperature not exceeding 40 °C is permitted.
- b) Color:** colorless.
- c) Odour:** Specific spicy suffocating odour (data source – formaldehyde REACH registration dossier).
- d) Melting point/freezing point:** between -92 °C and -118 °C at 1013hPa pressure (of pure formaldehyde); Approx. -18.8 °C at 1013 hPa pressure (of 30.19 % concentration of formaldehyde aqueous solution) (data source – formaldehyde REACH registration dossier).
- e) Boiling point or initial boiling point and boiling range:** ≥ -21 °C and ≤ -19.1 °C at 1013.25 hPa pressure (of pure formaldehyde); 98.9 to 99.4 °C at 1013.25 hPa pressure (of formaldehyde aqueous solution) (data source – formaldehyde REACH registration dossier).
- f) Flammability:** **highly flammable** (pure formaldehyde is gas). In formaldehyde REACH registration dossier, the results are derived on the basis of formaldehyde explosive limits: the lower limit is 7 % (by volume), the upper limit is 72 to 73 % (by volume). Formaldehyde aqueous solution containing > 10 % of methanol is highly flammable. Formaldehyde solution containing ≤ 10 % of methanol is flammable.
- g) Upper/lower flammability or explosive limits:** 7 to 73 % (by volume). Literature data.
- h) Flash point:** not applicable (for pure formaldehyde as it is in the gaseous aggregate state). The flash point of formaldehyde aqueous solutions depends on the formaldehyde and the methanol concentrations. Formaldehyde REACH registration dossier contains the conclusion that the flash point temperature of formaldehyde solutions containing no methanol is not lower than 80 °C. The flash point of formaldehyde solutions containing 15 % methanol is approx. 50 °C. The flash point of formaldehyde solutions containing 10 % of methanol is higher than 60 °C.
- i) Auto-ignition temperature:** 395 °C at 1013 hPa pressure (of pure formaldehyde) (data source – formaldehyde REACH registration dossier).
- j) Decomposition temperature:** > 300 °C (of pure formaldehyde gas). Literature data.
- k) pH:** 2.8 to 4.0 at 20 °C.
- l) Kinematic viscosity:** Viscosity of aqueous solutions of formaldehyde at 20 °C depending on the formaldehyde concentration (range 30.19 to 40.08 %) and the methanol concentration (range 0.95 to 11.95 %) between 2.083 and 2.835 mPa) (data source: formaldehyde registration dossier under REACH).
- m) Solubility:** pure formaldehyde solubility in water is about 550 g/l at 20 °C. Formaldehyde is soluble in alcohol and in ether. Formaldehyde aqueous solution mixes with alcohol and with acetone (data source – formaldehyde REACH registration dossier).
- n) Partition coefficient: n-octanol/water (log value):** Log Kow (Pow): 0.35 at 25 °C (data source – formaldehyde REACH registration dossier).
- o) Vapour pressure:** approx. 5176 to 5186 hPa at 25 °C (of pure formaldehyde, i. e. gas); 14 hPa at 20 °C and 92 hPa at 50 °C (of 55 % formaldehyde aqueous solution). Partial formaldehyde pressure above the water is 1.2 and 1.3 hPa at 20 °C, respectively 30 and 50 % of formaldehyde aqueous solutions (data source – formaldehyde REACH registration dossier).
- p) Density and / or relative density:** 0.815 g/cm³ at -20 °C (of pure formaldehyde); 1.069 to 1.12 g/cm³ at 20 °C (of formaldehyde aqueous solution, depending on concentration) (data source – formaldehyde REACH registration dossier).
- q) Relative vapour density:** approx. 1.03 to 1.067 at 20 °C (of pure formaldehyde, air =1) (data source – formaldehyde REACH registration dossier).
- r) Particle properties:** The product is a liquid and therefore not applicable.

9.2 Other information

There are no additional data that are important for the safety and health of users and the environment protection.

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SECTION 10. STABILITY AND REACTIVITY

10.1. Reactivity

The product is considered to be stable when the adequate use and storage conditions are ensured. May release formaldehyde when heated. A turbidity, i. e. paraform, may occur during storage (see Section 7: Handling and storage). Steel grows rusty when in contact with the product.

Suitable materials for storage containers are stainless steel, aluminium, enamel, glass, polyethylene, polyester, plastic, iron coated with epoxy resin.

10.2. Chemical stability

Formaldehyde polymeric product, i. e. paraform, is forming at a temperature under +11 °C. The initiators of this polymerisation reaction are alkali metals, acids, nitrogen oxides, hydrogen peroxide, oxidising agents, phenol (see Section 7: Handling and Storage).

According to the Ullmanns Encyclopaedia (2012), formaldehyde is unstable in polar solvents (such as alcohols or amines) as it reacts with these compounds.

10.3. Possibility of hazardous reactions

Intense reaction with oxidisers, spontaneous combustion.

10.4. Conditions to avoid

Avoid all sources of inflammation: heat, sparks, open flames. Avoid vapour/aerosol formation, oxidation agents. It is recommended to store the product in heated hermetic containers protected from direct sunlight in well-ventilated premises at 15 °C to +25 °C. Electrical equipment must have explosion protection.

10.5. Incompatible materials

Incompatible chemical substances are oxidising agents. Alkali metals, acids, nitrogen oxides, hydrogen peroxide, oxidising agents, phenol, once in the product, may cause polymerisation reaction. Then, a turbidity, i. e. paraform, forms in formalin.

10.6. Hazardous decomposition products

The product is stable when adequate use and storage conditions are ensured (see Section 7: Handling and storage). Under such conditions there are no hazardous decomposition products. Combustion may form formaldehyde, carbon monoxide, carbon dioxide and methanol gas, also these gas and air mixtures are explosive.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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Acute toxicity: Based on available data, the classification criteria are met according to Regulation (EC) No. 1272/2008 as acute toxic when inhaled, ingested and in contact with skin Cat. 3.

If swallowed LD₅₀ (rats): 100 mg/kg (of pure formaldehyde).

Through the skin LD₅₀ (rabbits): 220.1 mg/kg (of pure formaldehyde).

If inhaled LC₅₀ (rats): 0.578 mg/l/4 h (of pure formaldehyde).

High toxicity due to short-term access to the respiratory tract.

High toxicity if swallowed.

No data on acute toxicity through the skin.

Experimental/calculated data:

LD50 (rats) (if swallowed): 460 mg/kg.

In the EU, it must be classified as toxic.

LC50 (rats) (if inhaled): 588 mg/m³ (4 hours) (490 ppm).

In the EU, it must be classified as toxic.

Skin corrosion/irritation: Corrosive. Experimental/calculated data: Aqueous formaldehyde solutions (40 %) cause skin corrosion in rabbits. The skin irritation effect is at more than 3 % of the formaldehyde concentration in the solution. Eye irritation caused by gas formaldehyde (in humans) limit (0.3 to 0.6) ppm. Based on available data, the classification criteria are met according to Regulation (EC) No. 1272/2008 as irritating in contact with skin Cat. 1B.

Serious eye damage/irritation: Based on available data, the classification criteria are met according to Regulation (EC) No. 1272/2008 as serious eye damage Cat. 1.

Respiratory or skin sensitisation: Evaluation of respiratory or skin sensitisation: sensitising (through the skin). Experimental/calculated data: specialised studies did not provide evidence of formaldehyde conditioning the allergic respiratory illnesses. The symptoms may be related to irritation effects. Based on available data, the classification criteria are met according to Regulation (EC) No. 1272/2008 as a skin sensitizer Cat. 1.

Germ cell mutagenicity: Genetic toxicity: positive. Experimental/calculated data: although the available data of the tests with experimental animals indicate that formaldehyde has mutagenic effect, yet definitive conclusions regarding human exposure are not available. Not classified as a genotoxic substance. Based on available data, the classification criteria are met according to Regulation (EC) No. 1272/2008 as a germ cell mutagen in Cat. 2.

Carcinogenicity: positive (the product is a carcinogen). Experimental/calculated data: there is evidence that formaldehyde carcinogenicity for experimental animals increases the tumour formation potential. This occurs only in the event of severe local toxicity. Based on available data, the classification criteria are met according to Regulation (E C) No. 1272/2008 as a carcinogen in Cat. 1B.

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Reproductive toxicity: Adverse effects on reproduction were not observed. Based on available data, the classification criteria of Regulation (EC) No 1272/2008 are not met.

Specific target organ toxicity (STOT) (single exposure): hazardous to health if inhaled, due to skin contact, if swallowed, in the event of gas poisoning. Vulnerable organs: upper respiratory tract, nasal mucosa, lungs, stomach. Based on available data, the classification criteria are met according to Regulation (E C) No. 1272/2008 as specific target organ toxicity - single exposure Cat. 2.

Specific target organ toxicity (STOT) (repeated exposure):

CSA (if swallowed):

- NOAEL: 82 mg/kg bm/day;
- organs: digestion: stomach.

CSA (if inhaled):

- NOAEC: 1.2 mg/m³;

Target organs: respiratory: nose, larynx, trachea.

Based on available data, the classification criteria of Regulation (EC) No 1272/2008 are not met.

Aspiration hazard: None.

11.2. Information on the other hazards

None.

11.2.1. Endocrine disrupting properties

Data not available on the current product.

11.2.2. Other information

None.

SECTION 12. ECOLOGICAL INFORMATION

12.1. Toxicity

Formaldehyde is characterised by moderate chronic toxicity.

Toxicity to aquatic organisms

Short-term toxicity to fish: acute toxicity to fish:

LC50 (96 h) = 6.7 mg/l (Morone saxatilis).

Long-term toxicity to fish: no data available.

Short-term toxicity to aquatic invertebrates: acute toxicity to aquatic invertebrates:

EC50 (48 h) = 5.8 mg/l (Daphnia pulex).

Long-term toxicity to aquatic invertebrates: no data available.

Toxicity to algae and aquatic plants: acute toxicity to algae:

EC50 (72 h) = 4.89 mg/l (Desmodesmus subsipicatus).

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Other aquatic organisms: not regulated under REACH.

Toxicity to soil micro-organisms

Short-term toxicity to soil micro-organisms:

LC50 (48 h) Eisenia fetida (1 to 10) $\mu\text{g}/\text{cm}^2$ (filter paper, other toxicity tests).

Long-term toxicity to soil micro-organisms: no data available.

Effect on the atmosphere (climate change): no data available.

12.2. Persistence and degradability

Microbiological activity in sewage treatment systems:

Depending on the local conditions and existing concentrations, disturbance of biological active sludge process is potential.

Assessment of hydrolysis: hydrolysis is not expected.

Assessment of photo transformation in the air:

The reactions with hydroxyl radicals are considered as the most crucial in photo-oxidation process. Half elimination of formaldehyde in the atmosphere ranges between 7.1 and 71.3 hours.

Assessment of photo transformation in water: Not regulated under REACH.

12.3. Bioaccumulative potential

Low bioaccumulation potential. Does not accumulate in organisms.

The bioconcentration factor (BCF): 0.396 l/kg.

The Log Pow is approx. 0.35 at 20 °C and shows a low bioaccumulation risk.

Secondary poisoning. Since it does not accumulate in organisms, the probability of secondary poisoning is low.

12.4. Mobility in the soil

No data available.

12.5. Results of PBT and vPvB assessment

According to the REACH Regulation, Annex XIII, the product does not meet the PBT and vPvB criteria.

12.6. Endocrine disrupting properties:

No data available.

12.7 Other side effects:

No data available.

SECTION 13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods:

Waste from residues. Formaldehyde solution waste according to Regulation (EU) No. 1357/2014 is classified as hazardous waste with the following classification codes: **HP7** "Carcinogenic", hazard statement code: H350 "May cause cancer", **HP6** "Acute toxic", hazard statement codes H331 "Toxic if inhaled", H311 "Toxic in contact with skin" and H301 "Toxic if swallowed", **HP5** "Specific target organ toxicity (STOT)/Toxic if inhaled", hazard statement code H371 "May cause damage to organs", **HP4** "Irritant – irritating to the skin and causing damage to

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eyes”, hazard statement code H314 “Causes severe skin burns and eye damage”, **HP13** “Sensitising”, hazard statement code H317 “May cause an allergic skin reaction”, **HP15** “Waste that may develop any of the above hazardous property, which the primary waste directly did not demonstrate”, hazard statement EUH044 “Risk of explosion if heated under confinement”.

Formaldehyde solution waste must be transferred to waste management companies. Formaldehyde solution waste in Lithuania must be handled in accordance with the Law of the Republic of Lithuania on Waste Management, in other countries – in accordance with national legislation requirements.

Formaldehyde solution packaging waste. Formaldehyde solution packaging waste according to Regulation (EU) No. 1357/2014 is classified as hazardous waste with the following classification codes: **HP7** “Carcinogenic”, hazard statement code: H350 “May cause cancer”, **HP6** “Acute toxic”, hazard statement codes H331 “Toxic if inhaled”, H311 “Toxic in contact with skin” and H301 “Toxic if swallowed”, **HP5** “Specific target organ toxicity (STOT)/Toxic if inhaled”, hazard statement code H371 “May cause damage to organs”, **HP4** “Irritant – irritating to the skin and causing damage to eyes”, hazard statement code H314 “Causes severe skin burns and eye damage”, **HP13** “Sensitising”, hazard statement code H317 “May cause an allergic skin reaction”, **HP 15** “Waste that may develop any of the above hazardous property, which the primary waste directly did not demonstrate”, hazard statement EUH044 “Risk of explosion if heated under confinement”.

Formaldehyde solution packaging waste must be transferred to waste management companies. Formaldehyde solution packaging waste in Lithuania must be handled in accordance with the Law of the Republic of Lithuania on Waste Management, in other countries – in accordance with national legislation requirements.

SECTION 14. TRANSPORT INFORMATION

14.1. UN number or ID number

UN No. 2209

14.2. UN proper shipping name

Formaldehyde solution.

14.3. Transport hazard class(es)

6.1 and 8.

14.4. Packaging group

III

14.5. Environmental hazards

Classified as environmentally hazardous material according to UN Orange book and international transport codes RID (railway), ADR (road transport) and IMDG (maritime transport).

14.6. Special precautions for users

None.

14.7. Carriage of bulk cargoes by sea in accordance with IMO measures

The product is transported packaged in packaging and is therefore not subject to IMO measures.

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SECTION 15. REGULATORY INFORMATION

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

EU legislation:

- Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 of December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (published in the official journal of the European Union L 396/1, 2006) with all the subsequent amendments and additions;
- Commission Regulation no. (EU) 2020/878 amending Regulation of the European Parliament and of the Council Annex II to Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) (published in Official Journal of the European Union L 203 of 26 June 2020);
- Commission Regulation (EC) No. 552/2009, partially amending European Parliament and Council Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (published in the official journal of the European Union No. L164, 2009) with all the subsequent amendments and additions;
- The regulation (EC) No. 1272/2008 of 16 of December 2008 of the European Parliament and of the Council on Classification, Labelling and Packaging of Substances and Mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No. 1907/2006. (published in the official journal of the European Union L 353/1 2008) with all the subsequent amendments and additions;
- Commission Regulation (EC) No. 1357/2014 of 18 of December 2014 replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives (published in the official journal of the European Union No. L365/89, 2014) with all the subsequent amendments and additions;
- Regulation (EU) 2019/1148 of the European Parliament and of the Council 20th of June 2019 on trade in and use of explosives precursors and amending Regulation (EC) No. 1907/2006 and repealing Regulation (EU) No. 98/2013 (published in the Official Journal of the European Union L 186/1, 2019) as subsequently amended and supplemented;
- Directive 2012/18/EU of 4 of July 2012 of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing the Council Directive 96/82/EC (published in the official journal of the European Union No. L197/1, 2012) with all the subsequent amendments and additions;
- Directive (EU) 2019/983 of the European Parliament and of the Council June 5 amending Directive 2004/37 / EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (published in the Official Journal of the European Union No L164 / 23, 2019), with all the subsequent amendments and additions;
- European Agreement Concerning the International Carriage of Dangerous Goods by Roads (ADR) (Official Gazette, 2001, No. 91-3349, TAR identification code 103T001SUTARG031675), including all subsequent amendments and supplements;
- Regulations concerning the International Carriage of Dangerous Goods by Rail (RID);
- International Maritime Dangerous Goods Code (IMDG);
- 1973 International Convention for the Prevention of Pollution from Ships Official Gazette, 2004, No. 138-5030, TAR identification code 073T001KONVRG731618), including all subsequent amendments and supplements;

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- International Code for the Construction and Equipment of Ships Carrying Dangerous Chemical in Bulk (IBC code) including all subsequent amendments and supplements;
- Directive 2004/37 / EC of the European Parliament and of the Council of 29 of April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16 (1) of Directive 89/391 / EEC) (published in Official Journal of the European Union L158 / 50, 2004), including all subsequent amendments and supplements;
- The Safety Data Sheets and Exposure Scenario Manual (European Chemicals Agency, 2018 Reference: ECHA-18-G-07-EN), including all subsequent amendments and supplements;
- “2017 March 22 Commission Regulation (EU) 2017/542 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labeling and packaging of substances and mixtures by adding an Annex on harmonized information on emergency health emergencies with any subsequent amendments and additions”;

National legislation (Lithuania):

- Law of the Republic of Lithuania on the Supervision of Toxic Substances (No. IX-456 of 12 July 2001) (Official Gazette 2001, No. 64-2330; TAR identification code 1011010ISTA00IX-456) with all subsequent amendments and additions;
- Minister of Health of the Republic of Lithuania, 2002 June 26 Order No. 302 “On the Approval of the Rules for Issuing Permits for the Acquisition, Sale or Other Transfer of Toxic Substances” (Official Gazette, 2002, No. 70-2932, TAR identification code 1022250ISAK00000302) with all subsequent amendments and supplements;
- Law of the Republic of Lithuania on Waste Management (June 16, 1998, No. VIII-787) (Official Gazette, 1998, No. 61-1726, TAR identification code 0981010ISTAVVIII-787), including all subsequent amendments and supplements;
- Law of the Republic of Lithuania on Management of Packaging and Packaging Waste (September 25, 2001, No. IX-517) (Official Gazette, 2001, No. 85-2968, TAR identification code 1011010ISTA00IX-517), including all subsequent amendments and supplements;
- Minister of Health of the Republic of Lithuania and Minister of Social Security and Labor of the Republic of Lithuania September 1 2011 Order No. V-824 / A1-389 on the Approval of the Lithuanian Hygiene Norm HN 23: 2011 Occupational Exposure Limits, General Requirements for Measurement and Exposure Assessment of Chemicals (Official Gazette, 2011, No. 112-5274, TAR code 1112250ISAK4 / A1-389) including all subsequent amendments and supplements;
- Valid “Regulations for the protection of workers from chemical agents at work” and “Regulations for the protection of workers from exposure to carcinogens at work”;
- The applicable “Safety Data Sheet Requirements and Provisions for Professional Users”;
- Valid “Rules On Labelling and Indication of Prices of Items (Goods) for Sale in the Republic of Lithuania”;
- Minister of Environment of the Republic of Lithuania, 1999 July 14 Order No. 2017 “Approval of Waste Management Regulations” (Official Gazette, 1999, No. 63-2065, TAR identification code 099301MISAK000000217), including all subsequent amendments and supplements;
- Resolution No. 966 of the Government of the Republic of Lithuania of 17 August 2004 “On the Approval of the Provisions of the Prevention, Liquidation and Investigation of Industrial Accidents and of the List and the Description of Qualification Criteria for the Substances, Mixtures or Preparations Classified as Dangerous Substances in Dangerous Objects” with subsequent amendments and additions (Official Gazette, 2004, No. 130-4649; 2005, No. 131-4731; 2008, No. 109-4159; 2009, No. 90-3855; 2010, No. 59-2894; 2012, No. 61-3078) with all subsequent amendments and additions;
- Amendment to Order No. A1-178 of the Ministry of Social Affairs and Labour of the Republic of Lithuania of 30 May 2008 “On Approval of the Rules for the Maintenance of Stationary Unpressurized Tanks of Dangerous Substances and Mixtures”, Order No. A1-1132 of 20 November 2020 of the Ministry of Social Affairs and Labour of the Republic of Lithuania.
- Order No. 1-178 of 1st August 2006 of Chief State Labour Inspector of the Republic of Lithuania “On the approval of the list-classification of potentially hazardous equipment to be registered in the State Register, indicating their parameters” with

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all subsequent amendments and additions;

- LST EN 388 “Protective gloves against mechanical hazards”;
- LST EN 402 “Respiratory protective devices. A lung-operated, life-saving, autonomous, open-air compressed air breathing apparatus with full-face mask or mouthpiece set-up. Requirements, testing, marking”;
- LST EN 420 “Protective gloves. General requirements and testing methods”;
- LST EN 469 “Protective clothing for firefighters. Performance requirements for firefighting protective clothing”;
- LST EN 13034 “Protective clothing against liquid chemicals. Requirements for the use of short-term protective clothing against liquid chemicals (equipment type 6 and PB [6])”;
- LST EN ISO 13688 “Protective clothing. General requirements (ISO 13688: 2013)”;
- LST EN 14387 “Respiratory protective devices. Gas filters and composite filters. Requirements, testing, marking”;
- LST EN ISO 16321-1 „Eye and face protection equipment for work”. Part 1. General requirements (ISO 16321-1:2021)“;
- LST EN ISO 16321-3 „Eye and face protection equipment for work”. Part 3. Additional requirements for mesh guards (ISO 16321-3:2021)“;
- LST EN ISO 20345 “Personal protective equipment. Safe footwear (ISO 20345: 2011)”;
- LST EN ISO 21420 „Protective gloves. General requirements and test methods“.
- LR 2001 by the Minister of Social Security and Labor and the Minister of Health July 24 Order No.97 / 406 on the approval of provisions for the protection of workers from chemical agents at work and the protection of workers from the effects of carcinogens and mutagens at work (Official Gazette, 2001, No. 65-2396, TAR identification code 1012230ISAK0097 / 406), with all subsequent amendments and additions.

Additional information on the relevant Community provisions on safety, health and the environment for the product:

- The product is a toxic substance according to the Law of the Republic of Lithuania on the Supervision of Toxic Substances. According to the Law on the Supervision of Toxic Substances of the Republic of Lithuania, only competent persons who meet the requirements of this Law and have a permit referred to in Article 9 (1) of this Law to perform activities related to toxic substances (hereinafter - permit) public health center. Permits are issued in accordance with the Minister of Health of the Republic of Lithuania 2002 June 26 Order no. 302 “On the Approval of the Rules for Issuing Permits for the Acquisition, Sale or Other Transfer of Toxic Substances”, with all subsequent amendments and additions.

The product is subject to the requirements of Directive 2004/37 / EC of the European Parliament and of the Council, with all subsequent amendments and additions.

The product is a dangerous mixture and is subject to requirements according to the Resolution No. 966 of the Government of the Republic of Lithuania of 7 August 2004 “On the Approval of the Provisions of the Prevention, Liquidation and Investigation of Industrial Accidents and of the List and the Description of Qualification Criteria for the Substances, Mixtures or Preparations Classified as Dangerous Substances in Dangerous Objects” (Official Gazette, 2004, No. 130-4649) with subsequent amendments and additions or the Directive 2012/18/EU.

Restrictions on the product according to Regulation (EU) No. 2019/1148: The product is not subject to restrictions under Regulation (EU) No. 2019/1148.

15.2. Chemical safety assessment

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The product underwent the chemical safety assessment (see Annex).

SECTION 16. OTHER INFORMATION

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(i) Identified amendments: In the Safety Data Sheet, as compared to the previous version, the following amendments were made:

- Headline of SDS: Revision date, version number and issuing date of this safety data sheet has been changed;
- section 16: Revision date, version number and issuing date of this safety data sheet has been changed.

(ii) Abbreviations and acronyms:

Acute Tox. 3 – Acute toxicity category 3;
ADR – Agreement Concerning the International Carriage of Dangerous Goods by Roads;
Carc. 2 – Carcinogenicity category 2;
EC – European Community;
EC No. – EINECS and ELINCS number;
EU – the European Union;
EINECS – the European inventory of existing commercial chemical substances;
Eye Dam. – Serious eye damage;
Flam. Liquid 2 – Flammable liquids category 2;
HN – Hygiene norm;
IMDG – International Maritime Dangerous Cargoes;
IATA – International Air Transport Association;
IMO – Intergovernmental Maritime Transport Organisation;
UN – United Nations;
cat. – category;
LC50 – Lethal concentration 50 % of test population;
LD50 – Lethal dose 50 % of test population (average lethal dose);
Muta. 2 – Germ cell mutagen category 2;
PBT – Persistent, bioaccumulative and toxic;
PC – Product category;
ppm – a unit of measurement corresponding to a part per million.
RID – Regulations concerning the International Carriage of Dangerous Goods by Rail;
SDS – Safety Data Sheet;
SMGS – Agreement on International Goods Transport by Rail;
Skin Corr. 1B – Skin corrosion category 1B;
Skin Sens. 1 – Skin sensitising category 1;
STOT SE 1 – specific target organ toxicity - single exposure category 1;

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vPvB – Very persistent and very bioaccumulative

Explanation of sector of use (SU):

- SU3 – Industrial use: the use of substances as such or in mixtures.
- SU8 – Production of bulk, large scale chemicals (including petroleum products).
- SU9 – Production of fine chemicals.
- SU10 – Mixture preparation and/or re-packaging (excluding smelting).
- SU12 – Production of plastics, including blending and conversion.

(iii) References to key literature and data sources:

- 1) Formaldehyde REACH registration dossier published on the European Chemicals Agency web site [data as of 29 January 2021];
- 2) <http://gestis-en.itrust.de/nxt/gateway.dll?f=templates&fn=default.htm&vid=gestiseng:sdbeng> [data as of 29 January 2019].

(iv) Applicable classification and used procedures for the determination of mixtures classification according to Regulation (EC) No. 1272/2008 [CLP Regulation]:

Classification according to Regulation (EC) No. 1272/2008	Classification procedure
Carcinogen category 1B, H350	The product is classified as Carcinogen category 1B, H350, as the formaldehyde concentration it contains is higher than the concentration limit as specified in Table 3.6.2 in Regulation (EC) No. 1272/2008 that equals ≥ 0.1 %.
Germ cell mutagen category 2, H341	The product is classified as Germ cell mutagen category 2, H341, as the formaldehyde concentration it contains is higher than the concentration limit as specified in Table 3.5.2 in Regulation (EC) No. 1272/2008 that equals ≥ 1.0 %.
Acute toxicity if swallowed category 3, H301	The product is classified as Acute toxicity if swallowed category 3, H301, based on the linking rules for the product containing formaldehyde and methanol.
Acute toxicity if in contact with the skin category 3, H311	The product is classified as Acute toxicity if in contact with the skin category 3, H311, based on the linking rules for the product containing formaldehyde and methanol.
Acute toxicity if inhaled category 3, H331	The product is classified as Acute toxicity if inhaled category 3, H331, based on the linking rules for the product containing formaldehyde and methanol.
Specific target organ toxicity – single exposure category 2, H371	The product is classified as Specific target organ toxicity – single exposure category 2, H371, as it contains the methanol concentration within the scope of specific concentration limit interval of methanol as specified in Table 3.1 of the Regulation (EC) No. 1272/2008, Annex VI, that equals $3\% \leq C < 10\%$.
Serious eye damage category 1, H318	The product is classified as Serious eye damage, category 1, H318 as it contains higher concentrations of formaldehyde, which is classified as category 1. The limit concentration given in Table 3.3.3 of Regulation (EC) No 1272/2008 is 3%.
Skin corrosion 1B, H314	The product is classified as Skin corrosion 1B, H314, as it contains the formaldehyde concentration that is higher than the specific concentration limit of formaldehyde as specified in Table 3.1 of Regulation (EC) No. 1272/2008, Annex VI, that equals ≥ 25 %.
Skin sensitising category 1, H317	The product is classified as Skin sensitising category 1, H317, as it

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	contains the formaldehyde concentration that is higher than the specific concentration limit of formaldehyde as specified in Table 3.1 of Regulation (EC) No. 1272/2008, Annex VI, that equals $\geq 0.2\%$.
Product not classified as flammable liquids category 2, H225	The product is not classified as flammable liquids as it does not comply with the criteria for classification as specified in Table 2.6.1 of Regulation (EC) No. 1272/2008. The following parameters were based on: 1) The product flash point is $> 60\text{ }^{\circ}\text{C}$ based on the information in the formaldehyde REACH registration dossier stating that the flash point of formaldehyde aqueous solution containing 10 % of methanol is higher than $60\text{ }^{\circ}\text{C}$. 2) The product initial boiling point is higher than $60\text{ }^{\circ}\text{C}$ and equal to $98.9\text{ }^{\circ}\text{C}$ (based on the data of the formaldehyde REACH registration dossier).

(v) Hazard and precautionary statements:

- H301: Toxic if swallowed.
- 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.
- H331: Toxic if inhaled.
- H341: Suspected of causing genetic defects.
- H350: May cause cancer.
- H371: May cause damage to organs.
- P260: Do not breathe dust/fume/gas/mist/vapours/spray.
- P280: Wear protective gloves/protective clothing/eye protection/face protection.
- P401: Store at a temperature of at least $15\text{ }^{\circ}\text{C}$ and not exceeding $25\text{ }^{\circ}\text{C}$.
- P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
- P302 + P352: IF ON SKIN: wash with plenty of soap and water.
- P304 + P340: IF INHALED: Remove to fresh air and keep at rest in a position 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.
- P403 + P233: Store in a well-ventilated place. Keep container tightly closed.

(vi) Advice on training. Persons producing, handling, using or storing this product must be trained to work with toxic chemicals, hygiene skills, working with toxic substances, product properties, hazards, how to work with it, what personal protective equipment to use, first aid principles, information on emergency response procedures. Persons working with the product must be made aware of this safety data sheet. Persons must have been briefed prior to starting to work with the product.

NOTE. The data of this safety data sheet must be made available to all whose work is related with the chemical substance or the preparation. The data corresponds to our current knowledge and is intended to describe the chemical product in terms of occupational safety and health and environmental aspects. The information of the safety data sheet will be supplemented with new data about the effects of the chemical substance or the preparation on health and the environment, about preventive measures to reduce or completely avoid hazards. The information of the safety data sheet does not disclose other specific properties of the chemical substances or the preparation.

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ANNEX

Exposure scenarios:

- 1. Production of formaldehyde and formaldehyde aqueous solution;**
- 2. Production of mixtures (30 to 60 %)**

Exposure scenario No. 1: Production of formaldehyde and formaldehyde aqueous solution

Reference number	1
Short name	Production of formaldehyde and formaldehyde aqueous solution
The systematic name according to the use reference	SU 3,8,9,10,12 PROC 1, 2, 3, 4, 5, 6, 8a, 8b, 9, 15 ERC 1, 2, 3, 4, 6a, 6b, 6c, 6d, 7 The exposure scenario is intended for the following uses: formaldehyde production (IU1) the use as an intermediate product including the use as a monomer (IU2)
The exposure scenarios include the works and their corresponding PROC	Use in a closed process, no human exposure probability (PROC 1) Use in a closed uninterrupted process with a random controlled exposure on humans (PROC 2) Use in a closed production process (synthesis/preparation) (PROC 3) Use in a mixing or other process (synthesis), where there is human exposure probability (PROC 4) In a mixing process, where there is a considerable human contact with the substance (PROC 5) In scheduled operations (PROC 6) Transfer (filling/spill) of substances or mixtures from/to vessels/large containers in unadjusted equipment (PROC 8a) Transfer (filling/spill) of chemicals from/to vessels/large containers in compatible equipment (PROC 8b) Transfer of substances or mixtures into small containers (in an adapted filling line, including weighing) (PROC 9) Use as a laboratory reagent (PROC 15)
Environmental exposure assessment	Environmental assessment is not completed
Environmental exposure assessment method	Environmental assessment is not completed
9.1.1.2. Working conditions and risk assessment calculations	
Formaldehyde is unstable; therefore, it is stored as formalin (30 to 60 %). Formaldehyde vapour pressure is different than that of formalin. The vapour pressure used in the risk assessment is 100,000 Pa in terms of pure formaldehyde. For the purpose of product transportation assessment, formaldehyde is provided as formalin with vapour pressure of 1,520 Pa at higher temperatures (49 % formaldehyde solution in water at 55 °C and 1,400 Pa at room temperature (50 % formaldehyde solution in water at 2 % of methanol).	
In areas where formalin is used, conditions of its use are strictly controlled.	
The exposure scenario 1 under the control of the exposure to workers PROC 1	
Brief work description	Formalin production in a closed system
The use of descriptors	SU3, PROC 1
Processes, tasks, activities	PROC 1: Use in a closed process, no probability of human exposure
Assessment method	Effect on the skin: ECETOC TRA v2 (with modifications) Effect on the respiratory tract: ART
Description of the product	

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Vapours, formaldehyde 100 %, used in closed processes	
Used quantities	
Not applicable	
Frequency and period of use	
Every day, up to 480 minutes	
Human factor, which cannot be reduced through risk management	
It is assumed that the volume inhaled during light work is 10 m ³ /d. It is assumed that the worker's weight is 70 kg.	
Other work conditions impacting the exposure to workers	
Average and large production facilities (300 m ³) High-temperature processes (50 to 150 °C)	
Technical conditions and measurements of process parameters that eliminate the possibility of passby	
High tightness level (99.9 %) consisting of: <ul style="list-style-type: none"> • Sealed and closed system; • During the production, the system is not unsealed (not being opened); • The designed system minimises the surface area which can come into contact with the product. 	
Technical conditions and measures to control the product spread from the source to the worker	
General ventilation that ensures not less than 3 air volume changes per hour.	
Organisational measures limiting product spill, spread and exposure	
These measures are not necessary	
Conditions and measures related to personal protective equipment, hygiene and health evaluation	
Strict use of protective gloves, training for workers and the management supervision to minimise the exposure (the reduction factor is 98 %) in the operations that may lead to contact with the contaminated surface. Where an effect on the eyes is likely, wear suitable protective glasses, such as against splattering, for works above the head or where the worker's face must be close to the product.	
The exposure scenario 1 under the control of the exposure to workers PROC 2	
Brief work description	Formalin production in a closed system
The use of descriptors	SU3, PROC 2
Processes, tasks, activities	PROC 2: Used in a closed uninterrupted process with a random controlled exposure to humans PROC 2: Consists of processes in a closed system, in product transfer adjusted equipment, including sample collection.
Assessment method	Effect on the skin: ECETOC TRA v2 (with modifications) Effect on the respiratory tract: ART
Description of the product	
In closed processes: vapours, formaldehyde 100 %, used in closed processes. Transfer in a compatible equipment: Liquid, formalin (30 to 60 % formaldehyde solution in water). The final product (formalin) is supplied to the storage containers in storage rooms or for further processing.	
Used quantities	
In closed processes: Not applicable. Transfer in a compatible equipment: > 1000 l/min.	
Frequency and period of use	
In closed processes: Every day, up to 360 minutes. Transfer in a compatible equipment: Every day, up to 120 minutes.	
Human factor, which cannot be reduced through risk management	
It is assumed that the volume inhaled during light work is 10 m ³ /d. It is assumed that the worker's weight is 70 kg.	
Other work conditions conditioning the exposure to workers	
Average and large production facilities (300 m ³) High-temperature processes (50 to 150 °C)	
Technical conditions and measurements of process parameters that eliminate possibility of passby	

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Transfer in a compatible equipment: <ul style="list-style-type: none"> Filling through immersion Transfer in a compatible equipment and in closed processes: <ul style="list-style-type: none"> Average tightness level (99.9 %) consisting of: <ul style="list-style-type: none"> Enclosure of the emission source; Closed product transfer to the pre-connected container or sealed product container. For example, sealing heads, intermediate vessels, o-rings. Other sealing measures to ensure the protection from direct contact with the product. Suitable sealants must be selected. 	
Technical conditions and measures to control the product spread from the source to the worker	
Transfer in a compatible equipment and in closed processes: General ventilation that ensures not less than 3 air volume changes per hour. Transfer in a compatible equipment: transportation system is fitted with a vapour recovery system (80 %).	
Organisational measures limiting product spill, spread and exposure	
Product transfer and spill in compatible equipment must last no longer than 120 minutes When using this product, the process in a closed system may take place not longer than 360 minutes	
Conditions and measures related to personal protective equipment, hygiene and health evaluation	
Transfer in a compatible equipment and in closed processes: Where an effect on the eyes is likely, wear suitable protective glasses, such as against splattering, for works above the head or where the worker's face must be close to the product. In closed processes: Strict use of protective gloves, training for workers and the management supervision to minimise the exposure (the reduction factor is 98 %) in the operations that may lead to contact with the contaminated surface. Transfer in a compatible equipment: Strict use of protective gloves, training for workers and the management supervision to minimise the exposure (the reduction factor is 98 %). Transfer in a compatible equipment: Use filtering protection measures (90 % reduction).	
The exposure scenario 2 under the control of the exposure to workers PROC 3	
Brief work description	Formalin production in a closed system
The use of descriptors	SU3, PROC 3
Processes, tasks, activities	PROC 3: Use in a closed uninterrupted process with a random controlled exposure to humans. PROC 3: consists of processes in a closed system, in product transfer adjusted equipment, including sample collection.
Assessment method	Effect on the skin: ECETOC TRA v2 (with modifications) Effect on the respiratory tract: ART
Description of the product	
In closed processes: vapours, formaldehyde 100 %, used in closed processes. Transfer in a compatible equipment: Liquid, formalin (30 to 60 % formaldehyde solution in water). The final product (formalin) is supplied to the storage containers in storage rooms or for further processing.	
Used quantities	
In closed processes: Not applicable Transfer in a compatible equipment: > 1000 l/min.	
Frequency and period of use	
In closed processes: Every day, up to 360 minutes. Transfer in a compatible equipment: Every day, up to 120 minutes.	
Human factor, which cannot be reduced through risk management	
It is assumed that the volume inhaled during light work makes 10 m ³ /d. It is assumed that the worker's weight is 70 kg.	
Other work conditions conditioning the exposure to workers	

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Transfer in a compatible equipment and in closed processes: Average and large production facilities (300 m ³) High-temperature processes (50 to 150 °C)	
Technical conditions and measurements of process parameters that eliminate possibility of passby	
Transfer in a compatible equipment: <ul style="list-style-type: none"> Filling through immersion Transfer in a compatible equipment and in closed processes: - Average tightness level (99.9 %) consisting of: <ul style="list-style-type: none"> Enclosure of the emission source; Closed product transfer to the pre-connected container or sealed product container. For example, sealing heads, intermediate vessels, o-rings. Other sealing measures to ensure the protection from direct contact with the product. Suitable sealants must be selected. 	
Technical conditions and measures to control the product spread from the source to the worker	
Transfer in a compatible equipment and in closed processes: General ventilation that ensures not less than 3 air volume changes per hour. Transfer in a compatible equipment: transportation system is fitted with a vapour recovery system (80 % reduction).	
Organisational measures limiting product spill, spread and exposure	
Product transfer and spill in compatible equipment must last no longer than 120 minutes When using this product, the process in a closed system may take place not longer than 360 minutes	
Conditions and measures related to personal protective equipment, hygiene and health evaluation	
Transfer in a compatible equipment and in closed processes: Where an effect on the eyes is likely, wear suitable protective glasses, such as those against splattering, for works above the head or where the worker's face must be close to the product. In closed processes: Strict use of protective gloves, training for workers and the management supervision to minimise the exposure (the reduction factor is 98 %) in the operations that may lead to contact with the contaminated surface. Transfer in a compatible equipment: Strict use of protective gloves, training for workers and the management supervision to minimise the exposure (the reduction factor is 98 %). Transfer in a compatible equipment: Use filtering protection measures (90 % reduction).	
The exposure scenario 4 under the control of the exposure to workers PROC 4	
Brief work description	Formalin production in mixing and other processes.
The use of descriptors	SU3, PROC 4
Processes, tasks, activities	PROC 4: Use in mixing or other process (synthesis) where there is a possibility of exposure to humans. PROC 4 consists of the following three activities: <ul style="list-style-type: none"> Transfer in a compatible equipment and in closed processes. Closed process. Activities next to the open process areas.
Assessment method	Effect on the skin: ECETOC TRA v2 (with modifications) Effect on the respiratory tract: ART
Description of the product	
Transfer in a compatible equipment: Liquid, formalin (30 to 60 % formaldehyde solution in water). The final product (formalin) is supplied to the storage containers in storage rooms or for further processing. In closed processes: vapours, formaldehyde 100 %, used in closed processes. Activities next to the open process location: Liquid, formalin (30 to 60 % formaldehyde solution in water).	
Used quantities	
Transfer in a compatible equipment: > 1000 l/min. In closed processes: Not applicable Activities next to the open process areas: Not applicable	

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Frequency and period of use	
Transfer in a compatible equipment and activities near the open process areas: Every day, up to 60 min. In closed processes: Every day, up to 360 minutes.	
Human factor, which cannot be reduced through risk management	
It is assumed that the volume inhaled during light work makes 10 m ³ /d. It is assumed that the worker's weight is 70 kg.	
Other work conditions impacting the exposure to workers	
Transfer in a compatible equipment, closed processes and activities next to the open process areas: Average and large production facilities (300 m ³) High-temperature processes (50 to 150 °C)	
Technical conditions and measurements of process parameters that eliminate possibility of passby	
Transfer in a compatible equipment: <ul style="list-style-type: none"> Filling through immersion Transfer in a compatible equipment and in closed processes: - Average tightness level (99.9 %) consisting of: <ul style="list-style-type: none"> Enclosure of the emission source; Closed product transfer to the pre-connected container or sealed product container. For example, sealing heads, intermediate vessels, o-rings. Other sealing measures to ensure the protection from direct contact with the product. Suitable sealants must be selected. In activities next to the open process locations: <ul style="list-style-type: none"> Free surface < 0.1 m² 	
Technical conditions and measures to control the product spread from the source to the worker	
Transfer in a compatible equipment, closed processes and activities next to the open process areas: General ventilation that ensures not less than 3 air volume changes per hour. Transfer in a compatible equipment: transportation system is fitted with a vapour recovery system (80 % reduction). In activities next to the open process areas: local exhaust ventilation (90 % reduction) of potential emission sources.	
Organisational measures limiting product spill, spread and exposure	
Product transfer and spill in compatible equipment and activities next to the open process areas must last no longer than 60 minutes. When using this product, the process in a closed system may take place not longer than 360 minutes.	
Conditions and measures related to personal protective equipment, hygiene and health evaluation	
Transfer in a compatible equipment, closed processes and activities next to the open process areas: Where any effect on the eyes is likely, wear suitable protective glasses, such as those against splattering, for works above the head or where the worker's face must be close to the product. Transfer in a compatible equipment and activities near the open process areas: Strict use of protective gloves, training for workers and the management supervision to minimise the exposure (the reduction factor is 98 %) in the activities. In closed processes: strict use of protective gloves, training for workers and the management supervision to minimise the exposure (the reduction factor is 98 %) in the operations that may lead to contact with the contaminated surface. In activities next to the open process areas: Use filtering protection measures (95 % reduction). Transfer in a compatible equipment: Use filtering protection measures (90 % reduction).	
The exposure scenario 5 under the control of the exposure to workers PROC 5	
Brief work description	Formalin production; mixing and blending.
The use of descriptors	SU3, PROC 5
Processes, tasks, activities	PROC 5: In a mixing process where there is considerable human contact with the product. PROC 5 consists of the following three activities: <ul style="list-style-type: none"> Transfer in a compatible equipment and in closed processes. Closed process. Activities next to the open process areas.
Assessment method	Effect on the skin: ECETOC TRA v2 (with modifications) Effect on the respiratory tract: ART
Description of the product	

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Transfer in a compatible equipment: Liquid, formalin (30 to 60 % formaldehyde solution in water). The final product (formalin) is supplied to the storage containers in storage rooms or for further processing. In closed processes: vapours, formaldehyde 100 %, used in closed processes. Activities next to the open process location: Liquid, formalin (30 to 60 % formaldehyde solution in water).	
Used quantities	
Transfer in a compatible equipment: > 1000 l/min. In closed processes: Not applicable Activities next to the open process areas: Not applicable	
Frequency and period of use	
Transportation and activities next to the open process areas: Every day, up to 60 min. In closed processes: Every day, up to 360 minutes.	
Human factor, which cannot be reduced through risk management	
It is assumed that the volume inhaled during light work makes 10 m ³ /d. It is assumed that the worker's weight is 70 kg.	
Other work conditions impacting the exposure to workers	
Transfer in a compatible equipment, closed processes and activities next to the open process areas: Average premises and large production facilities (300 m ³) High-temperature processes (50 to 150 °C)	
Technical conditions and measurements of process parameters that eliminate possibility of passby	
Transfer in a compatible equipment: <ul style="list-style-type: none"> Filling through immersion Transfer in a compatible equipment and in closed processes: - Average tightness level (99.9 %) consisting of: <ul style="list-style-type: none"> Enclosure of the emission source; Closed product transfer to the pre-connected container or sealed product container. For example, sealing heads, intermediate vessels, o-rings. Other sealing measures to ensure the protection from direct contact with the product. Suitable sealants must be selected. In activities next to the open process locations: <ul style="list-style-type: none"> Free surface < 0.1 m² 	
Technical conditions and measures to control the product spread from the source to the worker	
Transfer in a compatible equipment, closed processes and activities next to the open process areas: General ventilation that ensures not less than 3 air volume changes per hour. Transfer in a compatible equipment: transportation system is fitted with a vapour recovery system (80 % reduction). In activities next to the open process areas: local exhaust ventilation (90 % reduction) of potential emission sources.	
Organisational measures limiting product spill, spread and exposure	
Product transfer and spill in compatible equipment and activities next to the open process areas must last no longer than 60 minutes. When using this product, the process in a closed system may take place not longer than 360 minutes.	
Conditions and measures related to personal protective equipment, hygiene and health evaluation	
Transfer in a compatible equipment, closed processes and activities next to the open process areas: Where an effect on the eyes is likely, wear suitable protective glasses, such as against splattering, for works above the head or where the worker's face must be close to the product. Transfer in a compatible equipment and activities near the open process areas: Strict use of protective gloves, training for workers and the management supervision to minimise the exposure (the reduction factor is 98 %) in the activities. In closed processes: strict use of protective gloves, training for workers and the management supervision to minimise the exposure (the reduction factor is 98 %) in the operations that may lead to contact with the contaminated surface. In activities next to the open process areas: Use filtering protection measures (95 % reduction). Transfer in a compatible equipment: Use filtering protection measures (90 % reduction).	
The exposure scenario 6 under the control of the exposure to workers PROC 6	
Brief work description	Formalin production; formalin use in scheduled operations
The use of descriptors	SU3, PROC 6
Processes, tasks, activities	PROC 6: Scheduled operations

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Assessment method*	ECETOC TRA v2 (with modifications) used for both skin and respiratory exposure assessment, as it is not possible to assess the evaporation from the solid phase using ART
Description of the product	
Liquid, formalin (30 to 60 % formaldehyde solution in water)	
Used quantities	
Not applicable	
Frequency and period of use	
Up to 4 hours, day rate.	
Human factor, which cannot be reduced through risk management	
It is assumed that the volume inhaled during light work makes 10 m ³ /d. It is assumed that the worker's weight is 70 kg.	
Other work conditions conditioning the exposure to workers	
The working environment, inner premises.	
Technical conditions and measurements of process parameters that eliminate possibility of passby	
Not applicable.	
Technical conditions and measures to control the product spread from the source to the worker	
Local exhaust ventilation (90 % efficiency).	
Organisational measures limiting product spill, spread and exposure	
Not applicable.	
Conditions and measures related to personal protective equipment, hygiene and health evaluation	
Strict use of protective gloves, training for workers and the management supervision to minimise the exposure (the reduction factor is 98 %) in the operations. Use filtering protection measures (90 % reduction). Where an effect on the eyes is likely, wear suitable protective glasses, such as against splattering, for works above the head or where the worker's face must be close to the product.	
The exposure scenario 7a under the control of the exposure to workers PROC 8a	
Brief work description	Formalin production (30 to 60% formaldehyde solution in water); transfer to large containers (in a compatible equipment).
The use of descriptors	SU3, PROC 8a
Processes, tasks, activities	PROC 8a: Transfer of substances or mixtures from/to vessels/large containers in unadjusted equipment.
Assessment method*	Effect on the skin: ECETOC TRA v2 (with modifications) Effect on the respiratory tract: ART
Description of the product	
Liquid, formalin (30 to 60 % formaldehyde solution in water)	
Used quantities	
100 to 1000 l/min.	
Frequency and period of use	
Every day, up to 480 minutes.	
Human factor, which cannot be reduced through risk management	
It is assumed that the volume inhaled during light work makes 10 m ³ /d. It is assumed that the worker's weight is 70 kg.	
Other work conditions conditioning the exposure to workers	
Average and large production facilities (300 m ³) High-temperature processes (50 to 150 °C) Use under the outdoor conditions is safe when there is a vapour recovery system equipped.	
Technical conditions and measurements of process parameters that eliminate possibility of passby	

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Filling through immersion Average tightness level (99.9 %) consisting of: <ul style="list-style-type: none"> • Enclosure of the emission source; • Closed product transfer to the pre-connected container or sealed product container. For example, sealing heads, intermediate vessels, o-rings. Other sealing measures to ensure the protection from direct contact with the product. Suitable sealants must be selected. 	
Technical conditions and measures to control the product spread from the source to the worker	
General ventilation that ensures not less than 3 air volume changes per hour.	
Organisational measures limiting product spill, spread and exposure	
Not applicable	
Conditions and measures related to personal protective equipment, hygiene and health evaluation	
Strict use of protective gloves, training for workers and the management supervision to minimise the exposure (the reduction factor is 98 %) in the operations. Use filtering protection measures (90 % reduction). Where an effect on the eyes is likely, wear suitable protective glasses, such as against splattering, for works above the head or where the worker's face must be close to the product.	
The exposure scenario 7a under the control of the exposure to workers PROC 8b	
Brief work description	Formalin production (30 to 60 % formaldehyde solution in water); transfer to large containers (in a compatible equipment).
The use of descriptors	SU3, PROC 8b
Processes, tasks, activities	PROC 8b: Transfer of substances or mixtures from/to vessels/large containers in a compatible equipment.
Assessment method*	Effect on the skin: ECETOC TRA v2 (with modifications) Effect on the respiratory tract: ART
Description of the product	
Liquid, formalin (30 to 60 % formaldehyde solution in water)	
Used quantities	
>1000 l/min.	
Frequency and period of use	
Every day, up to 480 minutes.	
Human factor, which cannot be reduced through risk management	
It is assumed that the volume inhaled during light work makes 10 m ³ /d. It is assumed that the worker's weight is 70 kg.	
Other work conditions conditioning the exposure to workers	
Average and large production facilities (300 m ³) High-temperature processes (50 to 150 °C) Use under the outdoor conditions is safe when there is a vapour recovery system equipped.	
Technical conditions and measurements of process parameters that eliminate possibility of passby	
Filling through immersion Average tightness level (99.9 %) consisting of: <ul style="list-style-type: none"> • Enclosure of the emission source; • Closed product transfer to the pre-connected container or sealed product container. For example, sealing heads, intermediate vessels, o-rings. Other sealing measures to ensure the protection from direct contact with the product. Suitable sealants must be selected. 	
Technical conditions and measures to control the product spread from the source to the worker	
General ventilation that ensures not less than 3 air volume changes per hour. The transportation system is equipped with a vapour recovery system (80 % reduction).	
Organisational measures limiting product spill, spread and exposure	
Not applicable	
Conditions and measures related to personal protective equipment, hygiene and health evaluation	

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Strict use of protective gloves, training for workers and the management supervision to minimise the exposure (the reduction factor is 98 %) in the operations. Use filtering protection measures (90 % reduction). Where an effect on the eyes is likely, wear suitable protective glasses, such as against splattering, for works above the head or where the worker's face must be close to the product.	
The exposure scenario 9 under the control of the exposure to workers PROC 9	
Brief work description	Formalin production (30 to 60 % formaldehyde solution in water); transfer to small containers (in a compatible equipment).
The use of descriptors	SU3, PROC 9
Processes, tasks, activities	Transfer of substances or mixtures into small containers (in a compatible filling line, including weighing).
Assessment method	Effect on the skin: ECETOC TRA v2 (with modifications) Effect on the respiratory tract: ART
Description of the product	
Liquid, formalin (30 to 60 % formaldehyde solution in water)	
Used quantities	
10 to 100 l/min.	
Frequency and period of use	
Every day, up to 480 minutes.	
Human factor, which cannot be reduced through risk management	
It is assumed that the volume inhaled during light work makes 10 m ³ /d. It is assumed that the worker's weight is 70 kg.	
Other work conditions conditioning the exposure to workers	
Average and large production facilities (300 m ³) High-temperature processes (50 to 150 °C)	
Technical conditions and measurements of process parameters that eliminate possibility of passby	
Filling through immersion Low tightness level (90 %), consisting of: <ul style="list-style-type: none"> • Enclosure of the emission source; • The air in the enclosure is ventilated inefficiently. The enclosure is closed throughout the process. The process is non-hermetic due to leakages. The tightness of the lines starting with transportation ending with receiving container is evaluated. Sealing elements: Muller sealants, clips and covers. 	
Technical conditions and measures to control the product spread from the source to the worker	
General ventilation that ensures not less than 3 air volume changes per hour. Local exhaust ventilation (90 % efficiency) from potential emissions sources.	
Organisational measures limiting product spill, spread and exposure	
Not applicable.	
Conditions and measures related to personal protective equipment, hygiene and health evaluation	
Strict use of protective gloves, training for workers and the management supervision to minimise the exposure (the reduction factor is 98 %) in the operations. Use filtering protection measures (90 % reduction). Where an effect on the eyes is likely, wear suitable protective glasses, such as against splattering, for works above the head or where the worker's face must be close to the product.	
The exposure scenario 11 under the control of the exposure to workers PROC 15	
Brief work description	Use as a laboratory reagent
The use of descriptors	SU3, PROC 15
Processes, tasks, activities	PROC 15: Use as a laboratory reagent
Assessment method	Effect on the skin: ECETOC TRA v2 (with modifications) Effect on the respiratory tract: ART
Description of the product	
Liquid, formalin (30 to 60 % formaldehyde solution in water)	
Used quantities	
<0.1 l/min.	

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Frequency and period of use
Every day, up to 480 minutes.
Human factor, which cannot be reduced through risk management
It is assumed that the volume inhaled during light work makes 10 m ³ /d. It is assumed that the worker's weight is 70 kg.
Other work conditions conditioning the exposure to workers
Inner small working premises (100 m ³) Evaluate both the industrial and professional working environment.
Technical conditions and measurements of process parameters that eliminate possibility of passby
Not applicable.
Technical conditions and measures to control the product spread from the source to the worker
General ventilation that ensures not less than 10 air volume changes per hour. Local exhaust ventilation (capturing hoods, smoke closet, 99 % reduction).
Organisational measures limiting product spill, spread and exposure
Not applicable
Conditions and measures related to personal protective equipment, hygiene and health evaluation
Strict use of protective gloves, training for workers and the management supervision to minimise the exposure (the reduction factor is 98 %) in the operations. Where an effect on the eyes is likely, wear suitable protective glasses, such as against splattering, for works above the head or where the worker's face must be close to the product.

1.1.2. Quantitative exposure assessment

The quantification of the corrosion effect on the eyes and skin.

Relevant to the use of formaldehyde and formalin solution in water where the concentration is >25 %.

- Exposure probability/frequency is considered to be very small for the processes PROC 1, 2, 3, 6, 8b, 9, 14 and 15 due to closed-process used in the manufacture with one of the potential random interaction when a strict use of gloves and eye protection measures is provided for all PROC.
- Exposure probability/frequency for skin and eye for the processes PROC 4,5 and 8a is considered as average. The potential exposure, due to contact with the skin during mixing and transportation, can be considerable. A large part of the exposure will be eliminated using chemically resistant gloves, work clothes, appropriate skin and/or eye protection where such a contact is estimated. The personnel must be specially trained in how to use personal protective equipment; training must be carried out under the management's supervision. In addition, workers must be informed on the avoidance of skin and eye contact with the product. If the product comes in contact with skin, wash with water immediately and inform about the skin/eye injuries/problems that may occur. The intensity of the exposure determined based on the evaluation of these factors/measurements is very low.

1.1.3. Quantitative exposure assessment

Table 1: Estimated exposure to workers according to the scenario 1

Exposure	Concentrations		References
	Value	Units	
Long-term systemic exposure to the skin	< 0.1	mg/kg bw/d	ECETOC TRA Version 2 modified (see Section 9) PROC 1
Long-term systemic exposure to the respiratory tract	0.025	mg/m ³	ART (75-p, interquartile) PROC 1
Long-term systemic combined exposure	Combined risk assessment was calculated in Section 10		
Long-term local exposure to the skin	Quantified local exposure to the skin		
Long-term local exposure to the respiratory tract	See "Long-term systemic exposure to the respiratory tract"		
Short-term systemic exposure to the	Short-term systemic exposure to the skin not evaluated due to absence of		

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skin	DNEL		
Short-term systemic exposure to the respiratory tract	0.05	mg/m ³	ART (75-p, interquartile) PROC 1
Short-term systemic combined exposure	Short-term systemic combined exposure not evaluated because it was not determined		
Short-term local exposure to the skin	Quantified local exposure to the skin		
Short-term local exposure to the respiratory tract	See “Short-term systemic exposure to the respiratory tract”		

NA = Not applicable

Table 2: Estimated exposure to workers according to the scenario 1

Exposure	Concentrations		References
	Value	Units	
Long-term systemic exposure to the skin	< 0.1	mg/kg bw/d	ECETOC TRA Version 2 modified (see Section 9) PROC 2
Long-term systemic exposure to the respiratory tract	0.253	mg/m ³	ART (75-p, interquartile) PROC 2 with the RPE factor ECETOC TRA
Long-term systemic combined exposure	Combined risk assessment was calculated in Section 10		
Long-term local exposure to the skin	Quantified local exposure to the skin		
Long-term local exposure to the respiratory tract	See “Long-term systemic exposure to the respiratory tract”		
Short-term systemic exposure to the skin	Short-term systemic exposure to the skin not evaluated due to absence of DNEL		
Short-term systemic exposure to the respiratory tract	0.51	mg/m ³	ART (75-p, interquartile) PROC 2 with the RPE factor ECETOC TRA
Short-term systemic combined exposure	Short-term systemic combined exposure not evaluated because it was not determined		
Short-term local exposure to the skin	Quantified local exposure to the skin		
Short-term local exposure to the respiratory tract	See “Short-term systemic exposure to the respiratory tract”		

NA = Not applicable

Table 2: Estimated exposure to workers according to the scenario 2

Exposure	Concentrations		References
	Value	Units	
Long-term systemic exposure to the skin	< 0.1	mg/kg bw/d	ECETOC TRA Version 2 modified (see Section 9) PROC 3
Long-term systemic exposure to the respiratory tract	0.253	mg/m ³	ART (75-p, interquartile) PROC 3 with the RPE factor ECETOC TRA
Long-term systemic combined	Combined risk assessment was calculated in Section 10		

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exposure			
Long-term local exposure to the skin	Quantified local exposure to the skin		
Long-term local exposure to the respiratory tract	See “Long-term systemic exposure to the respiratory tract”		
Short-term systemic exposure to the skin	Short-term systemic exposure to the skin not evaluated due to absence of DNEL		
Short-term systemic exposure to the respiratory tract	0.51	mg/m ³	ART (75-p, interquartile) PROC 3 with the RPE factor ECETOC TRA
Short-term systemic combined exposure	Short-term systemic combined exposure not evaluated because it was not determined		
Short-term local exposure to the skin	Quantified local exposure to the skin		
Short-term local exposure to the respiratory tract	See “Short-term systemic exposure to the respiratory tract”		

NA = Not applicable

Table 3: Estimated exposure to workers according to the scenario 3

Exposure	Concentrations		References
	Value	Units	
Long-term systemic exposure to the skin	< 0.1	mg/kg bw/d	ECETOC TRA Version 2 modified (see Section 9) PROC 4
Long-term systemic exposure to the respiratory tract	0.293	mg/m ³	ART (75-p, interquartile) PROC 4 with the RPE factor ECETOC TRA
Long-term systemic combined exposure	Combined risk assessment was calculated in Section 10		
Long-term local exposure to the skin	Quantified local exposure to the skin		
Long-term local exposure to the respiratory tract	See “Long-term systemic exposure to the respiratory tract”		
Short-term systemic exposure to the skin	Short-term systemic exposure to the skin not evaluated due to absence of DNEL		
Short-term systemic exposure to the respiratory tract	0.59	mg/m ³	ART (75-p, interquartile) PROC 4 with the RPE factor ECETOC TRA
Short-term systemic combined exposure	Short-term systemic combined exposure not evaluated because it was not determined		
Short-term local exposure to the skin	Quantified local exposure to the skin		
Short-term local exposure to the respiratory tract	See “Short-term systemic exposure to the respiratory tract”		

NA = Not applicable

Table 4: Estimated exposure to workers according to the scenario 4

Exposure	Concentrations		References
	Value	Units	

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Exposure	Concentrations		References
	Value	Units	
Long-term systemic exposure to the skin	0.2	mg/kg bw/d	ECETOC TRA Version 2 modified (see Section 9) PROC 5
Long-term systemic exposure to the respiratory tract	0.293	mg/m ³	ART (75-p, interquartile) PROC 5 with the RPE factor ECETOCTRA
Long-term systemic combined exposure	Combined risk assessment was calculated in Section 10		
Long-term local exposure to the skin	Quantified local exposure to the skin		
Long-term local exposure to the respiratory tract	See "Long-term systemic exposure to the respiratory tract"		
Short-term systemic exposure to the skin	Short-term systemic exposure to the skin not evaluated due to absence of DNEL		
Short-term systemic exposure to the respiratory tract	0.59	mg/m ³	ART (75-p, interquartile) PROC 5 with the RPE factor ECETOCTRA
Short-term systemic combined exposure	Short-term systemic combined exposure not evaluated because it was not determined		
Short-term local exposure to the skin	Quantified local exposure to the skin		
Short-term local exposure to the respiratory tract	See "Short-term systemic exposure to the respiratory tract"		

NA = Not applicable

Table 5: Estimated exposure to workers according to the scenario 6

Exposure	Concentrations		References
	Value	Units	
Long-term systemic exposure to the skin	0.3	mg/kg bw/d	ECETOC TRA Version 2 modified (see Section 9) PROC 6
Long-term systemic exposure to the respiratory tract	0.233	mg/m ³	ECETOC TRA Version 2 modified (see Section 9) PROC 6
Long-term systemic combined exposure	Combined risk assessment was calculated in Section 10		
Long-term local exposure to the skin	Quantified local exposure to the skin		
Long-term local exposure to the respiratory tract	See "Long-term systemic exposure to the respiratory tract"		
Short-term systemic exposure to the skin	Short-term systemic exposure to the skin not evaluated due to absence of DNEL		
Short-term systemic exposure to the respiratory tract	0.78	mg/m ³	ECETOC TRA Version 2 modified (see Section 9) PROC 6
Short-term systemic combined exposure	Short-term systemic combined exposure not evaluated because it was not determined		
Short-term local exposure to the skin	Quantified local exposure to the skin		
Short-term local exposure to the respiratory tract	See "Short-term systemic exposure to the respiratory tract"		

NA = Not applicable

Table 6: Estimated exposure to workers according to the scenario 7a

Exposure	Concentrations		References
	Value	Units	
Long-term systemic exposure to the skin	0.2	mg/kg bw/d	ECETOC TRA Version 2 modified (see Section 9) PROC 8a (30 to 60 % formaldehyde solution in water)

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Exposure	Concentrations		References
	Value	Units	
Long-term systemic exposure to the respiratory tract	0.350	mg/m ³	ART (75-p, interquartile) PROC 8a (30 to 60 % formaldehyde solution in water) with RPE factor ECETOCTRA
Long-term systemic combined exposure	Combined risk assessment was calculated in Section 10		
Long-term local exposure to the skin	Quantified local exposure to the skin		
Long-term local exposure to the respiratory tract	See “Long-term systemic exposure to the respiratory tract”		
Short-term systemic exposure to the skin	Short-term systemic exposure to the skin not evaluated due to absence of DNEL		
Short-term systemic exposure to the respiratory tract	0.70	mg/m ³	ART (75-p, interquartile) PROC 8a (30 to 60 % formaldehyde solution in water) with RPE factor ECETOCTRA
Short-term systemic combined exposure	Short-term systemic combined exposure not evaluated because it was not determined		
Short-term local exposure to the skin	Quantified local exposure to the skin		
Short-term local exposure to the respiratory tract	See “Short-term systemic exposure to the respiratory tract”		

NA = Not applicable

Table 7: Estimated exposure to workers according to the scenario 8a

Exposure	Concentrations		References
	Value	Units	
Long-term systemic exposure to the skin	< 0.1	mg/kg bw/d	ECETOC TRA Version 2 modified (see Section 9) PROC 8b (30 to 60 % formaldehyde solution in water)
Long-term systemic exposure to the respiratory tract	0.230	mg/m ³	ART (75-p, interquartile) PROC 8b (30 to 60 % formaldehyde solution in water) with RPE factor ECETOCTRA
Long-term systemic combined exposure	Combined risk assessment was calculated in Section 10		
Long-term local exposure to the skin	Quantified local exposure to the skin		
Long-term local exposure to the respiratory tract	See “Long-term systemic exposure to the respiratory tract”		
Short-term systemic exposure to the skin	Short-term systemic exposure to the skin not evaluated due to absence of DNEL		
Short-term systemic exposure to the respiratory tract	0.46	mg/m ³	ART (75-p, interquartile) PROC 8b (30 to 60 % formaldehyde solution in water) with RPE factor ECETOCTRA
Short-term systemic combined exposure	Short-term systemic combined exposure not evaluated because it was not determined		
Short-term local exposure to the skin	Quantified local exposure to the skin		

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Exposure	Concentrations	References
Short-term local exposure to the respiratory tract	See “Short-term systemic exposure to the respiratory tract”	

NA = Not applicable

Table 8: Estimated exposure to workers according to the scenario 9a

Exposure	Concentrations		References
	Value	Units	
Long-term systemic exposure to the skin	< 0.1	mg/kg bw/d	ECETOC TRA Version 2 modified (see Section 9) PROC 9 (30 to 60 % formaldehyde solution in water)
Long-term systemic exposure to the respiratory tract	0.120	mg/m ³	ART (75-p, interquartile) PROC 9 (30 to 60 % formaldehyde solution in water) with RPE factor ECETOCTRA
Long-term systemic combined exposure	Combined risk assessment was calculated in Section 10		
Long-term local exposure to the skin	Quantified local exposure to the skin		
Long-term local exposure to the respiratory tract	See “Long-term systemic exposure to the respiratory tract”		
Short-term systemic exposure to the skin	Short-term systemic exposure to the skin not evaluated due to absence of DNEL		
Short-term systemic exposure to the respiratory tract	0.24	mg/m ³	ART (75-p, interquartile) PROC 9 (30 to 60 % formaldehyde solution in water)
Short-term systemic combined exposure	Short-term systemic combined exposure not evaluated because it was not determined		
Short-term local exposure to the skin	Quantified local exposure to the skin		
Short-term local exposure to the respiratory tract	See “Short-term systemic exposure to the respiratory tract”		

NA = Not applicable

Table 9: Estimated exposure to workers according to the scenario 10

Exposure	Concentrations		References
	Value	Units	
Long-term systemic exposure to the skin	0.04	mg/kg bw/d	ECETOC TRA Version 2 modified (see Section 9) PROC 14
Long-term systemic exposure to the respiratory tract	0.233	mg/m ³	ECETOC TRA Version 2 modified (see Section 9) PROC 14
Long-term systemic combined exposure	Combined risk assessment was calculated in Section 10		
Long-term local exposure to the skin	Quantified local exposure to the skin		
Long-term local exposure to the respiratory tract	See “Long-term systemic exposure to the respiratory tract”		

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Exposure	Concentrations		References
Short-term systemic exposure to the skin	Short-term systemic exposure to the skin not evaluated due to absence of DNEL		
Short-term systemic exposure to the respiratory tract	0.78	mg/m ³	ECETOC TRA Version 2 modified (see Section 9) PROC 14 (30 to 60 % formaldehyde solution in water)
Short-term systemic combined exposure	Short-term systemic combined exposure not evaluated because it was not determined		
Short-term local exposure to the skin	Quantified local exposure to the skin		
Short-term local exposure to the respiratory tract	See “Short-term systemic exposure to the respiratory tract”		

NA = Not applicable

Table 10: Estimated exposure to workers according to the scenario 11

Exposure	Concentrations		References
	Value	Units	
Long-term systemic exposure to the skin	<0.1	mg/kg bw/d	ECETOC TRA Version 2 modified (see Section 9) PROC 15
Long-term systemic exposure to the respiratory tract	0.300	mg/m ³	ART (75-p, interquartile) PROC 15
Long-term systemic combined exposure	Combined risk assessment was calculated in Section 10		
Long-term local exposure to the skin	Quantified local exposure to the skin		
Long-term local exposure to the respiratory tract	See “Long-term systemic exposure to the respiratory tract”		
Short-term systemic exposure to the skin	Short-term systemic exposure to the skin not evaluated due to absence of DNEL		
Short-term systemic exposure to the respiratory tract	0.60	mg/m ³	ART (75-p, interquartile) PROC 15
Short-term systemic combined exposure	Short-term systemic combined exposure not evaluated because it was not determined		
Short-term local exposure to the skin	Quantified local exposure to the skin		
Short-term local exposure to the respiratory tract	See “Short-term systemic exposure to the respiratory tract”		

NA = Not applicable

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Exposure scenario No. 2: production of mixtures (30 to 60%)

1.2. Production of mixtures

General comments

Exposure scenario 2 “Production of mixtures” consists of the same use descriptors/references that describe the exposure scenario 1. Formalin concentration is identical to EU1. The same management conditions and hazard management measurement are valid for the risk management. Use Scenario 1 data to assess the exposure according to the provided scenarios.

1.2.1. Production of mixtures (30 to 60 %)

1.2.1.1. Exposure scenario

Reference number	2
Short name	Production of mixtures (30 to 60 %)
The systematic name according to the use reference	SU 3, 10 PROC 1, 2, 3, 4, 5, 6, 8a, 8b, 9, 14, 15 ERC 2, 3
Processes, tasks, activities	Use in a closed process, no human exposure probability (PROC 1) Use in a closed uninterrupted process with a random controlled exposure to humans (PROC 2) Use in a closed production process (synthesis/preparation) (PROC 3) Use in a mixing or other process (synthesis), where there is human exposure probability (PROC 4) In a mixing process, where there is a considerable human contact with the substance (PROC 5) In scheduled operations (PROC 6) Transfer (filling/spill) of substances or mixtures from/to vessels/large containers in unadjusted equipment (PROC 8a) Transfer (filling/spill) of chemicals from/to vessels/large containers in compatible equipment (PROC 8b) Transfer of substances or mixtures into small containers (in an adapted filling line, including weighing) (PROC 9) Use as a laboratory reagent (PROC 15)
Environmental exposure assessment	Environmental assessment is not completed
Assessment method	Use Exposure Scenario 1 to assess the exposure scenarios

1.3. Production of mixtures (EU 2)

1.3.1. Production of mixtures (30 to 60 %)

1.3.1.1. Exposure to human health

1.3.1.1.1. For workers

Exposure scenario 2 “Production of mixtures” consists of the same use descriptors/references that describe the exposure scenario 1. Formalin concentration is identical to EU1. The same management conditions and hazard management measurement are valid for the risk management. RCRs for each scenario in accordance with Paragraph 10.1.

1.4. Generalised exposure

1.4.1. Nature’s effect on humans

There are several publications on effect of naturally occurring formaldehyde on human health. A comprehensive overview is available in the International Chemical Assessment Document No. 40 published by the World Health Organisation (Geneva, 2002). The document specifies in detail the formalin sources and its effects and the exposure values of indoor and outdoor air. Maximum concentration values for the worst case is 94 µg/m³, average concentrations are 24 and 33 µg/m³. Drinking water formaldehyde concentration must be less than 100 µg/L (IPCS, 1989; IARC, 1995), the daily rate is 0.2 mg. Studies of the incoming formaldehyde quantities in food consumption have

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not been conducted. The formaldehyde quantities contained in different food products vary (3 to 23 mg/kg, IARC1982); therefore, it is difficult to accurately assess formaldehyde quantities entering with food. The derived average is 9.4 mg/kg, the daily rate is 0.13 mg/kg (Guideline for Canadian Bottled Water Quality: Supporting Documentation, 1997, <http://www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/formaldehyde/exposure-exposition-eng.php>). For the purpose of risk assessment, in respect to worst-case scenario, the daily rate is 23 mg/kg of formaldehyde per 1 kg of food.

Risk assessment

RCRs exposure to humans through the different natural environments is provided in the table (human weight 70 kg, daily food rate 1 kg).

Route of entry	Units	DNEL (for general population)	Exposure	RCR
Through respiratory tract (indoor and outdoor air, 24h)	mg/m ³	3.2 (chronic respiratory tract)	0.094 (= 94 µg/m ³)	0.029
Through the mouth (when drinking water)	mg/kg bw/day	4.1 (chronic oral somatics)	0.0028 (0.2 mg/per day)	0.00068
Through the mouth (food; in the worst case: 23 mg/kg)	mg/kg bw/day	4.1 (chronic oral somatics)	0.33 (23 mg FA kg for food * 1 kg of daily amount / 70 kg human weight)	0.08
Through the mouth (food and water)	mg/kg bw/day	4.1 (chronic oral somatics)	0.3328	0.081

End of the Safety Data Sheet