according to 1907/2006/EC, Article 31

Printing date 07.06.2021

Scharlau

#### Version number 2.0

Revision: 02.06.2021

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

- · 1.1 Product identifier
- Trade name: Formaldehyde, solution 37% w/w, Pharmpur®, Ph Eur, BP, USP, stabilized with methanol
- · Article number: FO0010
- · Registration number
- A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.
- **1.2** Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the preparation: Laboratory reagent
- 1.3 Details of the supplier of the safety data sheet

 Manufacturer/Supplier: Scharlab, S.L.
 C/Gato Pérez, 33. Pol.Ind. Mas d'en Cisa 08181 Sentmenat (Barcelona) SPAIN
 Tel: (+34) 93 745 64 00 - FAX: (+34) 93 715 27 65
 email: scharlab@scharlab.com
 Internet Web Site: www.scharlab.com
 Regional representation:

Scharlab, S.L. C/Gato Pérez, 33. Pol.Ind. Mas d'en Cisa 08181 Sentmenat (Barcelona) SPAIN Tel: (+34) 93 745 64 00 - FAX: (+34) 93 715 27 65 email: scharlab@scharlab.com Internet Web Site: www.scharlab.com

- · Further information obtainable from: technical department
- · 1.4 Emergency telephone number:

Toxicological Information National Institute of Toxicology and Forensic Sciences: + 34 91 562 04 20. The information will be provided (24h/365 days) Please contact the regional Scharlab distributor/dealer in your country During normal opening times: Scharlab, S.L. (+34) 93 715 18 11

## **SECTION 2: Hazards identification**

2.1 Classification of the substance or mixture
 Classification according to Regulation (EC) No 1272/2008



GHS06 skull and crossbones

Acute Tox. 3 H301 Toxic if swallowed. Acute Tox. 3 H311 Toxic in contact with skin. Acute Tox. 3 H331 Toxic if inhaled.



GHS08 health hazard

Muta. 2	H341 Suspected of causing genetic de	efects
Carc. 1B	H350 May cause cancer.	
STOT SE 2	H371 May cause damage to organs	

(Contd. on page 2)



according to 1907/2006/EC, Article 31

Printing date 07.06.2021

Version number 2.0

Revision: 02.06.2021

Trade name: Formaldehyde, solution 37% w/w, Pharmpur®, Ph Eur, BP, USP, stabilized with methanol

(Contd. of page 1)

GHS05 corrosion

Skin Corr. 1B H314 Causes severe skin burns and eye damage.

# GHS07

Skin Sens. 1 H317 May cause an allergic skin reaction. STOT SE 3 H335 May cause respiratory irritation.

## · 2.2 Label elements

- Labelling according to Regulation (EC) No 1272/2008 The product is classified and labelled according to the CLP regulation.
- Hazard pictograms



· Signal word Danger

## Hazard-determining components of labelling: formaldehyde methanol Hazard statements H301+H311+H331 Toxic if swallowed, in contact with skin or if inhaled. H314 Causes severe skin burns and eye damage. H317 May cause an allergic skin reaction. H241 Supported of reausing genetic defeate

H341	Suspected of causing genetic defects.					
H350	May cause cancer.					
H371	May cause damage to organs.					
H335	May cause respiratory irritation.					
Precautionary statements						
P301+P3	10 IF SWALLOWED: Immediately call a POISON CENTE					

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
 P321 Specific treatment (see on this label).
 P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P361+P364 Take off immediately all contaminated clothing and wash it before reuse.
 Store locked up.
 P501 Dispose of contents/container in accordance with local/regional/national/

P501 Dispose of contents/container in accordance with local/regional/national/ international regulations.

## · 2.3 Other hazards

- · Results of PBT and vPvB assessment
- · PBT: Not applicable.

· vPvB: Not applicable.

## **SECTION 3: Composition/information on ingredients**

· 3.2 Chemical characterisation: Mixtures

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

(Contd. on page 3)

ne wise chc

according to 1907/2006/EC, Article 31

Printing date 07.06.2021

Scharlau

Version number 2.0

Revision: 02.06.2021

Trade name: Formaldehyde, solution 37% w/w, Pharmpur®, Ph Eur, BP, USP, stabilized with methanol

 Dangerous components: CAS: 50-00-0

EINECS: 200-001-8

25-50%

(Contd. of page 2)

CAS: 67-56-1 EINECS: 200-659-6 Reg.nr.: 01-2119433307-44-XXXX

formaldehyde Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; H331; Muta. 2, H341; Carc. 1B, H350; Skin Corr. 1B, H314; 🚯 Skin Sens. 1, H317 methanol 5-10% 🚸 Flam. Liq. 2, H225; 🚸 Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; 🚯 STOT SE 1, H370

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

## **SECTION 4: First aid measures**

- 4.1 Description of first aid measures
- General information:
- Immediately remove any clothing soiled by the product. Remove breathing equipment only after contaminated clothing have been completely removed. In case of irregular breathing or respiratory arrest provide artificial respiration.
- After inhalation:

Supply fresh air or oxygen; call for doctor.

In case of unconsciousness place patient stably in side position for transportation.

- · After skin contact: Immediately wash with water and soap and rinse thoroughly.
- After eye contact:
- Rinse opened eye for several minutes under running water. Then consult a doctor.
- After swallowing: Do not induce vomiting; call for medical help immediately. Drink plenty of water and provide fresh air. Call for a doctor immediately.
- · 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- 4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.

## **SECTION 5: Firefighting measures**

- 5.1 Extinguishing media
- Suitable extinguishing agents:
- CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- 5.3 Advice for firefighters
- · Protective equipment: Mouth respiratory protective device.

## **SECTION 6: Accidental release measures**

- 6.1 Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away.
- · 6.2 Environmental precautions: Dilute with plenty of water.
- Do not allow to enter sewers/ surface or ground water.
- 6.3 Methods and material for containment and cleaning up:
- Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Use neutralising agent.
- Dispose contaminated material as waste according to item 13.

(Contd. on page 4)



according to 1907/2006/EC, Article 31

Printing date 07.06.2021

Version number 2.0

Revision: 02.06.2021

(Contd. of page 3)

Trade name: Formaldehyde, solution 37% w/w, Pharmpur®, Ph Eur, BP, USP, stabilized with methanol

- Ensure adequate ventilation. • **6.4 Reference to other sections** See Section 7 for information on safe handling.
- See Section 8 for information on personal protection equipment.
- See Section 13 for disposal information.

## **SECTION 7: Handling and storage**

- 7.1 Precautions for safe handling Ensure good ventilation/exhaustion at the workplace.
   Open and handle receptacle with care.
   Prevent formation of aerosols.
- Information about fire and explosion protection: Keep ignition sources away - Do not smoke. Keep respiratory protective device available.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: Keep container tightly sealed.
- 7.3 Specific end use(s) No further relevant information available.

## **SECTION 8: Exposure controls/personal protection**

- · 8.1 Control parameters
- Additional information about design of technical facilities: No further data; see item 7.
- Ingredients with limit values that require monitoring at the workplace:

## 50-00-0 formaldehyde

WEL Short-term value: 2.5 mg/m<sup>3</sup>, 2 ppm Long-term value: 2.5 mg/m<sup>3</sup>, 2 ppm Carc

## 67-56-1 methanol

- WEL Short-term value: 333 mg/m<sup>3</sup>, 250 ppm Long-term value: 266 mg/m<sup>3</sup>, 200 ppm Sk
- Additional information: The lists valid during the making were used as basis.

## · 8.2 Exposure controls

- · Personal protective equipment:
- · General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

- Wash hands before breaks and at the end of work.
- Store protective clothing separately. Avoid contact with the eyes and skin.

wise choil

- · Respiratory protection:
- In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

(Contd. on page 5)

according to 1907/2006/EC, Article 31

Printing date 07.06.2021

Scharlau

Version number 2.0

Revision: 02.06.2021

Trade name: Formaldehyde, solution 37% w/w, Pharmpur®, Ph Eur, BP, USP, stabilized with methanol

(Contd. of page 4)

Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

#### · Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:



Tightly sealed goggles

## **SECTION 9: Physical and chemical properties**

- · 9.1 Information on basic physical and chemical properties
- General Information
- Appearance:
- Form:
- Colour: Odour:
- · Odour threshold:
- · pH-value:

Fluid Colourless Pungent Not determined. Not determined.

Not applicable.

Not determined.

Product is not selfigniting.

Product does not present an explosion hazard.

62 °C

300 °C

5.5 Vol % 73 Vol %

128 hPa

1.09 g/cm<sup>3</sup>

- Change in condition Melting point/freezing point: Undetermined. Initial boiling point and boiling range: >93 °C
- · Flash point:
- Flammability (solid, gas):
- Signition temperature:
- · Decomposition temperature:
- · Auto-ignition temperature:
- · Explosive properties:
- Explosion limits: Lower: Upper:
- · Vapour pressure at 20 °C:
- Density at 20 °C:

(Contd. on page 6)

# Scharlau

## Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 07.06.2021

Version number 2.0

Revision: 02.06.2021

	Trade name: Formaldehyde, solution 37% w/w, Pharmpur®, Ph Eur, BP, USP, stabilized with methanol			
Ì				
	ANC .		(Contd. of page 5)	
	· Relative density	Not determined.		
	· Vapour density	Not determined.		

- Evaporation rate
- Solubility in / Miscibility with water:
- Partition coefficient: n-octanol/water:
- Viscosity: Dynamic: Kinematic:
- Solvent content: Organic solvents: Water:

Not determined. Fully miscible.

Not determined.

Not determined. Not determined.

47.0 % 53.0 %

• 9.2 Other information

No further relevant information available.

## **SECTION 10: Stability and reactivity**

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- · 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known.

## **SECTION 11: Toxicological information**

## · 11.1 Information on toxicological effects

- · Acute toxicity
- Toxic if swallowed, in contact with skin or if inhaled.

LD/LC50 values relevant for classification:

## 50-00-0 formaldehyde

Oral LD50 >200 mg/kg (rat)

## 67-56-1 methanol

Oral	LD50	100 mg/kg (rat)
Dermal	LD50	300 mg/kg (rabbit)

Inhalative LC50/4 h 3 mg/l (rat)

- Primary irritant effect:
- Skin corrosion/irritation

Causes severe skin burns and eye damage.

- Serious eye damage/irritation
- Causes severe skin burns and eye damage.
- · Respiratory or skin sensitisation
- May cause an allergic skin reaction.
- Additional toxicological information:
   CMP offects (corrigonanity, mytogenicity)
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- Germ cell mutagenicity
- Suspected of causing genetic defects.
- Carcinogenicity May cause cancer.
- Reproductive toxicity Based on available data, the classification criteria are not met.

(Contd. on page 7)

according to 1907/2006/EC, Article 31

Printing date 07.06.2021

Scharlau

Version number 2.0

Revision: 02.06.2021

(Contd. of page 6)

Trade name: Formaldehyde, solution 37% w/w, Pharmpur®, Ph Eur, BP, USP, stabilized with methanol

- · STOT-single exposure
- May cause damage to organs. May cause respiratory irritation.
- STOT-repeated exposure Based on available data, the classification criteria are not met.
- Aspiration hazard Based on available data, the classification criteria are not met.

## **SECTION 12: Ecological information**

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.
- Additional ecological information:
- · General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water Do not allow product to reach ground water, water course or sewage system. Must not reach sewage water or drainage ditch undiluted or unneutralised.

- Danger to drinking water if even small quantities leak into the ground.
- 12.5 Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- vPvB: Not applicable.

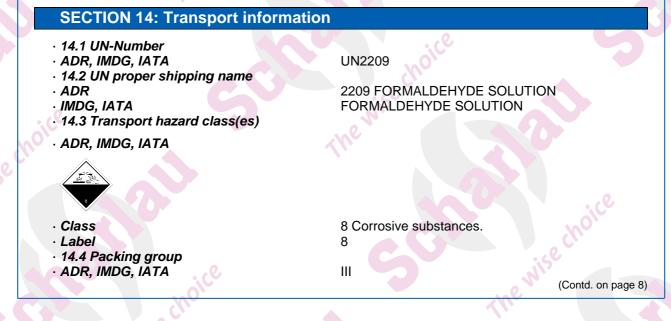
· 12.6 Other adverse effects No further relevant information available.

## **SECTION 13: Disposal considerations**

- · 13.1 Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- Uncleaned packaging:
- Recommendation: Disposal must be made according to official regulations.
- Recommended cleansing agents: Water, if necessary together with cleansing agents.





according to 1907/2006/EC, Article 31

Printing date 07.06.2021

Version number 2.0

Revision: 02.06.2021

Trade name: Formaldehyde, solution 37% w/w, Pharmpur®, Ph Eur, BP, USP, stabilized with methanol

<ul> <li>14.5 Environmental hazards:</li> <li>Marine pollutant:</li> <li>14.6 Special precautions for user</li> <li>Stowage Category</li> <li>14.7 Transport in bulk according to Anno of Marpol and the IBC Code</li> </ul>	No Warning: Corrosive substances. A	contd. of page 7
• Transport/Additional information:		
ADR     Limited quantities (LQ)     Transport category     Tunnel restriction code	5L 3	

- · Tunnel restriction code
- UN "Model Regulation":

UN 2209 FORMALDEHYDE SOLUTION, 8, III

## **SECTION 15: Regulatory information**

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Seveso category H2 ACUTE TOXIC
- · Qualifying quantity (tonnes) for the application of lower-tier requirements 50 t
- · Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3, 28, 69, 72
- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment Annex II
- None of the ingredients is listed.
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

## **SECTION 16: Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

#### Relevant phrases

- H225 Highly flammable liquid and vapour.
- H301 Toxic if swallowed.
- H311 Toxic in contact with skin.
- H314 Causes severe skin burns and eye damage.
- H317 May cause an allergic skin reaction.
- H331 Toxic if inhaled.
- H341 Suspected of causing genetic defects.
- H350 May cause cancer.
- H370 Causes damage to organs.
- Classification according to Regulation (EC) No 1272/2008
- The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.
- · Department issuing SDS: product safety department
- · Contact: msds@scharlab.com
- · Abbreviations and acronyms:
- RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail) ICAO: International Civil Aviation Organisation
- ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
- IMDG: International Maritime Code for Dangerous Goods

(Contd. on page 9)

wise cho



The wise choice

the wise choice

## Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 07.06.2021

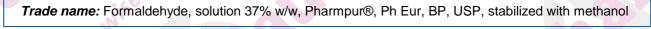
Version number 2.0

Revision: 02.06.2021

(Contd. of page 8)

The wise choice

The wise choice



the wise cho

the wise choice

IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) LC50: Lethal concentration, 50 percent D50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Flam. Liq. 2: Flammable liquids – Category 2 Acute Tox. 3: Acute toxicity – Category 3 Skin Corr. 1B: Skin corrosion/irritation – Category 1B Skin Sens. 1: Skin sensitisation – Category 2 Carc. 1B: Carcinogenicity – Category 1B STOT SE 1: Specific target organ toxicity (single exposure) – Category 1 STOT SE 2: Specific target organ toxicity (single exposure) – Category 2

the wise choice

The wise choice