SAFETY DATA SHEET

according to Commission Regulation (EU) 2020/878 as amended

Bouin solution

Creation date	21st January 2020	Version	5.0
Revision date	09th April 2026		

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

1.1. Product identifier — Bouin solution

Substance / mixture: mixture

UFI: K4HY-E0T0-X000-EM69

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

Mixture's intended use

Chemical production, analytical chemistry, laboratory synthesis, industrial applications.

Mixture uses advised against

The product should not be used in ways other than those referred in Section 1.

1.3. Details of the supplier of the safety data sheet

Supplier

Name or trade name	Ing. Petr Švec - PENTA s.r.o.
Address	Radiová 1122/1, Praha 10, 102 00 Czech Republic
Identification number (CRN)	02096013
VAT number	CZ02096013
Phone	+420 226 060 681
Email	info@pentachemicals.eu
Web address	www.pentachemicals.eu

Competent person responsible for the safety data sheet

Name	Ing. Petr Švec - PENTA s.r.o.
Email	info@pentachemicals.eu

1.4. Emergency telephone number

European emergency number: 112 112

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification of the mixture in accordance with Regulation (EC) No 1272/2008

The mixture is classified as dangerous.

Acute Tox. 4, H302
Skin Corr. 1B, H314
Skin Sens. 1A, H317
Eye Dam. 1, H318
Acute Tox. 2, H330
STOT SE 3, H335
Muta. 2, H341
Carc. 1B, H350

Most serious adverse effects on human health and the environment

Harmful if swallowed. Causes severe skin burns and eye damage. May cause an allergic skin reaction. Causes serious eye damage. Fatal if inhaled. May cause respiratory irritation. Suspected of causing genetic defects. May cause cancer.

2.2. Label elements

Hazard pictogram

Signal word

Danger

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Hazardous substances

formaldehyde …%
2,4,6-trinitrophenol

Hazard statements

H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H330	Fatal if inhaled.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H350	May cause cancer.

Precautionary statements

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a doctor.

Supplemental information

Restricted to professional users.

2.3. Other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Mixture does not contain any substance meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended. Does not contain any PMT or vPvM components.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Mixture contains these hazardous substances and substances with the highest permissible concentration in the working environment

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
Index: 605-001-00-5 CAS: 50-00-0 EC: 200-001-8 Registration number: 01-2119488953-20-0302	formaldehyde …%	60	Acute Tox. 4, H302 Skin Corr. 1B, H314 Skin Sens. 1A, H317 Acute Tox. 2, H330 STOT SE 3, H335 Muta. 2, H341 Carc. 1B, H350 Specific concentration limit: Skin Corr. 1B, H314: C ≥ 25 % Skin Irrit. 2, H315: 5 % ≤ C < 25 % Eye Irrit. 2, H319: 5 % ≤ C < 25 % STOT SE 3, H335: C ≥ 5 % ATE Inhalation (gases) = 100 ppm ATE Oral = 500 mg/kg bw	1, 2, 3, 5

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Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
Index: 607-002-00-6 CAS: 64-19-7 EC: 200-580-7 Registration number: 01-2119475328-30-xxxx	acetic acid … %	10	Flam. Liq. 3, H226 Skin Corr. 1A, H314 Eye Dam. 1, H318 Specific concentration limit: Skin Corr. 1A, H314: C ≥ 90 % Skin Irrit. 2, H315: 10 % ≤ C < 25 % Skin Corr. 1B, H314: 25 % ≤ C < 90 % Eye Irrit. 2, H319: 10 % ≤ C < 25 %	1, 4
Index: 609-009-00-X CAS: 88-89-1 EC: 201-865-9	2,4,6-trinitrophenol	1	Desen. Expl. 1, H206 Acute Tox. 4, H302 Acute Tox. 3, H311+H331	4

Notes

1 *Note B: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid … %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.*

2 *Note D: Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3 of Annex VI to Regulation (EC) No 1272/2008. However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the supplier who places such a substance on the market must state on the label the name of the substance followed by the words "non-stabilised".*

3 *Note F: This substance may contain a stabiliser. If the stabiliser changes the hazardous properties of the substance, as indicated by the classification in Part 3, classification and labelling should be provided in accordance with the rules for classification and labelling of hazardous mixtures.*

4 *A substance for which exposure limits are set.*

5 *The use of the substance is restricted by Annex XVII of REACH Regulation*

Full text of all classifications and hazard statements is given in the section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Take care of your own safety. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet. If unconscious, put the person in the stabilized (recovery) position on his side with his head slightly bent backwards and make sure that airways are free; never induce vomiting. If the person vomits by himself, make sure that the vomit is not inhaled. In life threatening conditions first of all provide resuscitation of the affected person and ensure medical assistance. Respiratory arrest - provide artificial respiration immediately. Cardiac arrest - provide indirect cardiac massage immediately.

If inhaled

Terminate the exposure immediately; move the affected person to fresh air. Take care of your own safety, do not let the affected person walk! Beware of the contaminated clothes. Depending on the situation, call the medical rescue service and ensure medical treatment considering the frequent need of further observation for at least 24 hours.

If on skin

Remove contaminated clothes. Take off any rings, watches, bracelets before or during washing if worn in the contaminated areas of the skin. Rinse contaminated areas with a flow of water, lukewarm at best, for 10-30 minutes; do not use any brush, soap or neutralizers. Depending on the situation, call the medical rescue service and always ensure medical treatment.

If in eyes

Rinse eyes immediately with a flow of running water, open the eyelids (also using force if needed); remove contact lenses immediately if worn by the affected person. No neutralization should be performed in any case! Rinsing should be continued for 10-30 minutes from the inner to the outer eye corner to make sure that the other eye is not involved. Depending on the situation, call medical rescue service or ensure medical treatment as promptly as possible. Everyone must be referred for treatment even if affected only a little.

If swallowed

Vomiting should be induced in the person only if conscious, within 1 hour from ingestion. If in doubt whether vomiting should be induced, contact the Toxicological Information Centre and give information about the substances or composition of the product as provided on the original packaging or in the safety data sheet of the product. FOLLOWING INGESTION OF TOXIC OR HIGHLY TOXIC SUBSTANCES, GIVE 10-20 CRUSHED TABLETS OF ACTIVATED CARBON, MIXED IN WATER, WITHIN NO LATER THAN 5 MINUTES - irrespective of whether vomiting could be induced. Call medical rescue service.

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

If inhaled

Inhaling vapours can cause corrosion of the breathing system. May cause respiratory irritation.

If on skin

Causes severe skin burns. May cause an allergic skin reaction.

If in eyes

Causes serious eye damage.

If swallowed

Corrosion of the digestion system can occur.

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

Symptomatic treatment.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist.

Unsuitable extinguishing media

Water - full jet.

5.2. Special hazards arising from the substance or mixture

In the event of fire, carbon monoxide, carbon dioxide and other toxic gases may arise. Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

5.3. Advice for firefighters

Self-Contained Breathing Apparatus (SCBA) with a chemical protection suit only where personal (close) contact is likely. Use a self-contained breathing apparatus and full-body protective clothing. Do not allow run-off of contaminated fire extinguishing material to enter drains or surface and ground water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment for work. Follow the instructions in the Sections 7 and 8. Do not inhale mist/vapours/spray. Prevent contact with skin and eyes.

6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water.

6.3. Methods and material for containment and cleaning up

Spilled product should be covered with suitable (non-flammable) absorbing material (sand, diatomaceous earth, earth and other suitable absorption materials); to be contained in well closed containers and removed as per the Section 13. In the event of leakage of the substantial amount of the product, inform fire brigade and other competent bodies. After removal of the product, wash the contaminated site with plenty of water. Do not use solvents.

6.4. Reference to other sections

See the Section 7, 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Prevent formation of gases and vapours in concentrations exceeding the occupational exposure limits. Do not inhale mist/vapours/spray. Prevent contact with skin and eyes. Contaminated work clothing should not be allowed out of the workplace. Obtain special instructions before use. Wash hands and exposed parts of the body thoroughly after handling. Do not eat, drink or smoke when using this product. Do not handle until all safety precautions have been read and understood. Use only outdoors or in a well-ventilated area. Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection.

7.2. Conditions for safe storage, including any incompatibilities

Store in tightly closed containers in cold, dry and well ventilated areas designated for this purpose. Store locked up. Keep container tightly closed.

Storage temperature min 15 °C, max 25 °C

7.3. Specific end use(s)

not available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

The mixture contains substances for which occupational exposure limits are set.

European Union **Commission Directive (EU) 2017/164**

Substance name (component)	Type	Value
acetic acid … % (CAS: 64−19−7)	OEL 8 hours	25 mg/m³
	OEL 8 hours	10 ppm
	OEL 15 minutes	50 mg/m³
	OEL 15 minutes	20 ppm

European Union **Commission Directive 91/322/EEC**

Substance name (component)	Type	Value
2,4,6−trinitrophenol (CAS: 88−89−1)	OEL 8 hours	0,1 mg/m³

DNEL

formaldehyde ...%			
Workers / consumers	Route of exposure	Value	Effect
Workers	Dermal	240 mg/kg bw/day	Chronic effects systemic
Workers	Inhalation	9 mg/m³	Chronic effects systemic
Workers	Inhalation	0.375 mg/m³	Acute effects systemic
Consumers	Inhalation	3.2 mg/kg	Chronic effects systemic
Consumers	Dermal	102 mg/kg bw/day	Chronic effects systemic
Workers	Inhalation	0.75 mg/m³	Acute effects local

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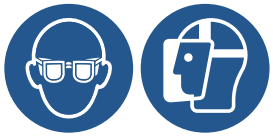
PNEC

formaldehyde ...%	
Route of exposure	Value
Marine water	0.44 mg/l
Soil (agricultural)	0.21 mg/l
Drinking water	0.44 mg/l

8.2. Exposure controls

Take off contaminated clothing and wash before reuse. Follow the usual measures intended for health protection at work and especially for good ventilation. This can be achieved only by local suction or efficient general ventilation. If exposure limits cannot be observed in this mode, suitable protection of airways must be used. Do not eat, drink and smoke during work. Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest.

Eye/face protection



Protective goggles or face shield (based on the nature of the work performed).

Skin protection

Hand protection: Protective gloves resistant to the product. When choosing appropriate thickness, material and permeability of the gloves, observe recommendations of their particular manufacturer. When selecting gloves, consider the properties of the product and the duration of exposure. Replace gloves at the first signs of wear or damage. Other protection: protective workwear. Contaminated skin should be washed thoroughly.

Glove material	Thickness	Breakthrough time	Class	Exposure time
Nitrile (NBR)	≥ 0.3 mm	>30 min	2	Short-term
Nitrile (NBR)	≥ 0.7 mm	>480 min	6	Repeated, Long-term

Respiratory protection

Use insulating breathing apparatus when the exposition limits of the substances are exceeded or at the place with insufficient ventilation.

Thermal hazard

Not available.

Environmental exposure controls

Observe usual measures for protection of the environment, see Section 6.2.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	liquid

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Colour	yellow
Odour	data not available
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	data not available
Flammability	data not available
Lower and upper explosion limit	data not available
Flash point	data not available
Auto-ignition temperature	data not available
Decomposition temperature	data not available
pH	data not available
Kinematic viscosity	data not available
Solubility in water	data not available
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	data not available
Relative vapour density	data not available
Particle characteristics	data not available

9.2. Other information

not available

SECTION 10: Stability and reactivity

10.1. Reactivity

not available

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Unknown.

10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost.

10.5. Incompatible materials

Protect against strong acids, bases and oxidizing agents.

10.6. Hazardous decomposition products

Not developed under normal uses. Dangerous outcomes such as carbon monoxide and carbon dioxide are formed at high temperature and in fire.

SECTION 11: Toxicological information

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

Hazardous substances in concentrations exceeding exposure limits may cause acute inhalation poisoning, depending on the concentration and duration of exposure. No toxicological data is available for the mixture.

Acute toxicity

Harmful if swallowed. Fatal if inhaled.

Bouin solution							
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination	Source
Oral	ATE	819.7 mg/kg				Calculation of value	
Dermal	ATE	30000 mg/kg				Calculation of value	

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Bouin solution							
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination	Source
Inhalation (dust/mist)	ATE	0.083195 mg/l				Calculation of value	

2,4,6-trinitrophenol							
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination	Source
Intraperitoneally	LD_{50}	56.3 mg/kg		Mouse			Merck
Skin		461.54 mg/kg				Calculation of value	Merck

acetic acid ... %							
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination	Source
Oral	LD_{50}	3310 mg/kg		Rat (Rattus norvegicus)			

formaldehyde ...%							
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination	Source
Inhalation (vapor)		6.122 mg/l	4 hours			Estimated value	
Inhalation (gases)		100 ppmV	4 hours			Estimated value	
Dermal		612.2 mg/kg				Estimated value	
Oral		500 mg/kg				Estimated value	
Inhalation (gases)	ATE	100 ppm					
Oral	ATE	500 mg/kg bw					

Skin corrosion/irritation
Causes severe skin burns and eye damage. Data for the components of the mixture are not available.

Serious eye damage/irritation
Causes severe skin burns and eye damage. Causes serious eye damage. Data for the components of the mixture are not available.

Respiratory or skin sensitisation
May cause an allergic skin reaction. Data for the components of the mixture are not available.

Germ cell mutagenicity
Suspected of causing genetic defects. Data for the components of the mixture are not available.

Carcinogenicity
May cause cancer. Data for the components of the mixture are not available.

Reproductive toxicity
No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Toxicity for specific target organ - single exposure

May cause respiratory irritation. Data for the components of the mixture are not available.

Toxicity for specific target organ - repeated exposure

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Aspiration hazard

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

11.2. Information on other hazards

Endocrine disrupting properties

Based on the available data, the criteria for classification of the mixture are not met. Does not contain any components that may cause endocrine disruption for humans.

Other information

not available

SECTION 12: Ecological information

12.1. Toxicity

Data for the mixture are not available. Based on the available data, the criteria for classification of the mixture are not met.

Acute toxicity

acetic acid ... %				
Parameter	Value	Exposure time	Species	Environment
LC_{50}	75 mg/l	96 hours	Fish (Lepomis macrochirus)	
EC_{50}	47 mg/l	24 hours	Daphnia (Daphnia magna)	

12.2. Persistence and degradability

No data are available for either the mixture or the components.

12.3. Bioaccumulative potential

No data are available for either the mixture or the components.

12.4. Mobility in soil

Based on the available data, the criteria for classification of the mixture are not met. Does not contain any PMT or vPvM components.

12.5. Results of PBT and vPvB assessment

Based on the available data, the criteria for classification of the mixture are not met. Does not contain any PBT or vPvB components. Product does not contain any substance meeting the criteria for PBT or vPvB in accordance with the Annex XIII of Regulation (EC) No 1907/2006 (REACH) as amended.

12.6. Endocrine disrupting properties

Based on the available data, the criteria for classification of the mixture are not met. Does not contain any components that may cause endocrine disruption in the environment.

12.7. Other adverse effects

Not available.

SECTION 13: Disposal considerations

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13.1. Waste treatment methods

Hazard of environmental contamination; dispose of the waste in accordance with the local and/or national regulations. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorised for waste removal (a specialized company) that is entitled for such activity. Do not empty unused product in drainage systems. The product must not be disposed of with municipal waste. Perfectly cleaned containers can be submitted for recycling.

Waste management legislation

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended. Decision 2000/532/EC establishing a list of wastes, as amended.

SECTION 14: Transport information

14.1. UN number or ID number

UN 1760

14.2. UN proper shipping name

CORROSIVE LIQUID, N.O.S. (BOUIN solution (contains formaldehyde, acetic acid glacial, picric acid))

14.3. Transport hazard class(es)

8 Corrosive substances

14.4. Packing group

II

14.5. Environmental hazards

not relevant

14.6. Special precautions for user

not available

14.7. Maritime transport in bulk according to IMO instruments

not relevant

Additional information

Hazard identification No.	80
UN number	1760
Classification code	C9
Safety signs	8

Tunnel restriction code	(E)

Air transport - ICAO/IATA

Packaging instructions passenger	851
Cargo packaging instructions	855

Marine transport - IMDG

EmS (emergency plan)	F-A, S-B
MFAG	760

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SECTION 15: Regulatory information

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

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the 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, as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Restrictions pursuant to Annex XVII of Regulation (EC) No. 1907/2006 (REACH), as amended

formaldehyde …%

Restriction	Conditions of restriction
28	1. Shall not be placed on the market, or used, — as substances, — as constituents of other substances, or, — in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than: — either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, — the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008. Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows: “Restricted to professional users”. 2. By way of derogation, paragraph 1 shall not apply to: (a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC; (b) cosmetic products as defined by Directive 76/768/EEC; (c) the following fuels and oil products: — motor fuels which are covered by Directive 98/70/EC, — mineral oil products intended for use as fuel in mobile or fixed combustion plants, — fuels sold in closed systems (e.g. liquid gas bottles); (d) artists’ paints covered by Regulation (EC) No 1272/2008; (e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date. (f) devices covered by Regulation (EU) 2017/745.

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formaldehyde …%

Restriction	Conditions of restriction
72	1. Shall not be placed on the market after 1 November 2020 in any of the following: (a) clothing or related accessories; (b) textiles other than clothing which, under normal or reasonably foreseeable conditions of use, come into contact with human skin to an extent similar to clothing; (c) footwear; if the clothing, related accessory, textile other than clothing or footwear is for use by consumers and the substance is present in a concentration, measured in homogeneous material, equal to or greater than that specified for that substance in Appendix 12. 2. By way of derogation, in relation to the placing on the market of formaldehyde [CAS No 50-00-0] in jackets, coats or upholstery, the relevant concentration for the purposes of paragraph 1 shall be 300 mg/kg during the period between 1 November 2020 and 1 November 2023. The concentration specified in Appendix 12 shall apply thereafter. 3. Paragraph 1 shall not apply to: (a) clothing, related accessories or footwear, or parts of clothing, related accessories or footwear, made exclusively of natural leather, fur or hide; (b) non-textile fasteners and non-textile decorative attachments; (c) second-hand clothing, related accessories, textiles other than clothing or footwear (d) wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners. 4. Paragraph 1 shall not apply to clothing, related accessories, textiles other than clothing, or footwear within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council (*) or Regulation (EU) 2017/745 of the European Parliament and of the Council (**). 5. Paragraph 1(b) shall not apply to disposable textiles. 'Disposable textiles' means textiles that are designed to be used only once or for a limited time and are not intended for subsequent use for the same or a similar purpose. 6. Paragraphs 1 and 2 shall apply without prejudice to the application of any stricter restrictions set out in this Annex or in other applicable Union legislation. 7. The Commission shall review the exemption in paragraph 3(d) and, if appropriate, modify that point accordingly. (*) Regulation (EU) 2016/425 of the European Parliament and of the Council of of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51). (**) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

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formaldehyde ...%

Restriction	Conditions of restriction
77	1. Shall not be placed on the market in articles, after 6 August 2026, if, under the test conditions specified in Appendix 14, the concentration of formaldehyde released from those articles exceeds: (a) 0,062 mg/m3 for furniture and wood-based articles; (b) 0,080 mg/m3 for articles other than furniture and wood-based articles. The first subparagraph shall not apply to: (a) articles in which formaldehyde or formaldehyde releasing substances are exclusively naturally present in the materials from which the articles are produced; (b) articles that are exclusively for outdoor use under foreseeable conditions; (c) articles in constructions, that are exclusively used outside the building shell and vapour barrier and that do not emit formaldehyde into indoor air; (d) articles exclusively for industrial or professional use unless formaldehyde released from them leads to exposure of the general public under foreseeable conditions of use; (e) articles for which the restriction laid down in entry 72 applies; (f) articles that are biocidal products within the scope of Regulation (EU) No 528/2012 of the European Parliament and of the Council; (g) devices within the scope of Regulation (EU) 2017/745; (h) personal protective equipment within the scope of Regulation (EU) 2016/425; (i) articles intended to come into contact directly or indirectly with food within the scope of Regulation (EC) No 1935/2004; (j) second-hand articles. 2. Shall not be placed on the market in road vehicles after 6 August 2027 if, under the test conditions specified in Appendix 14, the concentration of formaldehyde in the interior of those vehicles exceeds 0,062 mg/m3. The first subparagraph shall not apply to: (a) road vehicles exclusively for industrial or professional use unless the concentration of formaldehyde in the interior of those vehicles leads to exposure of the general public under foreseeable conditions of use; (b) second-hand vehicles.

15.2. Chemical safety assessment

A chemical safety assessment has not been carried out (mixture).

SECTION 16: Other information

A list of standard risk phrases used in the safety data sheet

H206	Fire, blast or projection hazard; increased risk of explosion if desensitising agent is reduced.
H226	Flammable liquid and vapour.
H302	Harmful if swallowed.
H311+H331	Toxic in contact with skin or if inhaled.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H350	May cause cancer.

Guidelines for safe handling used in the safety data sheet

P280	Wear protective gloves/protective clothing/eye protection/face protection.

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P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a doctor.

Other important information about human health protection

The product must not be - unless specifically approved by the manufacturer/importer - used for purposes other than as per the Section 1. The user is responsible for adherence to all related health protection regulations.

Key to abbreviations and acronyms used in the safety data sheet

Acute Tox.	Acute toxicity
ADR	Agreement concerning the international carriage of dangerous goods by road
ATE	Acute toxicity estimate
BCF	Bioconcentration Factor
Carc.	Carcinogenicity
CAS	Chemical Abstracts Service
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures
Desen. Expl.	Desensitised explosives
EC	Identification code for each substance listed in EINECS
EC_{50}	Concentration of a substance when it is affected 50 % of the population
EINECS	European Inventory of Existing Commercial Chemical Substances
EmS	Emergency Response Procedures for Ships Carrying Dangerous Goods
EU	European Union
EuPCS	European Product Categorisation System
Eye Dam.	Serious eye damage
Eye Irrit.	Eye irritation
Flam. Liq.	Flammable liquid
IATA	International Air Transport Association
IBC	International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
INCI	International Nomenclature of Cosmetic Ingredients
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LC_{50}	Lethal concentration of a substance in which it can be expected death of 50% of the population
LD_{50}	Lethal dose of a substance in which it can be expected death of 50% of the population
log Kow	Octanol-water partition coefficient
Muta.	Germ cell mutagenicity
OEL	Occupational Exposure Limits
PBT	Persistent, bioaccumulative and toxic
PMT	Persistent, mobile and toxic
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Regulation concerning the International Carriage of Dangerous Goods by Rail
Skin Corr.	Skin corrosion
Skin Irrit.	Skin irritation

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Skin Sens.	Skin sensitization
STOT SE	Specific target organ toxicity - single exposure
UN number	Four-figure identification number of the substance or article taken from the UN Model Regulations
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials
VOC	Volatile organic compounds
vPvB	Very persistent and very bioaccumulative
vPvM	Very persistent and very mobile

Training guidelines

Inform the personnel about the recommended ways of use, mandatory protective equipment, first aid and prohibited ways of handling the product.

Recommended restrictions of use

not available

Information about data sources used to compile the Safety Data Sheet

REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (REACH) as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

The changes (which information has been added, deleted or modified)

The version 5.0 replaces the SDS version from Friday, 28 March 2025. Changes were made in sections 2, 13, 15 and 16.

More information

Classification procedure - calculation method.

Statement

The safety data sheet provides information aimed at ensuring safety and health protection at work and environmental protection. The provided information corresponds to the current status of knowledge and experience and complies with valid legal regulations. The information should not be understood as guaranteeing the suitability and usability of the product for a particular application.