

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Paraformaldehyde , extra pure, granulated

article number: **0335**
Version: **6.0 en**
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Version: (5)

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

1.1 Product identifier

Identification of the substance	Paraformaldehyde , extra pure, granulated
Article number	0335
Registration number (REACH)	The substance does not require registration according to Regulation (EC) No 1907/2006 [REACH].
EC number	608-494-5
CAS number	30525-89-4

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

Relevant identified uses:	Laboratory chemical Laboratory and analytical use
Uses advised against:	Do not use for products which come into contact with foodstuffs. Do not use for private purposes (household). Food, drink and animal feeding-stuffs.

1.3 Details of the supplier of the safety data sheet

Carl Roth GmbH + Co. KG
Schoemperlenstr. 3-5
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e-mail: sicherheit@carlroth.de

Website: www.carlroth.de

Competent person responsible for the safety data sheet: Department Health, Safety and Environment

e-mail (competent person): sicherheit@carlroth.de

1.4 Emergency telephone number

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

Section	Hazard class	Cat-egory	Hazard class and category	Hazard statement
2.7	Flammable solid	2	Flam. Sol. 2	H228
3.10	Acute toxicity (oral)	4	Acute Tox. 4	H302
3.1I	Acute toxicity (inhal.)	4	Acute Tox. 4	H332
3.2	Skin corrosion/irritation	2	Skin Irrit. 2	H315
3.3	Serious eye damage/eye irritation	1	Eye Dam. 1	H318

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Paraformaldehyde , extra pure, granulated

article number: 0335

Section	Hazard class	Cat-egory	Hazard class and category	Hazard statement
3.4S	Skin sensitisation	1	Skin Sens. 1	H317
3.5	Germ cell mutagenicity	2	Muta. 2	H341
3.6	Carcinogenicity	1B	Carc. 1B	H350
3.8R	Specific target organ toxicity - single exposure (respiratory tract irritation)	3	STOT SE 3	H335

For full text of abbreviations: see SECTION 16

2.2 Label elements

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

Signal word

Danger

Pictograms

GHS02, GHS05,
GHS07, GHS08



Hazard statements

H228 Flammable solid
H302+H332 Harmful if swallowed or if inhaled
H315 Causes skin irritation
H317 May cause an allergic skin reaction
H318 Causes serious eye damage
H335 May cause respiratory irritation
H341 Suspected of causing genetic defects
H350 May cause cancer

Precautionary statements

Precautionary statements - prevention

P202 Do not handle until all safety precautions have been read and understood
P210 Keep away from heat. No smoking
P270 Do not eat, drink or smoke when using this product
P280 Wear protective gloves/eye protection

Precautionary statements - response

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P308+P313 IF exposed or concerned: Get medical advice/attention

For professional users only

Labelling of packages where the contents do not exceed 125 ml

Signal word: **Danger**

Symbol(s)



Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Paraformaldehyde , extra pure, granulated

article number: **0335**

H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H350	May cause cancer.
P202	Do not handle until all safety precautions have been read and understood.
P280	Wear protective gloves/eye protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313	IF exposed or concerned: Get medical advice/attention.

2.3 Other hazards

This material is combustible, but will not ignite readily.

Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of $\geq 0,1\%$.

SECTION 3: Composition/information on ingredients

3.1 Substances

Name of substance	Paraformaldehyde
Molecular formula	(CH ₂ O) _n
CAS No	30525-89-4
EC No	608-494-5

Impurities/additives/constituents:

Name of substance	Identifier	Wt%
Formaldehyde ... %	CAS No 50-00-0 EC No 200-001-8 Index No 605-001-00-5	0,2 - < 1
Methanol	CAS No 67-56-1 EC No 200-659-6 Index No 603-001-00-X	0,1 - < 1

Substance, Specific Conc. Limits, M-factors, ATE

Specific Conc. Limits	M-Factors	ATE	Exposure route
-	-	800 mg/kg 1,1 mg/l/4h	oral inhalation: dust/ mist

Remarks

For full text of abbreviations: see SECTION 16

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Paraformaldehyde , extra pure, granulated

article number: 0335

SECTION 4: First aid measures

4.1 Description of first aid measures



General notes

Take off contaminated clothing.

Following inhalation

Provide fresh air. In all cases of doubt, or when symptoms persist, seek medical advice.

Following skin contact

After contact with skin, wash immediately with plenty of water. In case of skin reactions, consult a physician. In case of skin irritation, consult a physician.

Following eye contact

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

Following ingestion

Rinse mouth with water (only if the person is conscious). In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

4.2 Most important symptoms and effects, both acute and delayed

Vomiting, Risk of blindness, Risk of serious damage to eyes, Irritation, Allergic reactions, Cough, Dyspnoea

4.3 Indication of any immediate medical attention and special treatment needed

none

SECTION 5: Firefighting measures

5.1 Extinguishing media



Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings!
water, foam, dry extinguishing powder, ABC-powder

Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

Combustible.

Hazardous combustion products

In case of fire may be liberated: Carbon monoxide (CO), Carbon dioxide (CO₂)

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Paraformaldehyde , extra pure, granulated

article number: 0335

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures



For non-emergency personnel

Use personal protective equipment as required. Avoid contact with skin, eyes and clothes. Do not breathe dust.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains. Take up mechanically.

Advice on how to clean up a spill

Take up mechanically. Control of dust.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Provision of sufficient ventilation. Avoid exposure. Avoid dust formation.

Measures to prevent fire as well as aerosol and dust generation



Keep away from sources of ignition - No smoking.

Removal of dust deposits.

Advice on general occupational hygiene

Wash hands before breaks and after work. Keep away from food, drink and animal feedingstuffs. When using do not smoke.

7.2 Conditions for safe storage, including any incompatibilities

Store in a dry place. Keep container tightly closed.

Incompatible substances or mixtures

Observe hints for combined storage.

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Paraformaldehyde , extra pure, granulated

article number: 0335

Consideration of other advice:

Ventilation requirements

Keep any substance that emits harmful vapours or gases in a place that allows these to be permanently extracted. Use local and general ventilation.

Specific designs for storage rooms or vessels

Recommended storage temperature: 4 - 15 °C

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

National limit values

Occupational exposure limit values (Workplace Exposure Limits)

This information is not available.

Relevant DNELs of components						
Name of substance	CAS No	End-point	Threshold level	Protection goal, route of exposure	Used in	Exposure time
Methanol	67-56-1	DNEL	130 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
Methanol	67-56-1	DNEL	130 mg/m ³	human, inhalatory	worker (industry)	acute - systemic effects
Methanol	67-56-1	DNEL	130 mg/m ³	human, inhalatory	worker (industry)	chronic - local effects
Methanol	67-56-1	DNEL	130 mg/m ³	human, inhalatory	worker (industry)	acute - local effects
Methanol	67-56-1	DNEL	20 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
Methanol	67-56-1	DNEL	20 mg/kg bw/day	human, dermal	worker (industry)	acute - systemic effects
Formaldehyde ... %	50-00-0	DNEL	9 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
Formaldehyde ... %	50-00-0	DNEL	0,375 mg/m ³	human, inhalatory	worker (industry)	chronic - local effects
Formaldehyde ... %	50-00-0	DNEL	0,75 mg/m ³	human, inhalatory	worker (industry)	acute - local effects
Formaldehyde ... %	50-00-0	DNEL	240 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
Formaldehyde ... %	50-00-0	DNEL	37 µg/cm ²	human, dermal	worker (industry)	chronic - local effects

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Paraformaldehyde , extra pure, granulated

article number: 0335

Relevant PNECs of components						
Name of substance	CAS No	End-point	Threshold level	Organism	Environmental compartment	Exposure time
Methanol	67-56-1	PNEC	20,8 mg/l	aquatic organisms	freshwater	short-term (single instance)
Methanol	67-56-1	PNEC	2,08 mg/l	aquatic organisms	marine water	short-term (single instance)
Methanol	67-56-1	PNEC	100 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Methanol	67-56-1	PNEC	77 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
Methanol	67-56-1	PNEC	7,7 mg/kg	aquatic organisms	marine sediment	short-term (single instance)
Methanol	67-56-1	PNEC	100 mg/kg	terrestrial organisms	soil	short-term (single instance)
Formaldehyde ... %	50-00-0	PNEC	0,44 mg/l	aquatic organisms	freshwater	short-term (single instance)
Formaldehyde ... %	50-00-0	PNEC	0,44 mg/l	aquatic organisms	marine water	short-term (single instance)
Formaldehyde ... %	50-00-0	PNEC	0,19 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Formaldehyde ... %	50-00-0	PNEC	2,3 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
Formaldehyde ... %	50-00-0	PNEC	2,3 mg/kg	aquatic organisms	marine sediment	short-term (single instance)
Formaldehyde ... %	50-00-0	PNEC	0,2 mg/kg	terrestrial organisms	soil	short-term (single instance)

8.2 Exposure controls

Individual protection measures (personal protective equipment)

Eye/face protection



Use safety goggle with side protection.

Skin protection



Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Paraformaldehyde , extra pure, granulated

article number: 0335

• hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. The times are approximate values from measurements at 22 ° C and permanent contact. Increased temperatures due to heated substances, body heat etc. and a reduction of the effective layer thickness by stretching can lead to a considerable reduction of the breakthrough time. If in doubt, contact manufacturer. At an approx. 1.5 times larger / smaller layer thickness, the respective breakthrough time is doubled / halved. The data apply only to the pure substance. When transferred to substance mixtures, they may only be considered as a guide.

• type of material

NBR (Nitrile rubber)

• material thickness

>0,11 mm

• breakthrough times of the glove material

>480 minutes (permeation: level 6)

• other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended.

Respiratory protection



Respiratory protection necessary at: Dust formation. Particulate filter device (EN 143). P2 (filters at least 94 % of airborne particles, colour code: White).

Environmental exposure controls

Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	solid
Colour	whitish
Odour	like formaldehyde
Melting point/freezing point	120 – 170 °C
Boiling point or initial boiling point and boiling range	not determined
Flammability	flammable solid in accordance with GHS criteria
Lower and upper explosion limit	7 vol% (LEL) - 73 vol% (UEL)
Flash point	70 °C
Auto-ignition temperature	not determined
Decomposition temperature	not relevant
pH (value)	4 – 5,5 (in aqueous solution: 10 ⁻⁹ /l, 20 °C)

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Paraformaldehyde , extra pure, granulated

article number: **0335**

Kinematic viscosity	not relevant
<u>Solubility(ies)</u>	
Water solubility	(poorly soluble)
<u>Partition coefficient</u>	
Partition coefficient n-octanol/water (log value):	this information is not available
Vapour pressure	1,5 – 2 hPa at 20 °C
<u>Density and/or relative density</u>	
Density	1,3 g/cm ³ at 20 °C
Relative vapour density	Information on this property is not available.
Bulk density	600 – 800 kg/m ³
Particle characteristics	No data available.
<u>Other safety parameters</u>	
Oxidising properties	none
9.2 Other information	
Information with regard to physical hazard classes:	There is no additional information.
Other safety characteristics:	
Temperature class (EU, acc. to ATEX)	T2 Maximum permissible surface temperature on the equipment: 300°C

SECTION 10: Stability and reactivity

10.1 Reactivity

It's a reactive substance. Risk of ignition. The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

If heated

Risk of ignition.

10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

10.3 Possibility of hazardous reactions

Violent reaction with: strong oxidiser, Alkalis, Amines, Acids

10.4 Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Paraformaldehyde , extra pure, granulated

article number: 0335

10.5 Incompatible materials

There is no additional information.

10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

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

Classification according to GHS (1272/2008/EC, CLP)

Acute toxicity

Harmful if swallowed. Harmful if inhaled.

Acute toxicity					
Exposure route	Endpoint	Value	Species	Method	Source
oral	LD50	800 mg/kg	rat		TOXNET
inhalation: dust/ mist	LC50	1,1 mg/l/4h	rat		TOXNET

Acute toxicity of components					
Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Methanol	67-56-1	inhalation: va- pour	LC50	131 mg/l/4h	rat
Methanol	67-56-1	oral	LD50	5.628 mg/kg	rat
Methanol	67-56-1	oral	LDLo	143 mg/kg	human
Methanol	67-56-1	dermal	LD50	15.800 mg/kg	rabbit

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/eye irritation

Causes serious eye damage.

Respiratory or skin sensitisation

May cause an allergic skin reaction.

Germ cell mutagenicity

Suspected of causing genetic defects.

Carcinogenicity

May cause cancer.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

May cause respiratory irritation.

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Paraformaldehyde , extra pure, granulated

article number: 0335

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

Symptoms related to the physical, chemical and toxicological characteristics

• If swallowed

vomiting, nausea, gastrointestinal complaints

• If in eyes

Causes serious eye damage, risk of blindness

• If inhaled

Irritation to respiratory tract, cough, Dyspnoea

• If on skin

causes skin irritation, May produce an allergic reaction, pruritis, localised redness

• Other information

none

11.2 Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of $\geq 0,1\%$.

11.3 Information on other hazards

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

Aquatic toxicity (acute)				
Endpoint	Value	Species	Source	Exposure time
LC50	46 mg/l	rainbow trout (Oncorhynchus mykiss)	ECOTOX Database	96 h

Aquatic toxicity (acute) of components					
Name of substance	CAS No	Endpoint	Value	Species	Exposure time
Methanol	67-56-1	LC50	15.400 mg/l	fish	96 h
Methanol	67-56-1	ErC50	22.000 mg/l	algae	96 h
Formaldehyde ... %	50-00-0	LC50	6,7 mg/l	fish	96 h
Formaldehyde ... %	50-00-0	EC50	5,8 mg/l	aquatic invertebrates	48 h
Formaldehyde ... %	50-00-0	ErC50	4,89 mg/l	algae	72 h

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Paraformaldehyde , extra pure, granulated

article number: 0335

Aquatic toxicity (chronic) of components

Name of substance	CAS No	Endpoint	Value	Species	Exposure time
Formaldehyde ... %	50-00-0	EC50	19 mg/l	microorganisms	3 h

12.2 Persistence and degradability

Process of degradability

Process	Degradation rate	Time
biotic/abiotic	97,4 %	5 d

Degradability of components

Name of substance	CAS No	Process	Degradation rate	Time	Method	Source
Methanol	67-56-1	biotic/abiotic	99 %	30 d		
Methanol	67-56-1	oxygen depletion	69 %	5 d		ECHA
Formaldehyde ... %	50-00-0	DOC removal	99 %	28 d		ECHA

12.3 Bioaccumulative potential

Data are not available.

Bioaccumulative potential of components

Name of substance	CAS No	BCF	Log KOW	BOD5/COD
Methanol	67-56-1		-0,77	

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Data are not available.

12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of $\geq 0,1\%$.

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods



This material and its container must be disposed of as hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations.

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Paraformaldehyde , extra pure, granulated

article number: 0335

Sewage disposal-relevant information

Do not empty into drains.

Waste treatment of containers/packagings

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used. Handle contaminated packages in the same way as the substance itself. Completely emptied packages can be recycled.

13.2 Relevant provisions relating to waste

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

Properties of waste which render it hazardous

- HP 3 flammable
- HP 4 irritant - skin irritation and eye damage
- HP 5 specific target organ toxicity (STOT)/aspiration toxicity
- HP 6 acute toxicity
- HP 7 carcinogenic
- HP 11 mutagenic
- HP 13 sensitising

13.3 Remarks

Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities. Please consider the relevant national or regional provisions. Non-contaminated packages may be recycled.

SECTION 14: Transport information

14.1 UN number or ID number

ADR	UN 2213
IMDG-Code	UN 2213
ICAO-TI	UN 2213

14.2 UN proper shipping name

ADR	PARAFORMALDEHYDE
IMDG-Code	PARAFORMALDEHYDE
ICAO-TI	Paraformaldehyde

14.3 Transport hazard class(es)

ADR	4.1
IMDG-Code	4.1
ICAO-TI	4.1

14.4 Packing group

ADR	III
IMDG-Code	III
ICAO-TI	III

14.5 Environmental hazards

non-environmentally hazardous acc. to the dangerous goods regulations

14.6 Special precautions for user

Provisions for dangerous goods (ADR) should be complied within the premises.

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Paraformaldehyde , extra pure, granulated

article number: 0335

14.7 Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

14.8 Information for each of the UN Model Regulations

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) Additional information

Proper shipping name	PARAFORMALDEHYDE
Particulars in the transport document	UN2213, PARAFORMALDEHYDE, 4.1, III, (E)
Classification code	F1
Danger label(s)	4.1



Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 kg
Transport category (TC)	3
Tunnel restriction code (TRC)	E
Hazard identification No	40

International Maritime Dangerous Goods Code (IMDG) - Additional information

Proper shipping name	PARAFORMALDEHYDE
Particulars in the shipper's declaration	UN2213, PARAFORMALDEHYDE, 4.1, III
Marine pollutant	-
Danger label(s)	4.1



Special provisions (SP)	223, 967
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 kg
EmS	F-A, S-G
Stowage category	A

International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information

Proper shipping name	Paraformaldehyde
Particulars in the shipper's declaration	UN2213, Paraformaldehyde, 4.1, III
Danger label(s)	4.1



Special provisions (SP)	A3
Excepted quantities (EQ)	E1

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Paraformaldehyde , extra pure, granulated

article number: 0335

Limited quantities (LQ)

10 kg

SECTION 15: Regulatory information

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

Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

Dangerous substances with restrictions (REACH, Annex XVII)				
Name of substance	Name acc. to inventory	CAS No	Restriction	No
Paraformaldehyde	flammable / pyrophoric		R40	40
Paraformaldehyde	substances in tattoo inks and permanent make-up		R75	75

Legend

- R40
1. Shall not be used, as substance or as mixtures in aerosol dispensers where these aerosol dispensers are intended for supply to the general public for entertainment and decorative purposes such as the following:
 - metallic glitter intended mainly for decoration,
 - artificial snow and frost,
 - 'whoopie' cushions,
 - silly string aerosols,
 - imitation excrement,
 - horns for parties,
 - decorative flakes and foams,
 - artificial cobwebs,
 - stink bombs.
 2. Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances, suppliers shall ensure before the placing on the market that the packaging of aerosol dispensers referred to above is marked visibly, legibly and indelibly with:
'For professional users only'.
 3. By way of derogation, paragraphs 1 and 2 shall not apply to the aerosol dispensers referred to Article 8 (1a) of Council Directive 75/324/EEC (2).
 4. The aerosol dispensers referred to in paragraphs 1 and 2 shall not be placed on the market unless they conform to the requirements indicated.

Paraformaldehyde , extra pure, granulated

article number: **0335**

Legend

- R75
1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:
 - (a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
 - (b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;
 - (c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;
 - (d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:
 - (i) 0,1 % by weight, if the substance is used solely as a pH regulator;
 - (ii) 0,01 % by weight, in all other cases;
 - (e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (*1), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
 - (f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:
 - (i) "Rinse-off products";
 - (ii) "Not to be used in products applied on mucous membranes";
 - (iii) "Not to be used in eye products";
 - (g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column;
 - (h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.
 2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.
 3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.
 4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
 - (a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
 - (b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).
 5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.
 6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.
 7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:
 - (a) the statement "Mixture for use in tattoos or permanent make-up";
 - (b) a reference number to uniquely identify the batch;
 - (c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;
 - (d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;
 - (e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;
 - (f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13;
 - (g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.The information shall be clearly visible, easily legible and marked in a way that is indelible. The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise. Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use. Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph.
 8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for tattooing purposes.

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Paraformaldehyde , extra pure, granulated

article number: 0335

Legend

9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).

10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

List of substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list

Not listed.

Seveso Directive

2012/18/EU (Seveso III)			
No	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the application of lower and upper-tier requirements	Notes
	not assigned		

Deco-Paint Directive

VOC content	0 %
VOC content	0 g/l

Industrial Emissions Directive (IED)

VOC content	100 %
VOC content	1.300 g/l

Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

not listed

Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

not listed

Water Framework Directive (WFD)

List of pollutants (WFD)				
Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Paraformaldehyde	Substances and preparations, or the breakdown products of such, which have been proved to possess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine-related functions in or via the aquatic environment		a)	

Legend

a) Indicative list of the main pollutants

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Paraformaldehyde , extra pure, granulated

article number: 0335

Regulation on the marketing and use of explosives precursors

not listed

Regulation on drug precursors

not listed

Regulation on substances that deplete the ozone layer (ODS)

not listed

Regulation concerning the export and import of hazardous chemicals (PIC)

not listed

Regulation on persistent organic pollutants (POP)

not listed

Other information

Directive 94/33/EC on the protection of young people at work. Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

National inventories

Country	Inventory	Status
AU	AIIC	substance is listed
CA	DSL	substance is listed
CN	IECSC	substance is listed
JP	CSCL-ENCS	substance is listed
KR	KECI	substance is listed
MX	INSQ	substance is listed
NZ	NZIoC	substance is listed
PH	PICCS	substance is listed
TW	TCSI	substance is listed
US	TSCA	substance is listed (ACTIVE)
VN	NCI	substance is listed

Legend

AIIC	Australian Inventory of Industrial Chemicals
CSCL-ENCS	List of Existing and New Chemical Substances (CSCL-ENCS)
DSL	Domestic Substances List (DSL)
IECSC	Inventory of Existing Chemical Substances Produced or Imported in China
INSQ	National Inventory of Chemical Substances
KECI	Korea Existing Chemicals Inventory
NCI	National Chemical Inventory
NZIoC	New Zealand Inventory of Chemicals
PICCS	Philippine Inventory of Chemicals and Chemical Substances (PICCS)
TCSI	Taiwan Chemical Substance Inventory
TSCA	Toxic Substance Control Act

15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance. According to REACH, Article 14 (1) a chemical safety assessment has been carried out for this substance or components of this mixture when the substance has been registered in quantities of 10 tonnes or more per year per registrant.

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Paraformaldehyde , extra pure, granulated

article number: 0335

SECTION 16: Other information

Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)	Safety-relevant
1.1	EC number: 200-001-8	EC number: 608-494-5	yes
2.2		Hazard statements: change in the listing (table)	yes
2.2		Labelling of packages where the contents do not exceed 125 ml: change in the listing (table)	yes
2.3		Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) at a concentration of $\geq 0,1\%$.	yes
15.1	VOC content: 0 % , 0 g/l	VOC content: 0 %	yes
15.1		VOC content: 0 g/l	yes
15.1		National inventories: change in the listing (table)	yes
15.2	Chemical Safety Assessment: No Chemical Safety Assessment has been carried out for this substance.	Chemical safety assessment: No Chemical Safety Assessment has been carried out for this substance. According to REACH, Article 14 (1) a chemical safety assessment has been carried out for this substance or components of this mixture when the substance has been registered in quantities of 10 tonnes or more per year per registrant.	yes

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BOD	Biochemical Oxygen Demand
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
COD	Chemical oxygen demand
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
ED	Endocrine disruptor

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Paraformaldehyde , extra pure, granulated

article number: **0335**

Abbr.	Descriptions of used abbreviations
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air
IMDG	International Maritime Dangerous Goods Code
IMDG-Code	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
LEL	Lower explosion limit (LEL)
log KOW	n-Octanol/water
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SVHC	Substance of Very High Concern
UEL	Upper explosion limit (UEL)
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.
Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Paraformaldehyde , extra pure, granulated

article number: 0335

List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H228	Flammable solid.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H350	May cause cancer.

Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.