

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2015/830/EU



N,N-Dimethylformamide PEPTIPURE® ≥99,8 % for peptide synthesis

article number: **A529**
Version: **2.1 en**
Replaces version of: 2022-05-10
Version: (2)

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Revision: 2022-10-20

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

1.1 Product identifier

Identification of the substance	N,N-Dimethylformamide PEPTIPURE® ≥99,8 % for peptide synthesis
Article number	A529
Registration number (REACH)	01-2119475605-32-xxxx
Index No	616-001-00-X
EC number	200-679-5
CAS number	68-12-2

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

Identified uses: laboratory chemical
laboratory and analytical use

1.3 Details of the supplier of the safety data sheet

Carl Roth GmbH + Co KG
Schoemperlenstr. 3-5
D-76185 Karlsruhe
Germany

Telephone: +49 (0) 721 - 56 06 0
Telefax: +49 (0) 721 - 56 06 149
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

Name	Street	Postal code/city	Telephone	Website
Giftzentrale München	Ismaninger Str. 22	81675 München	+49/(0)89 19240	http://www.toxinfo.med.tum.de/inhalt/giftnotrufmuenchen

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

Classification acc. to GHS			
Section	Hazard class	Hazard class and category	Hazard statement
2.6	flammable liquid	(Flam. Liq. 3)	H226
3.1D	acute toxicity (dermal)	(Acute Tox. 4)	H312

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Classification acc. to GHS			
Section	Hazard class	Hazard class and category	Hazard statement
3.1I	acute toxicity (inhal.)	(Acute Tox. 4)	H332
3.3	serious eye damage/eye irritation	(Eye Irrit. 2)	H319
3.7	reproductive toxicity	(Repr. 1B)	H360D

2.2 Label elements

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

Signal word

Danger

Pictograms

GHS02, GHS07,
GHS08



Hazard statements

H226 Flammable liquid and vapour
H312+H332 Harmful in contact with skin or if inhaled
H319 Causes serious eye irritation
H360D May damage the unborn child

Precautionary statements

Precautionary statements - prevention

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

Precautionary statements - response

P302+P352 IF ON SKIN: Wash with plenty of soap and water.
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)



H360D May damage the unborn child.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P308+P313 IF exposed or concerned: Get medical advice/attention.

2.3 Other hazards

There is no additional information.

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SECTION 3: Composition/information on ingredients

3.1 Substances

Name of substance	N,N-Dimethylformamide
Index No	616-001-00-X
Registration number (REACH)	01-2119475605-32-xxxx
EC number	200-679-5
CAS number	68-12-2
Molecular formula	C ₃ H ₇ NO
Molar mass	73.09 g/mol

Substance of Very High Concern (SVHC)

Name of substance	CAS No	Wt%	Listed in	Remarks
N,N-Dimethylformamide	68-12-2	100	Candidate list	Repr. A57a

Legend

candidate list
Repr. A57a

Substances meeting the criteria referred to in Article 57 and for eventual inclusion in Annex XIV
Toxic for reproduction (article 57c)

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

Rinse skin with water/shower.

Following eye contact

Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart. In case of eye irritation consult an ophthalmologist.

Following ingestion

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

Irritation

4.3 Indication of any immediate medical attention and special treatment needed

none

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SECTION 5: Firefighting measures

5.1 Extinguishing media



Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings
water spray, foam, dry extinguishing powder, carbon dioxide (CO₂)

Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

Combustible. Vapours are heavier than air, spread along floors and form explosive mixtures with air. Vapours can form explosive mixtures with air.

Hazardous combustion products

In case of fire may be liberated: nitrogen oxides (NO_x), carbon monoxide (CO), carbon dioxide (CO₂)

5.3 Advice for firefighters

Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures



For non-emergency personnel

Wearing of suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. Avoid contact with skin, eyes and clothes. Do not breathe vapour/spray. Avoidance of ignition sources.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Explosive properties.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains.

Advice on how to clean up a spill

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

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.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

Provision of sufficient ventilation.

- **Measures to prevent fire as well as aerosol and dust generation**



Keep away from sources of ignition - No smoking.

Take precautionary measures against static discharge.

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

Keep container tightly closed.

Incompatible substances or mixtures

Observe hints for combined storage.

Consideration of other advice

Ground/bond container and receiving equipment.

- **Ventilation requirements**

Use local and general ventilation.

- **Specific designs for storage rooms or vessels**

Recommended storage temperature: 15 – 25 °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)

Country	Name of agent	CAS No	Notation	Identifier	TWA [ppm]	TWA [mg/m ³]	STEL [ppm]	STEL [mg/m ³]	Ceiling-C [ppm]	Ceiling-C [mg/m ³]	Source
DE	N,N-dimethylformamide	68-12-2	H, Z	AGW	5	15	10	30			TRGS 900
EU	N,N-dimethylformamide	68-12-2	H	IOELV	5	15	10	30			2022/431/EU

Notation

Ceiling-C	Ceiling value is a limit value above which exposure should not occur
H	Absorbed through the skin
STEL	Short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)
TWA	Time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average (unless otherwise specified)
Z	A risk of developmental toxicity can not be ruled out even if AGW and BGW are complied with

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Biological limit values

Country	Name of agent	Parameter	Notation	Identifier	Value	Material	Source
DE	N,N-dimethylformamide	N-methylformamide, N-(hydroxymethyl)-N-methylacetamide		BAT	20 mg/l	urine	DFG
DE	N,N-dimethylformamide	N-Methylformamid plus N-Hydroxymethyl-N-methylformamid		BLV	20 mg/l	urine	TRGS 903
DE	N,N-dimethylformamide	N-Acetyl-S-(methylcarbamoyl)-L-cystein	crea	BLV	25 mg/g	urine	TRGS 903
DE	N,N-dimethylformamide	N-acetyl-S-(methylcarbamoyl)-cysteine	crea	BAT	25 mg/g	urine	DFG

Notation

crea Creatinine

Relevant DNELs/DMELs/PNECs and other threshold levels

• human health values

Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time
DNEL	6 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
DNEL	1.1 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects

• environmental values

Endpoint	Threshold level	Environmental compartment	Exposure time
PNEC	44 mg/l	sewage treatment plant (STP)	short-term (single instance)
PNEC	111 mg/kg	freshwater sediment	short-term (single instance)
PNEC	11.1 mg/kg	marine sediment	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



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• 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

Butyl caoutchouc (butyl rubber)

• material thickness

≥0,5 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: Aerosol or mist formation. P2 (filters at least 94 % of airborne particles, colour code: White). Type: A (against organic gases and vapours with a boiling point of > 65 °C, colour code: Brown).

Observe the wear time limits according GefStoffV in combination with the rules for using respiratory protection apparatus (BGR 190).

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

Appearance

Physical state	liquid (fluid)
Colour	colourless
Odour	like: amine
Odour threshold	0.329 ppm

Other physical and chemical parameters

pH (value)	7 (in aqueous solution: 200 g/l, 20 °C)
Melting point/freezing point	-61 °C
Initial boiling point and boiling range	153 °C at 1,013 hPa
Flash point	57.5 °C at 1,013 hPa
Evaporation rate	no data available

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Flammability (solid, gas)	not relevant (fluid)
<u>Explosive limits</u>	
• lower explosion limit (LEL)	2.2 vol% (70 g/m ³)
• upper explosion limit (UEL)	16 vol% (500 g/m ³)
Explosion limits of dust clouds	not relevant
Vapour pressure	3.77 hPa at 20 °C
Density	0.95 g/cm ³ at 20 °C
Vapour density	2.52 (air = 1)
Bulk density	Not applicable
Relative density	this information is not available
<u>Solubility(ies)</u>	
Water solubility	miscible in any proportion
<u>Partition coefficient</u>	
n-octanol/water (log KOW)	-1.01 (TOXNET)
Auto-ignition temperature	435 °C at 1,013 hPa
Decomposition temperature	>350 °C
Viscosity	
• kinematic viscosity	0.8947 mm ² /s at 20 °C
• dynamic viscosity	0.85 mPa s at 20 °C
Explosive properties	Shall not be classified as explosive.
Oxidising properties	none
9.2 Other information	
Refractive index	1.431
Temperature class (EU, acc. to ATEX)	T2 (Maximum permissible surface temperature on the equipment: 300°C)

SECTION 10: Stability and reactivity

10.1 Reactivity

Risk of ignition. In case of warming: Vapours can form explosive mixtures with air.

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

10.4 Conditions to avoid

Keep away from heat. Decomposition takes place from temperatures above: >350 °C.

10.5 Incompatible materials

There is no additional information.

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10.6 Hazardous decomposition products

Hazardous combustion products: see section 5. Release of: Formaldehyde. Ammonia (NH₃).

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Exposure route	Endpoint	Value	Species	Source
oral	LD50	3,010 mg/kg	rat	ECHA
dermal	LD50	>3,160 mg/kg	rat	ECHA

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Causes serious eye irritation.

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Summary of evaluation of the CMR properties

Reproductive toxicity:

May damage the unborn child

• Specific target organ toxicity - single exposure

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

• Specific target organ toxicity - repeated exposure

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

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

Symptoms related to the physical, chemical and toxicological characteristics

• If swallowed

data are not available

• If in eyes

Causes serious eye irritation

• If inhaled

data are not available

• If on skin

data are not available

Other information

None

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SECTION 12: Ecological information

12.1 Toxicity

acc. to 1272/2008/EC: Shall not be classified as hazardous to the aquatic environment.

Aquatic toxicity (acute)

Endpoint	Value	Species	Source	Exposure time
LC50	7,100 mg/l	fish	ECHA	96 h
EC50	13,100 mg/l	aquatic invertebrates	ECHA	48 h
ErC50	>1,000 mg/l	algae	ECHA	72 h

Aquatic toxicity (chronic)

Endpoint	Value	Species	Source	Exposure time
LC50	>102 mg/l	fish	ECHA	21 d
EC50	3,721 mg/l	aquatic invertebrates	ECHA	21 d
NOEC	>102 mg/l	fish	ECHA	21 d
LOEC	3,000 mg/l	aquatic invertebrates	ECHA	21 d

12.2 Process of degradability

Theoretical Oxygen Demand with nitrification: 2.298 mg/mg

Theoretical Oxygen Demand: 1.532 mg/mg

Theoretical Carbon Dioxide: 1.806 mg/mg

Process	Degradation rate	Time
biotic/abiotic	>90 %	28 d
DOC removal	1 %	1 d

12.3 Bioaccumulative potential

Does not significantly accumulate in organisms.

n-octanol/water (log KOW)

-1.01

BCF

0.3 – 1.2 (ECHA)

12.4 Mobility in soil

Data are not available.

Henry's law constant

0.377 Pa m³/mol at 25 °C

12.5 Results of PBT and vPvB assessment

Data are not available.

12.6 Other adverse effects

Hazardous to water. (AwSV)

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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.

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.


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.

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.

SECTION 14: Transport information

14.1	UN number	2265
14.2	UN proper shipping name	N,N-DIMETHYLFORMAMIDE
	Hazardous ingredients	N,N-Dimethylformamide
14.3	Transport hazard class(es)	
	Class	3 (flammable liquids)
14.4	Packing group	III (substance presenting low danger)
14.5	Environmental hazards	none (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.
14.7	Transport in bulk according to Annex II of MARPOL and the IBC Code	
		The cargo is not intended to be carried in bulk.
14.8	Information for each of the UN Model Regulations	
		• Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN)
	UN number	2265
	Proper shipping name	N,N-DIMETHYLFORMAMIDE
	Particulars in the transport document	UN2265, N,N-DIMETHYLFORMAMIDE, 3, III, (D/E)
	Class	3
	Classification code	F1

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Packing group III

Danger label(s) 3



Excepted quantities (EQ) E1

Limited quantities (LQ) 5 L

Transport category (TC) 3

Tunnel restriction code (TRC) D/E

Hazard identification No 30

• International Maritime Dangerous Goods Code (IMDG)

UN number 2265

Proper shipping name N,N-DIMETHYLFORMAMIDE

Particulars in the shipper's declaration UN2265, N,N-DIMETHYLFORMAMIDE, 3, III, 57.5°C c.c.

Class 3

Marine pollutant -

Packing group III

Danger label(s) 3



Special provisions (SP) -

Excepted quantities (EQ) E1

Limited quantities (LQ) 5 L

EmS F-E, S-D

Stowage category A

• International Civil Aviation Organization (ICAO-IATA/DGR)

UN number 2265

Proper shipping name N,N-Dimethylformamide

Particulars in the shipper's declaration UN2265, N,N-Dimethylformamide, 3, III

Class 3

Packing group III

Danger label(s) 3



Excepted quantities (EQ) E1

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Limited quantities (LQ)

10 L

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)

- **Regulation 649/2012/EU concerning the export and import of hazardous chemicals (PIC)**

Not listed.

- **Regulation 1005/2009/EC on substances that deplete the ozone layer (ODS)**

Not listed.

- **Regulation 850/2004/EC on persistent organic pollutants (POP)**

Not listed.

- **Restrictions according to REACH, Annex XVII**

Name of substance	CAS No	Type of registration	Conditions of restriction	No
N,N-Dimethylformamide	68-12-2	2018/1513/EC annex XVII	R72 R72_3000mg	72
N,N-Dimethylformamide	68-12-2	2021/2030/EC annex XVII	R76	76
N,N-Dimethylformamide		1907/2006/EC annex XVII	R3	3
N,N-Dimethylformamide		1907/2006/EC annex XVII	R28-30	30
N,N-Dimethylformamide		1907/2006/EC annex XVII	R40	40
N,N-Dimethylformamide		2020/2081/EC annex XVII	R75	75

Legend

R28-30

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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Legend

- R3
1. Shall not be used in:
 - ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays,
 - tricks and jokes,
 - games for one or more participants, or any article intended to be used as such, even with ornamental aspects,
 2. Articles not complying with paragraph 1 shall not be placed on the market.
 3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they:
 - can be used as fuel in decorative oil lamps for supply to the general public, and
 - present an aspiration hazard and are labelled with H304.
 4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation (CEN).
 5. Without prejudice to the implementation of other Union provisions relating to the classification, labelling and packaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:
 - (a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: "Keep lamps filled with this liquid out of the reach of children"; and, by 1 December 2010, "Just a sip of lamp oil – or even sucking the wick of lamps – may lead to life-threatening lung damage";
 - (b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: "Just a sip of grill lighter fluid may lead to life threatening lung damage";
 - (c) lamps oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010.;
- 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,
 - 'whoopee' 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.
- R72
R72_3000mg
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 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).
Appendix 12 (maximum concentration limits by weight in homogeneous materials): 3000 mg/kg

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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 sensitizer 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

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- for tattooing purposes.
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.
- R76 1. Shall not be placed on the market as a substance on its own, as a constituent of other substances, or in mixtures in a concentration equal to or greater than 0,3 % after 12 December 2023 unless manufacturers, importers and downstream users have included in the relevant chemical safety reports and safety data sheets, Derived No-Effect Levels (DNELs) relating to exposure of workers of 6 mg/m³ for exposure by inhalation and 1,1 mg/kg/day for dermal exposure.
2. Shall not be manufactured, or used, as a substance on its own, as a constituent of other substances, or in mixtures in a concentration equal to or greater than 0,3 % after 12 December 2023 unless manufacturers and downstream users take the appropriate risk management measures and provide the appropriate operational conditions to ensure that exposure of workers is below the DNELs specified in paragraph 1.
3. By way of derogation from paragraphs 1 and 2, the obligations laid down therein shall apply from 12 December 2024 in relation to placing on the market for use, or use, as a solvent in direct or transfer polyurethane coating processes of textiles and paper material or the production of polyurethane membranes, and from 12 December 2025 in relation to placing on the market for use, or use, as a solvent in the dry and wet spinning processes of synthetic fibres.

Name acc. to inventory	CAS No	Wt%	Listed in	Remarks
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		100	a)	

Legend

- A) Indicative list of the main pollutants

• Restrictions according to REACH, Title VIII

None.

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

Substance of Very High Concern (SVHC)			
Name acc. to inventory	CAS No	Listed in	Remarks
N,N-dimethylformamide	68-12-2	Candidate list	Repr. A57a

Legend

- candidate list Substances meeting the criteria referred to in Article 57 and for eventual inclusion in Annex XIV
Repr. A57a Toxic for reproduction (article 57c)

• 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
P5c	flammable liquids (cat. 2, 3)	5,000 50,000	51)

Notation

- 51) Flammable liquids, categories 2 or 3 not covered by P5a and P5b

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• Directive 75/324/EEC relating to aerosol dispensers

Filling batch

Deco-Paint Directive (2004/42/EC)

VOC content	100 % 950 g/l
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Directive on industrial emissions (VOCs, 2010/75/EU)

VOC content	100 %
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VOC content	950 g/l
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Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) - Annex II

not listed

Regulation 166/2006/EC concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

not listed

Directive 2000/60/EC establishing a framework for Community action in the field of water policy (WFD)

Name acc. to inventory	CAS No	Listed in	Remarks
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

Regulation 98/2013/EU on the marketing and use of explosives precursors

not listed

Regulation 111/2005/EC laying down rules for the monitoring of trade between the Community and third countries in drug precursors

not listed

National inventories

Substance is listed in the following national inventories:

Country	National inventories	Status
AU	AIIC	substance is listed
CA	DSL	substance is listed
CN	IECSC	substance is listed
EU	ECSI	substance is listed
EU	REACH Reg.	substance is listed
JP	CSCL-ENCS	substance is listed
KR	KECI	substance is listed
MX	INSQ	substance is listed
NZ	NZIoC	substance is listed

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Country	National inventories	Status
PH	PICCS	substance is listed
TR	CICR	substance is listed
TW	TCSI	substance is listed
US	TSCA	substance is listed

Legend

AIIC	Australian Inventory of Industrial Chemicals
CICR	Chemical Inventory and Control Regulation
CSCL-ENCS	List of Existing and New Chemical Substances (CSCL-ENCS)
DSL	Domestic Substances List (DSL)
EC SI	EC Substance Inventory (EINECS, ELINCS, NLP)
IECSC	Inventory of Existing Chemical Substances Produced or Imported in China
INSQ	National Inventory of Chemical Substances
KECI	Korea Existing Chemicals Inventory
NZIoC	New Zealand Inventory of Chemicals
PICCS	Philippine Inventory of Chemicals and Chemical Substances (PICCS)
REACH Reg.	REACH registered substances
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.

SECTION 16: Other information

Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)	Safety-relevant
8.1		Occupational exposure limit values (Workplace Exposure Limits): change in the listing (table)	yes
8.1		Biological limit values: change in the listing (table)	yes
8.1		• human health values: change in the listing (table)	yes
8.1		• environmental values: change in the listing (table)	yes

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
2022/431/EU	Directive (EU) 2022/431 of the European Parliament and of the Council of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
AGW	workplace exposure limit
AwSV	Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (Ordinance on facilities for handling substances hazardous to water)
BCF	bioconcentration factor
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)

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Abbr.	Descriptions of used abbreviations
Ceiling-C	ceiling value
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
CMR	Carcinogenic, Mutagenic or toxic for Reproduction
DFG	Deutsche Forschungsgemeinschaft MAK-und BAT-Werte-Liste, Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe, Wiley-VCH, Weinheim
DGR	Dangerous Goods Regulations (see IATA/DGR)
DMEL	Derived Minimal Effect Level
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
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
IMDG	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
IOELV	indicative occupational exposure limit value
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
LOEC	Lowest Observed Effect Concentration
MARPOL	International Convention for the Prevention of Pollution from Ships (abbr. of "Marine Pollutant")
NLP	No-Longer Polymer
NOEC	No Observed Effect Concentration
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
ppm	parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
Repr.	reproductive toxicity
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
STEL	short-term exposure limit
SVHC	Substance of Very High Concern
TRGS 900	Arbeitsplatzgrenzwerte (TRGS 900)

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Abbr.	Descriptions of used abbreviations
TRGS 903	Biologische Grenzwerte (TRGS 903)
TWA	time-weighted average
VOC	Volatile Organic Compounds
vPvB	very Persistent and very Bioaccumulative

Key literature references and sources for data

- Regulation (EC) No. 1907/2006 (REACH), amended by 2015/830/EU
- Regulation (EC) No. 1272/2008 (CLP, EU GHS)
- Dangerous Goods Regulations (DGR) for the air transport (IATA)
- International Maritime Dangerous Goods Code (IMDG)

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

Code	Text
H226	flammable liquid and vapour
H312	harmful in contact with skin
H319	causes serious eye irritation
H332	harmful if inhaled
H360D	may damage the unborn child

Disclaimer

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.