Version number: 1.0

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

1.1 **Product identifier** Identification of the substance 2-butoxyethanol **Trade name** 2-butoxyethanol **Product number** 104205 **Registration number (REACH)** 01-2119475108-36-xxxx **EC number** 203-905-0 **Index number in CLP Annex VI** 603-014-00-0 **CAS number** 111-76-2 1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses

Manufacture of substances Formulation [mixing] of preparations and/or repackaging (excluding alloys) Coating Use in cleaning agents

1.3 Details of the supplier of the safety data sheet

Häffner GmbH & Co. KG Friedrichstraße 3 71679 Asperg Germany

Telephone: +49 (0) 7141 67-0 Telefax: +49 (0) 7141 67 232 Website: www.hugohaeffner.com

Name	Street	Postal code/city	Telephone	Telefax
Dr. Wieland GmbH & Co. KG	Am Alten Kraftwerk 9	71672 Marbach	+49 7144 89650	+49 7144 8965499
Häffner Distribution Suisse S.A.	Aarauerstr. 112	5200 Brugg	+41 (0) 56 2651 001	+41 (0) 56 2651 002

e-mail (competent person)

sdb@hugohaeffner.com

1.4 Emergency telephone number

Emergency information service

+49 (0) 7141 67-0 This number is only available during the following office hours: Mon - Thu 07:30 - 16:00 Fri 07:30 - 12:00

Poison centre			
Country	Name	Telephone	
Germany	Giftinformationszentrum Mainz	+49 (0) 6131 - 19240 (Deutsch / Eng- lish)	

As above or nearest toxicological information centre.

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification Section Hazard class and Hazard class Category Hazard statecategory ment 3.10 acute toxicity (oral) 4 Acute Tox. 4 H302 3.1D acute toxicity (dermal) 4 Acute Tox. 4 H312 3.1I acute toxicity (inhal.) 4 Acute Tox. 4 H332 3.2 skin corrosion/irritation 2 Skin Irrit. 2 H315 Eye Irrit. 2 3.3 serious eye damage/eye irritation 2 H319

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

For full text of abbreviations: see SECTION 16

2.2 Label elements

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

Signal word warning

Pictograms

GHS07



Hazard statements

H302+H312+H332	Harmful if swallowed, in contact with skin or if inhaled.
H315	Causes skin irritation.
H319	Causes serious eye irritation.

Precautionary statements

P261	Avoid breathing mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P302+P352	IF ON SKIN: Wash with plenty of soap and 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.
P312	Call a POISON CENTRE/doctor if you feel unwell.

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.

SECTION 3: Composition/information on ingredients

3.1 Substances

Name of substance	2-butoxyethanol
Identifiers	
CAS No	111-76-2
EC No	203-905-0
Index No	603-014-00-0
Molecular formula	C6H14O2
Molar mass	118,2 ^g / _{mol}

concentration limit, M-factor, ATE

ATE	Exposure route
1.414 ^{mg} / _{kg}	oral
1.100 ^{mg} / _{kg}	dermal
11 ^{mg} / _l /4h	inhalation: vapour

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes

Take off immediately all contaminated clothing. Remove affected person from the danger area and lay down. Do not leave affected person unattended. Self-protection of the first aider. In case of unconsciousness place person in the recovery position. Never give anything by mouth.

Following inhalation

Provide fresh air.

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. Mouth to mouth resuscitation should be avoided. Use alternative methods, preferably with oxygen or compressed air driven apparatus.

Get medical advice/attention.

Following skin contact

After contact with skin, take off immediately all contaminated clothing, and wash immediately with plenty of water.

If skin irritation occurs: Get medical advice/attention.

Following eye contact

Rinse cautiously with water for several minutes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Following ingestion

Rinse mouth immediately and drink plenty of water. Do NOT induce vomiting. Call a physician immediately. Water, to which activated charcoal may be added.

Notes for the doctor

None.

4.2 Most important symptoms and effects, both acute and delayed

Following inhalation: Headache. Nausea. Dizziness. Unconsciousness.Following skin contact: Causes skin irritation.Following eye contact: Causes eye irritation.Following ingestion: Irritant effects. Pneumonia.

4.3 Indication of any immediate medical attention and special treatment needed

None.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

water spray, alcohol resistant foam, fire extinguishing powder, carbon dioxide (CO2)

Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

Hazardous decomposition products: Section 10.

Hazardous combustion products

carbon monoxide (CO), carbon dioxide (CO2), peroxides

5.3 Advice for firefighters

Keep containers cool with water spray. In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance. Danger of bursting container.

Special protective equipment for firefighters

wear self-contained breathing apparatus

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove persons to safety. Ventilate affected area. Do not get in eyes, on skin, or on clothing. Do not breathe vapour/spray. 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.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

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 clean up a spill

Collect spillage. Absorbent material (e.g. sand, diatomaceous earth, acid binder, universal binder, sawdust, etc.).

Appropriate containment techniques

Use of adsorbent materials.

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. Do not breathe vapour/spray. Avoid contact with skin and eyes. Do not use for squirting or spraying. Handle and open container with care.

Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Keep away from sources of ignition - No smoking. Take precautionary measures against static discharge.

Specific notes/details

None.

Measures to protect the environment

Avoid release to the environment.

Advice on general occupational hygiene

Do not eat, drink and smoke in work areas. Wash hands after use. Preventive skin protection (barrier creams/ointments) is recommended. Remove contaminated clothing and protective equipment before entering eating areas. Wash contaminated clothing before reuse.

7.2 Conditions for safe storage, including any incompatibilities

Flammability hazards

None.

Incompatible substances or mixtures

Incompatible materials: see section 10. Store away from oxidizing agents. Store away from acids.

Protect against external exposure, such as

heat, contact with air/oxygen

Consideration of other advice

Keep away from food, drink and animal feeding stuffs.

Ventilation requirements

Keep any substance that emits harmful vapours or gases in a place that allows these to be permanently extracted.

Provision of sufficient ventilation.

Specific designs for storage rooms or vessels

Keep container tightly closed and in a well-ventilated place. Keep cool.

Packaging compatibilities

Keep only in original container. Glass packaging. Stainless steel. Nickel. Polyethylene (PE). Polypropylene. Unsuitable materials: Aluminium.

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values (Workplace Exposure Limits)									
Coun- try	Name of agent	CAS No	Identi- fier	TWA [ppm]	TWA [mg/m³]	STEL [ppm]	STEL [mg/m³]	Nota- tion	Source
DE	2-butoxyethanol	111-76-2	AGW	10	49	20	98	Н, Ү	TRGS 900
EU	2-butoxyethanol	111-76-2	IOELV	20	98	50	246	-	2000/39/EC
Notation	Notation								

Н	absorbed through the skin

STEL short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15minute period (unless otherwise specified)

TWAtime-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of
8 hours time-weighted average (unless otherwise specified)

Y a risk of developmental toxicity does not need to be expected if the occupational exposure limit value and the biological limit value (BGW) are adhered to

Biological limit values						
Coun- try	Name of agent	Parameter	Nota- tion	Identifier	Value	Source
DE	2-butoxyethanol	2-butoxyacetic acid	hydr, crea	BAT	150 mg/l	DFG
DE	2-butoxyethanol	2-butoxyacetic acid	hydr, crea	BLV	150 mg/l	TRGS 903

Notation

crea creatinine

hydr hydrolysis

Human health values

Relevant DNE	Relevant DNELs and other threshold levels					
Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time		
DNEL	98 mg/m³	human, inhalatory	worker (industry)	chronic - systemic effects		

Environmental values

Relevant PNECs and other threshold levels				
Endpoint	Threshold level	Environmental compartment		
PNEC	8,8 ^{mg} / _l	freshwater		
PNEC	0,88 ^{mg} / _l	marine water		
PNEC	463 ^{mg} / _l	sewage treatment plant (STP)		
PNEC	34,6 ^{mg} / _{kg}	freshwater sediment		
PNEC	2,33 ^{mg} / _{kg}	soil		
PNEC	3,46 ^{mg} / _{kg}	marine sediment		
	PNEC Oral Secondary Po	oisoning 0,02 g/kg Food		

8.2 Exposure controls

Appropriate engineering controls

General ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection

Wear eye/face protection.

Hand protection

Protective gloves

Material	Material thickness	Breakthrough times of the glove material
IIR: isobutene-isoprene (butyl) rubber	≥ 0,7 mm	>480 minutes (permeation: level 6)
FKM: fluoro-elastomer	≥ 0,4 mm	>480 minutes (permeation: level 6)
NBR: acrylonitrile-butadiene rubber	≥ 0,5 mm	>480 minutes (permeation: level 6)

Unsuitable materials

Material
CR: chloroprene (chlorobutadiene) rubber
PVC: polyvinyl chloride

Wear suitable gloves.

Chemical protection gloves are suitable, which are tested according to EN 374.

Check leak-tightness/impermeability prior to use.

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.

Respiratory protection

In case of inadequate ventilation wear respiratory protection. Type: A (against organic gases and vapours with a boiling point of > 65 °C , colour code: Brown).

Environmental exposure controls

Use appropriate container to avoid environmental contamination. 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	liquid
Colour	colourless
Odour	sweetish characteristic
Odour threshold	0,5 – 2,3 ^{mg} / _{m³}
Melting point/freezing point	-75 °C
Boiling point or initial boiling point and boiling range	~167 – 173 °C
Flammability	this material is combustible, but will not ignite readily
Lower and upper explosion limit	1,1 vol% - 10,6 vol%
Flash point	67 °C (DIN 51758)
Auto-ignition temperature	230 °C
Decomposition temperature	not relevant
pH (value)	not determined
Kinematic viscosity	3,642 ^{mm²} / _s at 20 °C
Dynamic viscosity	3,3 mPa s at 20 °C
Solubility(ies)	
Water solubility	900 ^g / _l at 25 °C
Partition coefficient n-octanol/water (log value)	0,81 (pH value: 7, 25 °C)
Vapour pressure	1,17 hPa at 25 °C
Density and/or relative density	
Density	not determined

	Particle characteristics	not relevant (liquid)
9.2	Other information	
	Information with regard to physical hazard classes	hazard classes acc. to GHS (physical hazards): not relevant
	Other safety characteristics	
	Temperature class (EU, acc. to ATEX)	T3 (maximum permissible surface temperature on the equip- ment: 200°C)

SECTION 10: Stability and reactivity

10.1 Reactivity

This information is not available.

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

In case of insufficient ventilation and/or in use, may form flammable/explosive vapour-air mixture. Dangerous/dangerous reactions with: Oxidiser, Bases: Danger of fire. Air / Oxygen: Peroxides - Development.

10.4 Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Contact with air/oxygen.

10.5 Incompatible materials

bases, oxidisers

10.6 Hazardous decomposition products

Carbon monoxide (CO). Carbon dioxide (CO2).

SECTION 11: Toxicological information

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

If not otherwise specified the classification is based on:

Animal studies; Evidence from any other toxicity tests; Expert judgement (weight of evidence determination).

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

Acute toxicity

Harmful if swallowed. Harmful in contact with skin. Harmful if inhaled.

Exposure route	Endpoint	Value	Species	Method	Source
oral	LD50	1.414 ^{mg} / _{kg}	guinea pig	OECD Guideline 401	ECHA

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/eye irritation

Causes serious eye irritation. (ECHA, OECD Guideline 405)

Respiratory or skin sensitisation Skin sensitisation

Shall not be classified as a skin sensitiser. (ECHA, OECD Guideline 406)

Respiratory sensitisation

Classification could not be established because: Data are lacking, inconclusive, or conclusive but not sufficient for classification.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Classification could not be established because: Data are lacking, inconclusive, or conclusive but not sufficient for classification.

Reproductive toxicity

Classification could not be established because: Data are lacking, inconclusive, or conclusive but not sufficient for classification.

Specific target organ toxicity - single exposure

Classification could not be established because: Data are lacking, inconclusive, or conclusive but not sufficient for classification.

Specific target organ toxicity - repeated exposure

Classification could not be established because: Data are lacking, inconclusive, or conclusive but not sufficient for classification.

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

Symptoms related to the physical, chemical and toxicological characteristics

If inhaled:

narcosis

11.2 Information on other hazards

There is no additional information.

Endocrine disrupting properties

Not listed.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity (acute)

Based on available data, the classification criteria are not met.

Endpoint	Exposure time	Value	Species	Method	Source
LC50	96 h	1.474 ^{mg} / _l	rainbow trout (Onco- rhynchus mykiss)	OECD Guideline 203	ECHA
ErC50	72 h	>1.000 ^{mg} /l	algae (pseudokirch- neriella subcapitata)	OECD Guideline 201	ECHA
EC50	48 h	1.550 ^{mg} /l	daphnia magna	OECD Guideline 202	ECHA
EbC50	72 h	623 ^{mg} / _l	algae (Desmod- esmus subspicatus)	OECD Guideline 201	ECHA

Aquatic toxicity (chronic)

Based on available data, the classification criteria are not met.

Endpoint	Exposure time	Value	Species	Method	Source
EC50	21 d	297 ^{mg} / _l	daphnia magna	OECD Guideline 211	ECHA
NOEC	72 h	62,5 ^{mg} / _l	algae (pseudokirch- neriella subcapitata)	OECD Guideline 201	ECHA
NOEC	21 d	100 ^{mg} / _l	daphnia magna	OECD Guideline 211	ECHA
growth (EbCx) 10%	21 d	134 ^{mg} / _l	daphnia magna	OECD Guideline 211	ECHA
growth (EbCx) 10%	72 h	308 ^{mg} / _l	algae (pseudokirch- neriella subcapitata)	OECD Guideline 201	ECHA
growth rate (ErCx) 10%	72 h	679 ^{mg} / _l	algae (pseudokirch- neriella subcapitata)	OECD Guideline 201	ECHA

12.2 Persistence and degradability

Process of degradability				
Process	Degradation rate	Time	Method	Source
carbon dioxide gener- ation	90,4 %	28 d	OECD Guideline 301 B	ECHA

Biodegradation

The substance is readily biodegradable.

Persistence

No data available.

12.3 Bioaccumulative potential

n-octanol/water (log KOW)

12.4 Mobility in soil

Henry's law constant

0,1621 ^{Pa m³}/_{mol} at 25 °C (ECHA)

0,81 (pH value: 7, 25 °C)

(ECHA)

12.5 Results of PBT and vPvB assessment

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

12.6 Endocrine disrupting properties

Not listed.

12.7 Other adverse effects

Data are not available.

Remarks

Wassergefährdungsklasse, WGK (water hazard class): 1

SECTION 13: Disposal considerations

13.1 Waste treatment methods

This material and its container must be disposed of as hazardous waste.

Sewage disposal-relevant information

Do not empty into drains.

Waste treatment of containers/packagings

Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

Remarks

Please consider the relevant national or regional provisions.

SECTION 14: Transport information			
14.1	UN number or ID number	not assigned	
14.2	UN proper shipping name	-	
14.3	Transport hazard class(es)	-	
14.4	Packing group	-	
14.5	Environmental hazards	-	
14.6	Special precautions for user	-	
14.7	Maritime transport in bulk according to IMO	-	

instruments

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

Name	Name acc. to inventory	CAS No	Restriction
2-butoxyethanol	this product meets the criteria for clas- sification in accordance with Regulation No 1272/2008/EC	-	R3
2-butoxyethanol	substances in tattoo inks and perman- ent make-up	-	R75

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

Legend

black opaque containers not exceeding 1 litre by 1 December 2010.';

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 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";

Legend

(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.

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 or an accessory to a medical device or an accessory to a medical device. (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

Not assigned.

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

Not listed.

Regulation on the marketing and use of explosives 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.

National regulations (Germany)

Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (Ordinance on facilities for handling substances hazardous to water) (AwSV)

Wassergefährdungsklasse, WGK (water hazard class)

Index number

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Technical instructions on air quality control (Germany)

Number	Group of substances	Class	Conc.	Mass flow	Mass con- centration	Nota- tion
5.2.5	organic substances	-	≥25 wt%	0,5 ^{kg} / _h	50 ^{mg} / _{m³}	3)

Notation

3) a total mass flow of 0.50 kg/h or a total mass concentration of 50 mg/m³, each of which to be indicated as total carbon, shall not be exceeded (except organic particulate matter)

Storage of hazardous substances in non-stationary containers (TRGS 510) (Germany)

Storage class (LGK)	
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(combustible liquids)

Other information

Observe employment restrictions for young people according to § 22 JArbSchG. Observe occupational restrictions for mothers acc. to § 11 MuSchG!

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15.2 Chemical Safety Assessment

For this substance a chemical safety assessment has been carried out.

SECTION 16: Other information

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
2000/39/EC	Commission Directive establishing a first list of indicative occupational exposure limit values in imple- mentation of Council Directive 98/24/EC
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de nav- igation 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 con- cerning the International Carriage of Dangerous Goods by Road)

Abbr.	Descriptions of used abbreviations	
AGW	Workplace exposure limit	
ATE	Acute Toxicity Estimate	
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical sub- stances)	
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures	
DFG	Deutsche Forschungsgemeinschaft MAK-und BAT-Werte-Liste, Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe, Wiley-VCH, Weinheim	
DGR	Dangerous Goods Regulations (see IATA/DGR)	
DNEL	Derived No-Effect Level	
EbC50	≡ 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	
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance caus- ing 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)	
EINECS	European Inventory of Existing Commercial Chemical Substances	
ELINCS	European List of Notified Chemical Substances	
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)	
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 Regula- tion (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 dur- ing a specified time interval	
LGK	Lagerklasse (storage class according to TRGS 510, Germany)	
M-factor	Means a multiplying factor. It is applied to the concentration of a substance classified as hazardous to the aquatic environment acute category 1 or chronic category 1, and is used to derive by the sum- mation method the classification of a mixture in which the substance is present	
NLP	No-Longer Polymer	
NOEC	No Observed Effect Concentration	

Abbr.	Descriptions of used abbreviations	
PBT	Persistent, Bioaccumulative and Toxic	
PNEC	Predicted No-Effect Concentration	
ppm	Parts per million	
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals	
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regula- tions concerning the International carriage of Dangerous goods by Rail)	
STEL	Short-term exposure limit	
SVHC	Substance of Very High Concern	
TRGS	Technische Regeln für GefahrStoffe (technical rules for hazardous substances, Germany)	
TRGS 900	Arbeitsplatzgrenzwerte (TRGS 900)	
TRGS 903	Biologische Grenzwerte (TRGS 903)	
TWA	Time-weighted average	
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).

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

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

Code	Text
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.

Responsible for the safety data sheet

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Disclaimer

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