

Mehrzweck-Getriebeöl GL4 80W-140

Version number: 1.0

Date of compilation: 23.08.2023

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Trade name **Mehrzweck-Getriebeöl GL4 80W-140**
Registration number (REACH) Not relevant (mixture)

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

Relevant identified uses Lubricants, greases, release products

1.3 Details of the supplier of the safety data sheet

FRIEDRICH SCHARR KG
Liebknechtstraße 50
70565 Stuttgart
Germany

Telephone: +49 711 7868-0
Telefax: +49 711 7868-489
e-mail: info@scharr.de
Website: www.scharr.de

e-mail (competent person) produktsicherheit@scharr.de

1.4 Emergency telephone number

Poison centre			
Country	Name	Postal code/city	Telephone
Germany	Giftinformation Freiburg	79106 Freiburg im Breisgau	+49 (0)761 19240

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture**

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

Hazard class	Category	Hazard class and category	Hazard statement
hazardous to the aquatic environment - chronic hazard	3	Aquatic Chronic 3	H412

For full text of abbreviations: see SECTION 16.

The most important adverse physicochemical, human health and environmental effects

Spillage and fire water can cause pollution of watercourses.

2.2 Label elements

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

- signal word not required
- pictograms not required
- hazard statements
H412 Harmful to aquatic life with long lasting effects.

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- precautionary statements

P273 Avoid release to the environment.
P501 Dispose of contents/container to industrial combustion plant.

- supplemental hazard information

EUH208 Contains Amines, C12-14-tert-alkyl. May produce an allergic reaction.

2.3 Other hazards

Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance in a concentration of $\geq 0,1\%$.

Endocrine disrupting properties

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

SECTION 3: Composition/information on ingredients

3.1 Substances

Not relevant (mixture)

3.2 Mixtures

Hazardous ingredients

Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms
Amines, C12-14-tert-alkyl	CAS No 68955-53-3 EC No 701-175-2 REACH Reg. No 01-2119456798-18- xxxx	< 1	Acute Tox. 4 / H302 Acute Tox. 3 / H311 Acute Tox. 2 / H330 Skin Corr. 1 / H314 Eye Dam. 1 / H318 Skin Sens. 1 / H317 Aquatic Acute 1 / H400 Aquatic Chronic 1 / H410	
C16-18-(even numbered, saturated and unsaturated)-alkylamines	CAS No 1213789-63-9 EC No 627-034-4 REACH Reg. No 01-2119473797-19- xxxx	< 1	Acute Tox. 4 / H302 Skin Corr. 1B / H314 Eye Dam. 1 / H318 STOT SE 3 / H335 STOT RE 2 / H373 Asp. Tox. 1 / H304 Aquatic Acute 1 / H400 Aquatic Chronic 1 / H410	

Name of substance	Specific Conc. Limits	M-Factors	ATE	Exposure route
Amines, C12-14-tert-alkyl	-	-	>500 mg/kg 251 mg/kg 0,5 mg/l/4h	oral dermal inhalation: vapour
C16-18-(even numbered, saturated and unsaturated)-alkylamines	-	M-factor (acute) = 10 M-factor (chronic) = 10	1.689 mg/kg	oral

For full text of abbreviations: see SECTION 16.

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SECTION 4: First aid measures

4.1 Description of first aid measures

General notes

Do not leave affected person unattended. Remove victim out of the danger area. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice. In case of unconsciousness place person in the recovery position. Never give anything by mouth. Self-protection of the first aider.

Following inhalation

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. Provide fresh air.

Following skin contact

Wash with plenty of soap and water.

Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart.

Following ingestion

Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting. Call a physician immediately.

4.2 Most important symptoms and effects, both acute and delayed

Breathing difficulties. Headache. Vertigo.

4.3 Indication of any immediate medical attention and special treatment needed

Subsequent observance for pneumonia and pulmonary oedema. Supervise the blood circulation.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water spray, BC-powder, Carbon dioxide (CO₂), Sand

Unsuitable extinguishing media

Water jet

5.2 Special hazards arising from the substance or mixture

Danger of bursting container.

Hazardous combustion products

Carbon monoxide (CO), Carbon dioxide (CO₂)

5.3 Advice for firefighters

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.

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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. Avoidance of ignition sources.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases. Provision of sufficient ventilation.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it. If substance has entered a water course or sewer, inform the responsible authority.

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

Wipe up with absorbent material (e.g. cloth, fleece). Collect spillage: sawdust, kieselgur (diatomite), sand, universal binder

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

Recommendations

- measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Use only in well-ventilated areas.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

- Lagerklasse (storage class according to TRGS 510, 10 (combustible liquids) Germany)

7.3 Specific end use(s)

See section 16 for a general overview.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values (Workplace Exposure Limits)
this information is not available

Relevant DNELs of components of the mixture						
Name of sub-stance	CAS No	End-point	Threshold level	Protection goal, route of exposure	Used in	Exposure time
Amines, C12-14-tert-alkyl	68955-53-3	DNEL	12,1 mg/m ³	human, inhalat-ory	worker (industry)	acute - systemic effects
Amines, C12-14-tert-alkyl	68955-53-3	DNEL	12,5 mg/m ³	human, inhalat-ory	worker (industry)	chronic - systemic effects
Amines, C12-14-tert-alkyl	68955-53-3	DNEL	12,1 mg/m ³	human, inhalat-ory	worker (industry)	chronic - local ef-fects
C16-18-(even numbered, satur-ated and unsatur-ated)-alkylamines	1213789-63-9	DNEL	0,38 mg/m ³	human, inhalat-ory	worker (industry)	chronic - systemic effects
C16-18-(even numbered, satur-ated and unsatur-ated)-alkylamines	1213789-63-9	DNEL	1 mg/m ³	human, inhalat-ory	worker (industry)	chronic - local ef-fects
C16-18-(even numbered, satur-ated and unsatur-ated)-alkylamines	1213789-63-9	DNEL	1 mg/m ³	human, inhalat-ory	worker (industry)	acute - local ef-fects

Relevant PNECs of components of the mixture						
Name of sub-stance	CAS No	End-point	Threshold level	Organism	Environmental compartment	Exposure time
Amines, C12-14-tert-alkyl	68955-53-3	PNEC	0,004 mg/l	aquatic organ-isms	water	intermittent re-lease
Amines, C12-14-tert-alkyl	68955-53-3	PNEC	0,001 mg/l	aquatic organ-isms	freshwater	short-term (single instance)
Amines, C12-14-tert-alkyl	68955-53-3	PNEC	0 mg/l	aquatic organ-isms	marine water	short-term (single instance)
Amines, C12-14-tert-alkyl	68955-53-3	PNEC	0,635 mg/l	aquatic organ-isms	sewage treatment plant (STP)	short-term (single instance)
Amines, C12-14-tert-alkyl	68955-53-3	PNEC	2,14 mg/kg	aquatic organ-isms	freshwater sedi-ment	short-term (single instance)
Amines, C12-14-tert-alkyl	68955-53-3	PNEC	0,214 mg/kg	aquatic organ-isms	marine sediment	short-term (single instance)
Amines, C12-14-tert-alkyl	68955-53-3	PNEC	0,428 mg/kg	terrestrial organ-isms	soil	short-term (single instance)

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Relevant PNECs of components of the mixture						
Name of sub-stance	CAS No	End-point	Threshold level	Organism	Environmental compartment	Exposure time
C16-18-(even numbered, saturated and unsaturated)-alkylamines	1213789-63-9	PNEC	0,26 µg/l	aquatic organisms	freshwater	short-term (single instance)
C16-18-(even numbered, saturated and unsaturated)-alkylamines	1213789-63-9	PNEC	0,026 µg/l	aquatic organisms	marine water	short-term (single instance)
C16-18-(even numbered, saturated and unsaturated)-alkylamines	1213789-63-9	PNEC	550 µg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
C16-18-(even numbered, saturated and unsaturated)-alkylamines	1213789-63-9	PNEC	3,76 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
C16-18-(even numbered, saturated and unsaturated)-alkylamines	1213789-63-9	PNEC	0,376 mg/kg	aquatic organisms	marine sediment	short-term (single instance)
C16-18-(even numbered, saturated and unsaturated)-alkylamines	1213789-63-9	PNEC	10 mg/kg	terrestrial organisms	soil	short-term (single instance)

8.2 Exposure controls

Appropriate engineering controls

General ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection

Wear eye/face protection.

Skin protection

- hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. Check leak-tightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well. 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.

- type of material

PE: polyethylene, CR: chloroprene (chlorobutadiene) rubber, IIR: isobutene-isoprene (butyl) rubber

- material thickness > 0,35 mm

- breakthrough times of the glove material 0,4 mm

>120 minutes (permeation: level 4)

- other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

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Respiratory protection

[In case of inadequate ventilation] wear respiratory protection. Combination filtering device (EN 141). 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	yellowish brown
Odour	characteristic
Melting point/freezing point	<-15 °C
Boiling point or initial boiling point and boiling range	not determined
Evaporation rate	not determined
Flammability	this material is combustible, but will not ignite readily
Lower and upper explosion limit	0,6 vol% - 6,5 vol%
Flash point	>200 °C
Auto-ignition temperature	not determined
pH (value)	not determined
Kinematic viscosity	15 mm ² /s at 100 °C
Solubility(ies)	not determined

Partition coefficient

Partition coefficient n-octanol/water (log value)	this information is not available
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Vapour pressure	not determined
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Density and/or relative density

Density	0,888 g/cm ³ at 15 °C
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Particle characteristics	not relevant (liquid)
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9.2 Other information

Information with regard to physical hazard classes	hazard classes acc. to GHS (physical hazards): not relevant
Other safety characteristics	there is no additional information

SECTION 10: Stability and reactivity

10.1 Reactivity

Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials".

10.2 Chemical stability

See below "Conditions to avoid".

10.3 Possibility of hazardous reactions

In case of insufficient ventilation and/or in use, may form flammable/explosive vapour-air mixture.

10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

10.5 Incompatible materials

Oxidisers

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

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

Test data are not available for the complete mixture.

Classification procedure

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

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

Acute toxicity

Shall not be classified as acutely toxic.

Acute toxicity estimate (ATE) of components of the mixture			
Name of substance	CAS No	Exposure route	ATE
Amines, C12-14-tert-alkyl	68955-53-3	oral	>500 mg/kg
Amines, C12-14-tert-alkyl	68955-53-3	dermal	251 mg/kg
Amines, C12-14-tert-alkyl	68955-53-3	inhalation: vapour	0,5 mg/l/4h
C16-18-(even numbered, saturated and unsaturated)-alkylamines	1213789-63-9	oral	1.689 mg/kg

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Acute toxicity of components of the mixture					
Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Amines, C12-14-tert-alkyl	68955-53-3	oral	LD50	>500 mg/kg	rat
Amines, C12-14-tert-alkyl	68955-53-3	dermal	LD50	251 mg/kg	rat
C16-18-(even numbered, saturated and unsaturated)-alkylamines	1213789-63-9	oral	LD50	1.689 mg/kg	rat
C16-18-(even numbered, saturated and unsaturated)-alkylamines	1213789-63-9	dermal	LD50	>2.000 mg/kg	rat

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

Respiratory or skin sensitisation

Contains Amines, C12-14-tert-alkyl. May produce an allergic reaction.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

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.

11.2 Information on other hazards

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Acc. to 1272/2008/EC: Harmful to aquatic life with long lasting effects.
Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (Ordinance on facilities for handling substances hazardous to water) (AwSV): WGK 2, obviously hazardous to water (Germany)

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Aquatic toxicity (acute) of components of the mixture

Name of substance	CAS No	Endpoint	Value	Species	Exposure time
Amines, C12-14-tert-alkyl	68955-53-3	LC50	1,3 mg/l	fish	96 h
Amines, C12-14-tert-alkyl	68955-53-3	EC50	≤6 mg/l	aquatic invertebrates	48 h
Amines, C12-14-tert-alkyl	68955-53-3	ErC50	0,44 mg/l	algae	72 h
C16-18-(even numbered, saturated and unsaturated)-alkylamines	1213789-63-9	LC50	0,84 mg/l	fish	96 h
C16-18-(even numbered, saturated and unsaturated)-alkylamines	1213789-63-9	EC50	0,32 mg/l	aquatic invertebrates	48 h
C16-18-(even numbered, saturated and unsaturated)-alkylamines	1213789-63-9	ErC50	0,39 mg/l	algae	72 h

Aquatic toxicity (chronic) of components of the mixture

Name of substance	CAS No	Endpoint	Value	Species	Exposure time
Amines, C12-14-tert-alkyl	68955-53-3	EC50	63,5 mg/l	microorganisms	30 min
C16-18-(even numbered, saturated and unsaturated)-alkylamines	1213789-63-9	EC50	0,24 mg/l	aquatic invertebrates	21 d

12.2 Persistence and degradability

Biodegradation

Data are not available.

Degradability of components of the mixture

Name of substance	CAS No	Process	Degradation rate	Time	Method	Source
Amines, C12-14-tert-alkyl	68955-53-3	oxygen depletion	22 %	28 d		ECHA
C16-18-(even numbered, saturated and unsaturated)-alkylamines	1213789-63-9	carbon dioxide generation	18 %	6 d		ECHA

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Degradability of components of the mixture

Name of substance	CAS No	Process	Degradation rate	Time	Method	Source
C16-18-(even numbered, saturated and unsaturated)-alkylamines	1213789-63-9	oxygen depletion	34 %	5 d		ECHA

12.3 Bioaccumulative potential

Data are not available.

Bioaccumulative potential of components of the mixture

Name of substance	CAS No	BCF	Log KOW	BOD5/COD
Amines, C12-14-tert-alkyl	68955-53-3		2,9 (pH value: ~7, 23 °C)	

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB. Does not contain a PBT-/vPvB-substance in a concentration of $\geq 0,1\%$.

12.6 Endocrine disrupting properties

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

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packagings

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

Relevant provisions relating to waste

Mineral-based non-chlorinated engine, gear and lubricating oils 13 02 05*

Remarks

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

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SECTION 14: Transport information

- 14.1 UN number or ID number** not subject to transport regulations
- 14.2 UN proper shipping name** not relevant
- 14.3 Transport hazard class(es)** none
- 14.4 Packing group** not assigned
- 14.5 Environmental hazards** non-environmentally hazardous acc. to the dangerous goods regulations
- 14.6 Special precautions for user**
There is no additional information.
- 14.7 Maritime transport in bulk according to IMO instruments**
The cargo is not intended to be carried in bulk.

Information for each of the UN Model Regulations

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - additional information

Not subject to ADR, RID and ADN.

International Maritime Dangerous Goods Code (IMDG) - additional information

Not subject to IMDG.

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

Not subject to ICAO-IATA.

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
Mehrzweck-Getriebeöl GL4 80W-140	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC		R3	3
Amines, C12-14-tert-alkyl	substances in tattoo inks and permanent make-up		R75	75
C16-18-(even numbered, saturated and unsaturated)-alkylamines	substances in tattoo inks and permanent make-up		R75	75

Legend

- R3**
- 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,
 - Articles not complying with paragraph 1 shall not be placed on the market.
 - 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.

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Legend

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.;

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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 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 proced-

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ure 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, 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

none of the ingredients are 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		

Industrial Emissions Directive (IED)

VOC content	0,3526 %
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Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

none of the ingredients are listed

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

none of the ingredients are listed

Regulation on persistent organic pollutants (POP)

none of the ingredients are listed

National regulations (Austria)

Ordinance on combustible liquids (VbF) not applicable (mass fraction of liquids with a flash point of more than 100° C or of solids is higher than 30 %)

National regulations (Germany)

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

Wassergefährdungsklasse, WGK 2 obviously hazardous to water
(water hazard class)

National regulations Switzerland

Ordinance on the incentive tax on volatile organic compounds (VOCV)

The product is exempt from the tax. Product in which the VOC content does not exceed 3 per cent (% by weight).

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National inventories

Country	Inventory	Status
AU	AIIC	not all ingredients are listed
CA	DSL	not all ingredients are listed
CN	IECSC	not all ingredients are listed
EU	ECSI	not all ingredients are listed
EU	REACH Reg.	not all ingredients are listed
JP	CSCL-ENCS	not all ingredients are listed
KR	KECI	not all ingredients are listed
MX	INSQ	not all ingredients are listed
NZ	NZIoC	not all ingredients are listed
PH	PICCS	not all ingredients are listed
TR	CICR	not all ingredients are listed
TW	TCSI	not all ingredients are listed
US	TSCA	not all ingredients are 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)
ECSI	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

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
Acute Tox.	Acute toxicity
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)
Aquatic Acute	Hazardous to the aquatic environment - acute hazard
Aquatic Chronic	Hazardous to the aquatic environment - chronic hazard

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Abbr.	Descriptions of used abbreviations
Asp. Tox.	Aspiration hazard
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)
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
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye
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
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
log KOW	n-Octanol/water
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 summation method the classification of a mixture in which the substance is present
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals

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Abbr.	Descriptions of used abbreviations
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
Skin Sens.	Skin sensitisation
STOT RE	Specific target organ toxicity - repeated exposure
STOT SE	Specific target organ toxicity - single exposure
SVHC	Substance of Very High Concern
TRGS	Technische Regeln für Gefahrstoffe (technical rules for hazardous substances, Germany)
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.

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).

Classification procedure

Physical and chemical properties: The classification is based on tested mixture.

Health hazards, Environmental hazards: The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

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

Code	Text
H302	Harmful if swallowed.
H304	May be fatal if swallowed and enters airways.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H335	May cause respiratory irritation.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

Disclaimer

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