Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH)

n-Alkane standard solution (C10-C40, all even) 16 components (each 50 mg/l) in n-hexane

article number: **1772**
Version: **1.0 en**

date of compilation: 2022-04-13

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

1.1 Product identifier

Identification of the substance	**n-Alkane standard solution (C10-C40, all even)** 16 components (each 50 mg/l) in n-hexane
Article number	1772
Registration number (REACH)	not relevant (mixture)
Alternative name(s)	n-Hexane

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

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

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
National Poisons Information Service City Hospital	Dudley Rd	B187QH Birmingham	844 892 0111	

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

Section	Hazard class	Cat-egory	Hazard class and category	Hazard statement
2.6	Flammable liquid	2	Flam. Liq. 2	H225
3.2	Skin corrosion/irritation	2	Skin Irrit. 2	H315
3.7	Reproductive toxicity	2	Repr. 2	H361f
3.8D	Specific target organ toxicity - single exposure (narcotic effects, drowsiness)	3	STOT SE 3	H336
3.9	Specific target organ toxicity - repeated exposure	2	STOT RE 2	H373
3.10	Aspiration hazard	1	Asp. Tox. 1	H304
4.1C	Hazardous to the aquatic environment - chronic hazard	2	Aquatic Chronic 2	H411

For full text of abbreviations: see SECTION 16

The most important adverse physicochemical, human health and environmental effects

Delayed or immediate effects can be expected after short or long-term exposure. The product is combustible and can be ignited by potential ignition sources. Spillage and fire water can cause pollution of watercourses.

2.2 Label elements

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

Signal word **Danger**

Pictograms

GHS02, GHS07, GHS08, GHS09

Hazard statements

H225	Highly flammable liquid and vapour
H304	May be fatal if swallowed and enters airways
H315	Causes skin irritation
H336	May cause drowsiness or dizziness
H361f	Suspected of damaging fertility
H373	May cause damage to organs (nervous system) through prolonged or repeated exposure (if inhaled)
H411	Toxic to aquatic life with long lasting effects

Precautionary statements

Precautionary statements - prevention

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking
P280	Wear protective gloves/eye protection

Precautionary statements - response

P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor
P308+P313	IF exposed or concerned: Get medical advice/attention

For professional users only

Hazardous ingredients for labelling: n-Hexane, n-Tetradecane, Hexadecane

Labelling of packages where the contents do not exceed 125 ml

Signal word: **Danger**

Symbol(s)

H304	May be fatal if swallowed and enters airways.
H361f	Suspected of damaging fertility.
P280	Wear protective gloves/eye protection.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P308+P313	IF exposed or concerned: Get medical advice/attention.
contains:	n-Hexane, n-Tetradecane, Hexadecane

2.3 Other hazards

Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

SECTION 3: Composition/information on ingredients

3.1 Substances

not relevant (mixture)

3.2 Mixtures

Description of the mixture

Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
n-Hexane	CAS No 110-54-3 EC No 203-777-6 Index No 601-037-00-0	100	Flam. Liq. 2 / H225 Skin Irrit. 2 / H315 Repr. 2 / H361f STOT SE 3 / H336 STOT RE 2 / H373 Asp. Tox. 1 / H304 Aquatic Chronic 2 / H411		GHS-HC IOELV

Notes

GHS-HC: Harmonised classification (the classification of the substance corresponds to the entry in the list according to 1272/2008/EC, Annex VI)
IOELV: Substance with a community indicative occupational exposure limit value

Name of substance	Identifier	Specific Conc. Limits	M-Factors	ATE	Exposure route
n-Hexane	CAS No 110-54-3 EC No 203-777-6 Index No 601-037-00-0	STOT RE 2; H373: C ≥ 5 %	-	-	

For full text of abbreviations: see SECTION 16

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. In case of skin irritation, consult a physician.

Following eye contact

Rinse cautiously with water for several minutes. In all cases of doubt, or when symptoms persist, seek medical advice.

Following ingestion

Call a physician immediately. In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Observe aspiration hazard if vomiting occurs.

4.2 Most important symptoms and effects, both acute and delayed

Aspiration hazard, Irritation, Dizziness, Drowsiness, Narcosis

4.3 Indication of any immediate medical attention and special treatment needed

none

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings
water spray, dry extinguishing powder, BC-powder, carbon dioxide (CO_2)

Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

Combustible. In case of insufficient ventilation and/or in use, may form flammable/explosive vapour-air mixture. Solvent vapours are heavier than air and may spread along floors. Places which are not ventilated, e.g. unventilated below ground level areas such as trenches, conduits and shafts, are particularly prone to the presence of flammable substances or mixtures. Vapours are heavier than air, spread along floors and form explosive mixtures with air. Vapours may form explosive mixtures with air.

Hazardous combustion products

In case of fire may be liberated: Carbon monoxide (CO), Carbon dioxide (CO_2), May produce toxic fumes of carbon monoxide if burning.

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Do not allow firefighting water to enter drains or water courses. 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

Use personal protective equipment as required. 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. Retain contaminated washing water and dispose of it. Danger of explosion.

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.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Provision of sufficient ventilation. Avoid exposure.

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. Due to danger of explosion, prevent leakage

of vapours into cellars, flues and ditches.

Measures to protect the environment

Avoid release to the environment.

Advice on general occupational hygiene

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

7.2 Conditions for safe storage, including any incompatibilities

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

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: 2 – 8 °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	Identifier	TWA [ppm]	TWA [mg/m³]	STEL [ppm]	STEL [mg/m³]	Ceiling-C [ppm]	Ceiling-C [mg/m³]	Notation	Source
EU	n-hexane	110-54-3	IOELV	20	72						2006/15/EC
GB	n-hexane	110-54-3	WEL	20	72						EH40/2005

Notation

Ceiling-C	Ceiling value is a limit value above which exposure should not occur
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)

Human health values

Relevant DNELs and other threshold levels				
Endpoint	**Threshold level**	**Protection goal, route of exposure**	**Used in**	**Exposure time**
DNEL	75 mg/m³	human, inhalatory	worker (industry)	chronic - systemic effects
DNEL	11 mg/kg bw/ day	human, dermal	worker (industry)	chronic - systemic effects

Relevant DNELs of components of the mixture						
Name of sub-stance	**CAS No**	**End-point**	**Threshol d level**	**Protection goal, route of exposure**	**Used in**	**Exposure time**
n-Hexane	110-54-3	DNEL	75 mg/m³	human, inhalat-ory	worker (industry)	chronic - systemic effects
n-Hexane	110-54-3	DNEL	11 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects

8.2 Exposure controls

Individual protection measures (personal protective equipment)

Eye/face protection

Use safety goggle with side protection.

Skin protection

• 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 consider-able reduction of the breakthrough time. If in doubt, contact manufacturer. At an approx. 1.5 times larger / smaller layer thickness, the respective breakthrough time is doubled / halved. The data apply only to the pure substance. When transferred to substance mixtures, they may only be considered as a guide.

• type of material

NBR (Nitrile rubber)

• material thickness

≥0,4 mm

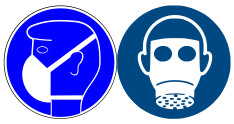
• breakthrough times of the glove material

>480 minutes (permeation: level 6)

• other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended.
Flame-retardant protective clothing.

Respiratory protection



Respiratory protection necessary at: Aerosol or mist formation. Type: A (against organic gases and vapours with a boiling point of > 65 °C , colour code: Brown).

Environmental exposure controls

Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	liquid
Colour	colourless
Odour	like: - Gasoline
Melting point/freezing point	-95,35 °C at 101,3 kPa (ECHA)
Boiling point or initial boiling point and boiling range	68,73 °C at 101,3 kPa (ECHA)
Flammability	flammable liquid in accordance with GHS criteria
Lower and upper explosion limit	42 g/m³ (LEL) - 295 g/m³ (UEL) / 1,1 vol% (LEL) - 7,5 vol% (UEL)
Flash point	-22 °C at 101,3 kPa (ECHA)
Auto-ignition temperature	225 °C at 101,3 kPa (ECHA) (auto-ignition temperature (liquids and gases))
Decomposition temperature	not relevant
pH (value)	not determined
Kinematic viscosity	0,5 $^{mm^2}/_{s}$ at 20 °C
Dynamic viscosity	0,3 mPa s at 25 °C
Solubility(ies)	
Water solubility	0,01 $^{g}/_{l}$ at 25 °C (ECHA)
Partition coefficient	
Partition coefficient n-octanol/water (log value):	4 (pH value: 7, 20 °C) (ECHA)
Soil organic carbon/water (log KOC)	3,34 (ECHA)
Vapour pressure	10 kPa at 9,8 °C

Density and/or relative density	
Density	0,661 $^{g}/_{cm^3}$ at 25 °C (ECHA)
Relative vapour density	2,79 (air = 1)
Particle characteristics	not relevant (liquid)
Other safety parameters	
Oxidising properties	none

9.2 Other information

Information with regard to physical hazard classes:	There is no additional information.
Other safety characteristics:	
Temperature class (EU, acc. to ATEX)	T3 Maximum permissible surface temperature on the equipment: 200°C

SECTION 10: Stability and reactivity

10.1 Reactivity

The mixture contains reactive substance(s). Risk of ignition. Vapours may form explosive mixtures with air.

If heated

Risk of ignition.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

Violent reaction with: strong oxidiser, Chlorine, Iodine, Peroxides, Nitrogen oxides (NOx),
=> Explosive properties

10.4 Conditions to avoid

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

10.5 Incompatible materials

Rubber articles, different plastics

10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

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

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

Exposure route	Endpoint	Value	Species	Method	Source
inhalation: vapour	LC50	172 $^{mg}/_{l}$/4h	rat		RTECS
oral	LD50	25.000 $^{mg}/_{kg}$	rat		RTECS
dermal	LD50	>2.000 $^{mg}/_{kg}$	rabbit		

Acute toxicity of components of the mixture

Name of substance	CAS No	Exposure route	Endpoint	Value	Species
n-Hexane	110-54-3	inhalation: vapour	LC50	185 $^{mg}/_{l}$/4h	rat
n-Hexane	110-54-3	oral	LD50	25.000 $^{mg}/_{kg}$	rat
n-Hexane	110-54-3	dermal	LD50	>2.000 $^{mg}/_{kg}$	rabbit

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/eye irritation

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

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

Suspected of damaging fertility.

Specific target organ toxicity - single exposure

May cause drowsiness or dizziness.

Specific target organ toxicity - repeated exposure

May cause damage to organs (nervous system) through prolonged or repeated exposure (if inhaled).

Hazard category	Target organ	Exposure route
2	nervous system	if inhaled

Aspiration hazard

May be fatal if swallowed and enters airways.

Symptoms related to the physical, chemical and toxicological characteristics

• If swallowed

nausea, vomiting, aspiration hazard

• If in eyes

slightly irritant but not relevant for classification

• If inhaled

irritant effects, headache, vertigo, fatigue, dizziness, narcosis

• If on skin

causes skin irritation

• Other information

none

11.2 Endocrine disrupting properties

None of the ingredients are listed.

11.3 Information on other hazards

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Toxic to aquatic life with long lasting effects.

Aquatic toxicity (acute)

Endpoint	Value	Species	Source	Exposure time
EC50	2,1 $^{mg}/_{l}$	daphnia magna		48 h
LC50	2,5 $^{mg}/_{l}$	Pimephales promelas		96 h
LL50	12,51 $^{mg}/_{l}$	fish	ECHA	96 h
EL50	21,85 $^{mg}/_{l}$	aquatic invertebrates	ECHA	48 h

Aquatic toxicity (acute) of components of the mixture

Name of sub-stance	CAS No	Endpoint	Value	Species	Exposure time
n-Hexane	110-54-3	LL50	12,51 $^{mg}/_{l}$	fish	96 h
n-Hexane	110-54-3	EL50	21,85 $^{mg}/_{l}$	aquatic invertebrates	48 h

Biodegradation

The relevant substances of the mixture are readily biodegradable.

12.2 Process of degradability

Theoretical Oxygen Demand: 3,52 $^{g}/_{g}$

Process of degradability		
Process	**Degradation rate**	**Time**
oxygen depletion	83 %	10 d

Degradability of components of the mixture						
Name of substance	**CAS No**	**Process**	**Degradation rate**	**Time**	**Method**	**Source**
n-Hexane	110-54-3	oxygen depletion	83 %	10 d		ECHA

12.3 Bioaccumulative potential

Does not significantly accumulate in organisms.

Bioaccumulative potential of components of the mixture				
Name of substance	**CAS No**	**BCF**	**Log KOW**	**BOD5/COD**
n-Hexane	110-54-3	501,2	4 (pH value: 7, 20 °C)	

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Data are not available.

12.6 Endocrine disrupting properties

None of the ingredients are listed.

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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

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

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. Waste catalogue ordinance (Germany).

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 or ID number

ADRRID	UN 1208
IMDG-Code	UN 1208
ICAO-TI	UN 1208

14.2 UN proper shipping name

ADRRID	HEXANES
IMDG-Code	HEXANES
ICAO-TI	Hexanes

14.3 Transport hazard class(es)

ADRRID	3
IMDG-Code	3
ICAO-TI	3

14.4 Packing group

ADRRID	II
IMDG-Code	II
ICAO-TI	II

14.5 Environmental hazards

hazardous to the aquatic environment

Environmentally hazardous substance (aquatic environment):	n-Hexane

14.6 Special precautions for user

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

14.7 Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

14.8 Information for each of the UN Model Regulations

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

Proper shipping name	HEXANES
Particulars in the transport document	UN1208, HEXANES, 3, II, (D/E), environmentally hazardous
Classification code	F1

Danger label(s)	3, "Fish and tree"

Environmental hazards	yes (hazardous to the aquatic environment)
Excepted quantities (EQ)	E2
Limited quantities (LQ)	1 L
Transport category (TC)	2
Tunnel restriction code (TRC)	D/E
Hazard identification No	33
Emergency Action Code	3YE

Regulations concerning the International Carriage of Dangerous Goods by Rail (RID)Additional information

Classification code	3
Danger label(s)	3 Fish and tree

Environmental hazards	Yes Hazardous to water
Excepted quantities (EQ)	E2
Limited quantities (LQ)	1 L
Transport category (TC)	2
Hazard identification No	33

International Maritime Dangerous Goods Code (IMDG) - Additional information

Proper shipping name	HEXANES
Particulars in the shipper's declaration	UN1208, HEXANES, 3, II, -22°C c.c., MARINE POL-LUTANT
Marine pollutant	yes (P) (hazardous to the aquatic environment)
Danger label(s)	3, "Fish and tree"

Special provisions (SP)	-
Excepted quantities (EQ)	E2
Limited quantities (LQ)	1 L
EmS	F-E, S-D
Stowage category	E

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

Proper shipping name	Hexanes
Particulars in the shipper's declaration	UN1208, Hexanes, 3, II
Environmental hazards	yes (hazardous to the aquatic environment)
Danger label(s)	3

Excepted quantities (EQ)	E2
Limited quantities (LQ)	1 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)

Restrictions according to REACH, Annex XVII

Dangerous substances with restrictions (REACH, Annex XVII)

Name of substance	Name acc. to inventory	CAS No	Restriction	No
n-Alkane standard solution (C10-C40, all even)	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC		R3	3
n-Hexane	flammable / pyrophoric		R40	40
n-Hexane	substances in tattoo inks and permanent make-up		R75	75

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.’;

Legend

R40 1. Shall not be used, as substance or as mixtures in aerosol dispensers where these aerosol dispensers are intended for supply to the general public for entertainment and decorative purposes such as the following:
- metallic glitter intended mainly for decoration,
- artificial snow and frost,
- '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.

Legend

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

Legend

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
E2	environmental hazards (hazardous to the aquatic environment, cat. 2)	200	500	57)

Notation

57) Hazardous to the Aquatic Environment in category Chronic 2

Deco-Paint Directive

VOC content	100 % 661 $^{g}/_{l}$

Industrial Emissions Directive (IED)

VOC content	100 %
VOC content	661 $^{g}/_{l}$

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

Water Framework Directive (WFD)

List of pollutants (WFD)

Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
n-Hexane	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 on the marketing and use of explosives precursors
none of the ingredients are listed

Regulation on drug precursors
none of the ingredients are listed

Regulation on substances that deplete the ozone layer (ODS)
none of the ingredients are listed

Regulation concerning the export and import of hazardous chemicals (PIC)
none of the ingredients are listed

Regulation on persistent organic pollutants (POP)
none of the ingredients are listed

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

National inventories

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

Legend

AICS	Australian Inventory of Chemical Substances
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
ISHA-ENCS	Inventory of Existing and New Chemical Substances (ISHA-ENCS)
KECI	Korea Existing Chemicals Inventory
NDSL	Non-domestic Substances List (NDSL)

Legend

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
2006/15/EC	Commission Directive establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC
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 Chronic	Hazardous to the aquatic environment - chronic hazard
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)
Ceiling-C	Ceiling value
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)
EH40/2005	EH40/2005 Workplace exposure limits (http://www.nationalarchives.gov.uk/doc/open-government-licence/)
EINECS	European Inventory of Existing Commercial Chemical Substances
EL50	Effective Loading 50 %: the EL50 corresponds to the loading rate required to produce a response in 50% of the test organisms
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
Flam. Liq.	Flammable liquid

Abbr.	Descriptions of used abbreviations
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air
IMDG	International Maritime Dangerous Goods Code
IMDG-Code	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
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
LEL	Lower explosion limit (LEL)
LL50	Lethal Loading 50 %: the LL50 corresponds to the loading rate causing 50 % lethality
log KOW	n-Octanol/water
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
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)
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
STEL	Short-term exposure limit
STOT RE	Specific target organ toxicity - repeated exposure
STOT SE	Specific target organ toxicity - single exposure
SVHC	Substance of Very High Concern
TWA	Time-weighted average
UEL	Upper explosion limit (UEL)
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative
WEL	Workplace exposure limit

Key literature references and sources for data

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

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). 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
H225	Highly flammable liquid and vapour.
H304	May be fatal if swallowed and enters airways.
H315	Causes skin irritation.
H336	May cause drowsiness or dizziness.
H361f	Suspected of damaging fertility.
H373	May cause damage to organs (nervous system) through prolonged or repeated exposure (if inhaled).
H411	Toxic 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.