Safety data sheet

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

ROTIPHORESE®NF-Acrylamide/Bis-solution 40 % (29:1), ready-to-use, gas-stabilized, fluorescence-free

article number: **A121**
Version: **3.1 en**
Replaces version of: 10.06.2022
Version: (3)

date of compilation: 19.11.2015
Revision: 18.07.2022

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

1.1 Product identifier

Identification of the substance	**ROTIPHORESE®NF-Acrylamide/Bis-solution 40 %** (29:1), ready-to-use, gas-stabilized, fluorescence-free
Article number	A121
Registration number (REACH)	not relevant (mixture)

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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

Section	Hazard class	Category	Hazard class and category	Hazard statement
3.1O	Acute toxicity (oral)	3	Acute Tox. 3	H301
3.1I	Acute toxicity (inhal.)	4	Acute Tox. 4	H332
3.2	Skin corrosion/irritation	2	Skin Irrit. 2	H315
3.3	Serious eye damage/eye irritation	2	Eye Irrit. 2	H319
3.4S	Skin sensitisation	1	Skin Sens. 1	H317
3.5	Germ cell mutagenicity	1B	Muta. 1B	H340

Section	Hazard class	Cat-egory	Hazard class and category	Hazard statement
3.6	Carcinogenicity	1B	Carc. 1B	H350
3.7	Reproductive toxicity	2	Repr. 2	H361f
3.9	Specific target organ toxicity - repeated exposure	1	STOT RE 1	H372

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.

2.2 Label elements

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

Signal word **Danger**

Pictograms

GHS06, GHS08

Hazard statements

H301	Toxic if swallowed
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H332	Harmful if inhaled
H340	May cause genetic defects
H350	May cause cancer
H361f	Suspected of damaging fertility (if swallowed)
H372	Causes damage to organs through prolonged or repeated exposure

Precautionary statements

Precautionary statements - prevention

P201	Obtain special instructions before use
P280	Wear protective gloves/eye protection

Precautionary statements - response

P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor
P302+P352	IF ON SKIN: Wash with plenty of soap and water
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P308+P313	IF exposed or concerned: Get medical advice/attention

For professional users only

Hazardous ingredients for labelling: Acrylamide, N,N'-Methylene bisacrylamide

Labelling of packages where the contents do not exceed 125 ml

Signal word: **Danger**

Symbol(s)

H301	Toxic if swallowed.
H317	May cause an allergic skin reaction.
H340	May cause genetic defects.
H350	May cause cancer.
H361f	Suspected of damaging fertility (if swallowed).
H372	Causes damage to organs through prolonged or repeated exposure.
P201	Obtain special instructions before use.
P280	Wear protective gloves/eye protection.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P308+P313	IF exposed or concerned: Get medical advice/attention.
contains:	Acrylamide, N,N'-Methylene bisacrylamide

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
Acrylamide	CAS No 79-06-1 EC No 201-173-7 Index No 616-003-00-0 REACH Reg. No 01-2119463260-48-xxxx	30 – 40	Acute Tox. 3 / H301 Acute Tox. 4 / H312 Acute Tox. 4 / H332 Skin Irrit. 2 / H315 Eye Irrit. 2 / H319 Skin Sens. 1 / H317 Muta. 1B / H340 Carc. 1B / H350 Repr. 2 / H361f STOT RE 1 / H372		D GHS-HC IOELV
N,N'-Methylene bisacrylamide	CAS No 110-26-9 EC No 203-750-9 REACH Reg. No 01-2120745928-38-xxxx	1 – 2,5	Acute Tox. 3 / H301 Acute Tox. 4 / H312 Acute Tox. 4 / H332 Muta. 1B / H340 Carc. 1B / H350 Repr. 2 / H361fd STOT RE 1 / H372		

Notes

D: Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3. However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the supplier must state on the label the name of the substance followed by the words 'non-stabilised'.

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
Acrylamide	CAS No 79-06-1 EC No 201-173-7 Index No 616-003-00-0	-	-	100 $^{mg}/_{kg}$ 1.141 $^{mg}/_{kg}$ 1,5 $^{mg}/_{l}$/4h	oral dermal inhalation: dust/ mist
N,N'-Methylene bisacrylamide	CAS No 110-26-9 EC No 203-750-9	-	-	100 $^{mg}/_{kg}$ 1.141 $^{mg}/_{kg}$ 3,025 $^{mg}/_{l}$/4h	oral dermal inhalation: dust/ mist

Substance of Very High Concern (SVHC)

Name of substance	Name acc. to inventory	CAS No	EC No	Listed in	Remarks
Acrylamide	acrylamide	79-06-1	201-173-7	Candidate list	Carc. A57a Muta. A57b

Legend

candidate list	Substances meeting the criteria referred to in Article 57 and for eventual inclusion in Annex XIV
Carc. A57a	Carcinogenic (article 57a)
Muta. A57b	Mutagenic (article 57b)

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

Following eye contact

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

Following ingestion

Rinse mouth immediately and drink plenty of water. In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

4.2 Most important symptoms and effects, both acute and delayed

Nausea, Vomiting, Irritation, Allergic reactions

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, alcohol resistant foam, dry extinguishing powder, BC-powder, carbon dioxide (CO_2)

Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

Ingredients of the mixture combustible. The product itself does not burn.

Hazardous combustion products

In case of fire may be liberated: Nitrogen oxides (NOx), Carbon monoxide (CO), Carbon dioxide (CO_2)

5.3 Advice for firefighters

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

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.

6.2 Environmental precautions

Keep away from drains, surface and ground water.

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

Provide adequate ventilation as well as local exhaustion at critical locations. Use extractor hood (laboratory). Avoid exposure. When not in use, keep containers tightly closed. Clear contaminated areas thoroughly. Do not dry up the product. Measures to prevent aerosol and dust generation.

Advice on general occupational hygiene

When using do not eat or drink. Thorough skin-cleansing after handling the product.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a cool place.

Incompatible substances or mixtures

Observe hints for combined storage.

Protect against external exposure, such as

high temperatures, UV-radiation/sunlight

Consideration of other advice:

Store locked up.

Ventilation requirements

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

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	acrylamide	79-06-1	IOELV		0,1						2017/2398/EU

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)

Relevant DNELs of components of the mixture

Name of substance	CAS No	End-point	Threshold level	Protection goal, route of exposure	Used in	Exposure time
Acrylamide	79-06-1	DNEL	120 mg/m³	human, inhalatory	worker (industry)	acute - systemic effects
Acrylamide	79-06-1	DNEL	120 mg/m³	human, inhalatory	worker (industry)	acute - local effects
Acrylamide	79-06-1	DNEL	3 mg/kg bw/day	human, dermal	worker (industry)	acute - systemic effects
N,N'-Methylene bisacrylamide	110-26-9	DNEL	3 mg/kg bw/day	human, dermal	worker (industry)	acute - systemic effects

Relevant PNECs of components of the mixture

Name of substance	CAS No	End-point	Threshold level	Organism	Environmental compartment	Exposure time
Acrylamide	79-06-1	PNEC	0,032 mg/l	aquatic organisms	freshwater	short-term (single instance)
Acrylamide	79-06-1	PNEC	2 µg/l	aquatic organisms	marine water	short-term (single instance)
Acrylamide	79-06-1	PNEC	0,2 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)

8.2 Exposure controls

Individual protection measures (personal protective equipment)

Eye/face protection

Use safety goggle with side protection.

Skin protection

• hand protection

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

• type of material

NBR (Nitrile rubber)

• material thickness

>0,3 mm

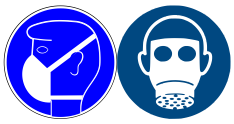
• breakthrough times of the glove material

>480 minutes (permeation: level 6)

• other protection measures

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

Respiratory protection



Respiratory protection necessary at: Aerosol or mist formation. Type: A-P2 (combined filters against particles and organic gases and vapours, colour code: Brown/White).

Environmental exposure controls

Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	liquid
Colour	clear - colourless
Odour	characteristic
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	~100 °C
Flammability	non-combustible
Lower and upper explosion limit	not determined
Flash point	not determined
Auto-ignition temperature	not determined
Decomposition temperature	not relevant
pH (value)	5 – 7 (20 °C)
Kinematic viscosity	not determined
Solubility(ies)	
Water solubility	miscible in any proportion
Partition coefficient	
Partition coefficient n-octanol/water (log value):	this information is not available

Vapour pressure	not determined
Density and/or relative density	
Density	1,03 $^{g}/_{cm^3}$ at 20 °C
Relative vapour density	information on this property is not available
Particle characteristics	not relevant (liquid)
Other safety parameters	
Oxidising properties	none

9.2 Other information

Information with regard to physical hazard classes:	hazard classes acc. to GHS (physical hazards): not relevant
Other safety characteristics:	
Miscibility	completely miscible with water

SECTION 10: Stability and reactivity

10.1 Reactivity

Unstabilized product can polymerize spontaneously.

If heated

Danger of polymerisation.

If exposed to light

Danger of polymerisation.

10.2 Chemical stability

Reactivity if exposed to light. Reactivity if heated.

10.3 Possibility of hazardous reactions

Violent reaction with: strong oxidiser, Peroxides, Reducing agents, Acids, Caustic solutions

10.4 Conditions to avoid

UV-radiation/sunlight. Keep away from heat.

10.5 Incompatible materials

There is no additional information.

10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

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

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

Toxic if swallowed. Harmful if inhaled.

Acute toxicity estimate (ATE) of components of the mixture

Name of substance	CAS No	Exposure route	ATE
Acrylamide	79-06-1	oral	100 $^{mg}/_{kg}$
Acrylamide	79-06-1	dermal	1.141 $^{mg}/_{kg}$
Acrylamide	79-06-1	inhalation: dust/mist	1,5 $^{mg}/_{l}$/4h
N,N'-Methylene bisacrylamide	110-26-9	oral	100 $^{mg}/_{kg}$
N,N'-Methylene bisacrylamide	110-26-9	dermal	1.141 $^{mg}/_{kg}$
N,N'-Methylene bisacrylamide	110-26-9	inhalation: dust/mist	3,025 $^{mg}/_{l}$/4h

Acute toxicity of components of the mixture

Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Acrylamide	79-06-1	oral	LD50	354 $^{mg}/_{kg}$	rat
Acrylamide	79-06-1	dermal	LD50	1.141 $^{mg}/_{kg}$	rabbit
N,N'-Methylene bisacrylamide	110-26-9	oral	LD50	390 $^{mg}/_{kg}$	rat
N,N'-Methylene bisacrylamide	110-26-9	dermal	LD50	1.141 $^{mg}/_{kg}$	rabbit
N,N'-Methylene bisacrylamide	110-26-9	inhalation: dust/mist	LC50	12,1 $^{mg}/_{l}$/1h	rat

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/eye irritation

Causes serious eye irritation.

Respiratory or skin sensitisation

May cause an allergic skin reaction.

Germ cell mutagenicity

May cause genetic defects.

Carcinogenicity

May cause cancer.

Reproductive toxicity

Suspected of damaging fertility (if swallowed).

Specific target organ toxicity - single exposure

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

Specific target organ toxicity - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Hazard category	Target organ	Exposure route
2	peripheral nervous system	if swallowed

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

Symptoms related to the physical, chemical and toxicological characteristics

• If swallowed

vomiting, nausea

• If in eyes

Causes serious eye irritation

• If inhaled

Data are not available.

• If on skin

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

• Other information

Loss of righting reflex, and ataxia, Disorientation, Impaired memory function

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

Shall not be classified as hazardous to the aquatic environment.

Aquatic toxicity (acute) of components of the mixture

Name of substance	CAS No	Endpoint	Value	Species	Exposure time
Acrylamide	79-06-1	EC50	98 $^{mg}/_{l}$	aquatic invertebrates	48 h
N,N'-Methylene bisacrylamide	110-26-9	LC50	835 $^{mg}/_{l}$	aquatic invertebrates	48 h
N,N'-Methylene bisacrylamide	110-26-9	ErC50	>100 $^{mg}/_{l}$	algae	72 h

Biodegradation

Data are not available.

12.2 Process of degradability

Degradability of components of the mixture

Name of substance	CAS No	Process	Degradation rate	Time	Method	Source
Acrylamide	79-06-1	biotic/abiotic	100 %	28 d	geschlossene Flasche	
Acrylamide	79-06-1	oxygen depletion	7,4 %	5 d		ECHA
N,N'-Methylene bisacrylamide	110-26-9	oxygen depletion	2,1 %	28 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
Acrylamide	79-06-1		-0,9 (pH value: ~7, 20 °C)	
N,N'-Methylene bisacrylamide	110-26-9		-0,08 (24 °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.

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

ADR	UN 3426
IMDG-Code	UN 3426
ICAO-TI	UN 3426

14.2 UN proper shipping name

ADR	ACRYLAMIDE SOLUTION
IMDG-Code	ACRYLAMIDE SOLUTION
ICAO-TI	Acrylamide solution

14.3 Transport hazard class(es)

ADR	6.1
IMDG-Code	6.1
ICAO-TI	6.1

14.4 Packing group

ADR	III
IMDG-Code	III
ICAO-TI	III

14.5 Environmental hazards

non-environmentally hazardous acc. to the dangerous goods regulations

14.6 Special precautions for user

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

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	ACRYLAMIDE SOLUTION
Particulars in the transport document	UN3426, ACRYLAMIDE SOLUTION, 6.1, III, (E)
Classification code	T1
Danger label(s)	6.1

Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 L
Transport category (TC)	2
Tunnel restriction code (TRC)	E
Hazard identification No	60

International Maritime Dangerous Goods Code (IMDG) - Additional information

Proper shipping name	ACRYLAMIDE SOLUTION
Particulars in the shipper's declaration	UN3426, ACRYLAMIDE SOLUTION, 6.1, III
Marine pollutant	-
Danger label(s)	6.1

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

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

Proper shipping name	Acrylamide solution
Particulars in the shipper's declaration	UN3426, Acrylamide solution, 6.1, III
Danger label(s)	6.1

Special provisions (SP)	A3
Excepted quantities (EQ)	E1
Limited quantities (LQ)	2 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
ROTIPHORESE®Gel 40 (29:1)	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC		R3	3
N,N'-Methylene bisacrylamide	substances in tattoo inks and permanent make-up		R75	75
Acrylamide	acrylamide	79-06-1	R60	60
Acrylamide	carcinogenic		R28-30	28
Acrylamide	germ cell mutagenic (mutagenic)		R28-30	29
Acrylamide	substances in tattoo inks and permanent make-up		R75	75

Legend

R28-30 1. Shall not be placed on the market, or used,
- as substances,
- as constituents of other substances, or,
- in mixtures,

for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:
- either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or,
- the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008.

Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows:
'Restricted to professional users'.
2. By way of derogation, paragraph 1 shall not apply to:
(a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC;
(b) cosmetic products as defined by Directive 76/768/EEC;
(c) the following fuels and oil products:
- motor fuels which are covered by Directive 98/70/EC,
- mineral oil products intended for use as fuel in mobile or fixed combustion plants,
- fuels sold in closed systems (e.g. liquid gas bottles);

(d) artists' paints covered by Regulation (EC) No 1272/2008;
(e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date;
(f) devices covered by Regulation (EU) 2017/745.

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.';

R60 Shall not be placed on the market or used as a substance or constituent of mixtures in a concentration, equal to or greater than 0,1 % by weight for grouting applications after 5 November 2012.

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

Substance of Very High Concern (SVHC)

Name acc. to inventory	CAS No	Listed in	Remarks	Latest application date	Sunset date	Date of inclusion
acrylamide	79-06-1	Candidate list	Carc. A57a Muta. A57b			30.03.2010

Legend

candidate list	Substances meeting the criteria referred to in Article 57 and for eventual inclusion in Annex XIV
Carc. A57a	Carcinogenic (article 57a)
Muta. A57b	Mutagenic (article 57b)

Seveso Directive

2012/18/EU (Seveso III)

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

Deco-Paint Directive

VOC content	25 – 40 % 1.119 $^{g}/_{l}$

Industrial Emissions Directive (IED)

VOC content	0 %
VOC content (Water content was discounted)	0 $^{g}/_{l}$

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,N'-Methylene bisacrylamide	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)	
Acrylamide	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	AIIC	all ingredients are listed
CA	DSL	all ingredients are listed
CN	IECSC	all ingredients are listed
EU	ECSI	all ingredients are listed
EU	REACH Reg.	all ingredients are listed
JP	CSCL-ENCS	all ingredients are listed
KR	KECI	all ingredients are listed

Country	Inventory	Status
MX	INSQ	all ingredients are listed
NZ	NZIoC	all ingredients are listed
PH	PICCS	all ingredients are listed
TR	CICR	not all ingredients are listed
TW	TCSI	all ingredients are listed
US	TSCA	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

Indication of changes (revised safety data sheet)

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

Restructuring: section 9, section 14

Section	Former entry (text/value)	Actual entry (text/value)	Safety-relevant
2.1		Classification according to Regulation (EC) No 1272/2008 (CLP): change in the listing (table)	yes
2.1		The most important adverse physicochemical, human health and environmental effects: Delayed or immediate effects can be expected after short or long-term exposure.	yes
2.2		Hazard statements: change in the listing (table)	yes
2.2		Labelling of packages where the contents do not exceed 125 ml: change in the listing (table)	yes
2.3	Other hazards: There is no additional information.	Other hazards	yes
2.3		Results of PBT and vPvB assessment: This mixture does not contain any substances that are assessed to be a PBT or a vPvB.	yes

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
2017/2398/EU	Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
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)
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BOD	Biochemical Oxygen Demand
Carc.	Carcinogenicity
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)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
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
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

Abbr.	Descriptions of used abbreviations
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
log KOW	n-Octanol/water
Muta.	Germ cell mutagenicity
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
Repr.	Reproductive toxicity
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
Skin Sens.	Skin sensitisation
STEL	Short-term exposure limit
STOT RE	Specific target organ toxicity - repeated exposure
SVHC	Substance of Very High Concern
TWA	Time-weighted average
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

Key literature references and sources for data

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

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

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
H301	Toxic if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H340	May cause genetic defects.
H350	May cause cancer.
H361f	Suspected of damaging fertility (if swallowed).
H361fd	Suspected of damaging fertility. Suspected of damaging the unborn child (if swallowed).
H372	Causes damage to organs through prolonged or repeated exposure.

Disclaimer

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