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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907 date of compilation: 22.07.2015

Version: **5.0 en** Revision: 26.10.2022 Replaces version of: 22.03.2022

Version: (4)

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

Product identifier 1.1

Identification of the substance ROTI®Histofix ECO Plus SOLVAGREEN® ready-

to-use, formalin-free

Article number 8907

Registration number (REACH) not relevant (mixture)

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

Relevant identified uses: Laboratory and analytical use

Laboratory chemical

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 :Department Health, Safety and Environment

sheet:

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	Cat- egory	Hazard class and category	Hazard statement
3.45	Skin sensitisation	1	Skin Sens. 1	H317

For full text of abbreviations: see SECTION 16

2.2 Label elements

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

Signal word Warning

Page 1 / 28 Malta (en)

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

Pictograms

GHS07



Hazard statements

H317 May cause an allergic skin reaction

Precautionary statements

Precautionary statements - prevention

P280 Wear protective gloves

Precautionary statements - response

P302+P352 IF ON SKIN: Wash with plenty of water

P333+P313 If skin irritation or rash occurs: Get medical advice/attention

Labelling of packages where the contents do not exceed 125 ml

Signal word: Warning

Symbol(s)



H317 May cause an allergic skin reaction.

P280 Wear protective gloves.

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

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

contains: Hexamethylene tetramine

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 sub- stance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
Water	CAS No 7732-18-5	87,31			
	EC No 231-791-2				

Malta (en) Page 2 / 28

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

Name of sub- stance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
Hexamethylene tetra- mine	CAS No 100-97-0	< 2,5	Flam. Sol. 2 / H228 Skin Sens. 1 / H317		GHS-HC
	EC No 202-905-8				
	Index No 612-101-00-2				
Glycerine	CAS No 56-81-5	<2			IOELV
	EC No 200-289-5				
Citric acid	CAS No 77-92-9	<2	Eye Irrit. 2 / H319 STOT SE 3 / H335	<u>(1)</u>	GHS-HC
	EC No 201-069-1				
	Index No 607-750-00-3				
Ethanol	CAS No 64-17-5	< 1,5	Flam. Liq. 2 / H225 Eye Irrit. 2 / H319	(b) (1)	GHS-HC IARC: 1
	EC No 200-578-6				
	Index No 603-002-00-5				
2-Propanol	CAS No 67-63-0	< 1,5	Flam. Liq. 2 / H225 Eye Irrit. 2 / H319 STOT SE 3 / H336	<u>(4)</u>	GHS-HC
	EC No 200-661-7		3101 SE 37 H330		
	Index No 603-117-00-0				
Ethylene glycol	CAS No 107-21-1	<1	Acute Tox. 4 / H302 STOT RE 2 / H373	<u>(!)</u>	GHS-HC IOELV
	EC No 203-473-3				
	Index No 603-027-00-1				
Ammonium chloride	CAS No 12125-02-9	<1	Acute Tox. 4 / H302 Eye Irrit. 2 / H319	<u>(1)</u>	GHS-HC
	EC No 235-186-4				
	Index No 017-014-00-8				
DL-Lactic acid	CAS No 598-82-3	<1	Skin Irrit. 2 / H315 Eye Dam. 1 / H318		
	EC No 209-954-4				

Malta (en) Page 3 / 28

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

Name of sub- stance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
Methanol	CAS No 67-56-1 EC No 200-659-6 Index No 603-001-00-X	<1	Flam. Liq. 2 / H225 Acute Tox. 3 / H301 Acute Tox. 3 / H311 Acute Tox. 3 / H331 STOT SE 1 / H370		GHS-HC IOELV
Sodium azide	CAS No 26628-22-8 EC No 247-852-1 Index No 011-004-00-7	< 0,1	Acute Tox. 2 / H300 Acute Tox. 1 / H310 Acute Tox. 2 / H330 STOT RE 2 / H373 Aquatic Acute 1 / H400 Aquatic Chronic 1 / H410 EUH032	1 1 1 1 1 1 1 1 1 1	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)

IARC: 1: IARC group 1: carcinogenic to humans (International Agency for Research on Cancer)

IOELV: Substance with a community indicative occupational exposure limit value

Name of sub- stance	Identifier	Specific Conc. Limits	M-Factors	ATE	Exposure route
Ammonium chloride	CAS No 12125-02-9	-	-	1.410 ^{mg} / _{kg}	oral
	EC No 235-186-4				
	Index No 017-014-00-8				
Methanol	CAS No 67-56-1	STOT SE 1; H370: C ≥ 10 % STOT SE 2; H371: 3 % ≤ C < 10 %	-	100 ^{mg} / _{kg} 300 ^{mg} / _{kg} 3 ^{mg} / _l /4h	oral dermal inhalation: va-
	EC No 200-659-6			J -//	pour
	Index No 603-001-00-X				
Ethylene glycol	CAS No 107-21-1	-	-	500 ^{mg} / _{kg}	oral
	EC No 203-473-3				
	Index No 603-027-00-1				
Sodium azide	CAS No 26628-22-8	-	-	27 ^{mg} / _{kg} 20 ^{mg} / _{kg} >0,054 ^{mg} / _I /	oral dermal inhalation: dust/
	EC No 247-852-1			20,034 3/l/ 4h	mist
	Index No 011-004-00-7				

For full text of abbreviations: see SECTION 16

Malta (en) Page 4 / 28

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

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

After contact with skin, wash immediately with plenty of water. In case of skin reactions, 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

Rinse mouth. Call a doctor if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

Vomiting, 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 (CO₂)

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 (CO₂)

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.

Malta (en) Page 5 / 28

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures



For non-emergency personnel

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

No special measures are necessary.

Advice on general occupational hygiene

Wash hands before breaks and after work. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed.

Incompatible substances or mixtures

Observe hints for combined storage.

Protect against external exposure, such as

UV-radiation/sunlight

Consideration of other advice:

Specific designs for storage rooms or vessels

Recommended storage temperature: 15 - 25 °C

7.3 Specific end use(s)

No information available.

Malta (en) Page 6 / 28

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

SECTION 8: Exposure controls/personal protection

Control parameters

National limit values

Occupational exposure limit values (Workplace Exposure Limits)

Cou ntr y	Name of agent	CAS No	Identi- fier	TW A [pp m]	TWA [mg/ m³]	STE L [pp m]	STEL [mg/ m³]	Ceil ing- C [pp m]	Ceil- ing-C [mg/ m³]	Nota- tion	Source
EU	ethylene glycol	107-21-1	IOELV	20	52	40	104			Н	2000/39/ EC
EU	sodium azide	26628- 22-8	IOELV		0,1		0,3			Н	2000/39/ EC
EU	methanol	67-56-1	IOELV	200	260					Н	2006/15/ EC
MT	ethylene glycol	107-21-1	OELV	20	52	40	104			Н	CAP. 424
MT	sodium azide	26628- 22-8	OELV		0,1		0,3			Н	CAP. 424
MT	methanol	67-56-1	OELV	200	260					Н	CAP. 424

Notation

Ceiling-C H

STEL

Ceiling value is a limit value above which exposure should not occur
Absorbed through the skin
Short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15minute period (unless otherwise specified)
Time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 **TWA**

hours time-weighted average (unless otherwise specified)

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
Hexamethylene tet- ramine	100-97-0	DNEL	5,6 mg/m ³	human, inhalat- ory	worker (industry)	chronic - systemic effects
Hexamethylene tet- ramine	100-97-0	DNEL	6,4 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
Glycerine	56-81-5	DNEL	220 mg/m ³	human, inhalat- ory	worker (industry)	chronic - local ef- fects
Ethanol	64-17-5	DNEL	1.900 mg/ m³	human, inhalat- ory	worker (industry)	acute - systemic effects
Ethanol	64-17-5	DNEL	343 mg/kg	human, dermal	worker (industry)	chronic - systemic effects
Ethanol	64-17-5	DNEL	950 mg/m³	human, inhalat- ory	worker (industry)	chronic - systemic effects
2-Propanol	67-63-0	DNEL	500 mg/m ³	human, inhalat- ory	worker (industry)	chronic - systemic effects
2-Propanol	67-63-0	DNEL	888 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
Methanol	67-56-1	DNEL	130 mg/m ³	human, inhalat- ory	worker (industry)	chronic - systemic effects

Malta (en) Page 7 / 28

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

Relevant DNELs	of compone	nts of th	e mixture			
Name of sub- stance	CAS No	End- point	Threshol d level	Protection goal, route of exposure	Used in	Exposure time
Methanol	67-56-1	DNEL	130 mg/m ³	human, inhalat- ory	worker (industry)	acute - systemic effects
Methanol	67-56-1	DNEL	130 mg/m ³	human, inhalat- ory	worker (industry)	chronic - local ef- fects
Methanol	67-56-1	DNEL	130 mg/m ³	human, inhalat- ory	worker (industry)	acute - local ef- fects
Methanol	67-56-1	DNEL	20 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
Methanol	67-56-1	DNEL	20 mg/kg bw/day	human, dermal	worker (industry)	acute - systemic effects
Ethylene glycol	107-21-1	DNEL	35 mg/m³	human, inhalat- ory	worker (industry)	chronic - local ef- fects
Ethylene glycol	107-21-1	DNEL	106 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
DL-Lactic acid	598-82-3	DNEL	592 mg/m³	human, inhalat- ory	worker (industry)	chronic - local ef- fects
DL-Lactic acid	598-82-3	DNEL	592 mg/m³	human, inhalat- ory	worker (industry)	acute - local ef- fects
Sodium azide	26628-22-8	DNEL	0,164 mg/ m³	human, inhalat- ory	worker (industry)	chronic - systemic effects

Relevant PNECs of components of the mixture

26628-22-8

DNEL

46,7 μg/kg

human, dermal

worker (industry)

chronic - systemic effects

Sodium azide

Name of sub- stance	CAS No	End- point	Threshol d level	Organism	Environmental compartment	Exposure time
Hexamethylene tet- ramine	100-97-0	PNEC	3 ^{mg} / _l	aquatic organ- isms	freshwater	short-term (single instance)
Hexamethylene tet- ramine	100-97-0	PNEC	0,3 ^{mg} / _l	aquatic organ- isms	marine water	short-term (single instance)
Hexamethylene tet- ramine	100-97-0	PNEC	100 ^{mg} / _l	aquatic organ- isms	sewage treatment plant (STP)	short-term (single instance)
Hexamethylene tet- ramine	100-97-0	PNEC	10,2 ^{mg} / _{kg}	aquatic organ- isms	freshwater sedi- ment	short-term (single instance)
Hexamethylene tet- ramine	100-97-0	PNEC	1,02 ^{mg} / _{kg}	aquatic organ- isms	marine sediment	short-term (single instance)
Hexamethylene tet- ramine	100-97-0	PNEC	0,28 ^{mg} / _{kg}	terrestrial organ- isms	soil	short-term (single instance)
Citric acid	77-92-9	PNEC	0,44 ^{mg} / _l	aquatic organ- isms	freshwater	short-term (single instance)
Citric acid	77-92-9	PNEC	0,044 ^{mg} / _l	aquatic organ- isms	marine water	short-term (single instance)
Citric acid	77-92-9	PNEC	1.000 ^{mg} / _l	aquatic organ- isms	sewage treatment plant (STP)	short-term (single instance)

Malta (en) Page 8 / 28

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

Relevant PNECs of components of the mixture									
Name of sub- stance	CAS No	End- point	Threshol d level	Organism	Environmental compartment	Exposure tim			
Citric acid	77-92-9	PNEC	34,6 ^{mg} / _{kg}	aquatic organ- isms	freshwater sedi- ment	short-term (sing instance)			
Citric acid	77-92-9	PNEC	3,46 ^{mg} / _{kg}	aquatic organ- isms	marine sediment	short-term (sing instance)			
Citric acid	77-92-9	PNEC	33,1 ^{mg} / _{kg}	terrestrial organ- isms	soil	short-term (sing instance)			
Glycerine	56-81-5	PNEC	1.000 ^{mg} / _l	aquatic organ- isms	sewage treatment plant (STP)	short-term (sing instance)			
Ethanol	64-17-5	PNEC	0,79 ^{mg} / _{cm³}	unknown	marine water	intermittent re lease			
Ethanol	64-17-5	PNEC	2,75 ^{mg} / _{cm³}	unknown	air	intermittent r			
Ethanol	64-17-5	PNEC	3,6 ^{mg} / _{cm³}	unknown	freshwater sedi- ment	intermittent r lease			
Ethanol	64-17-5	PNEC	580 ^{mg} / _{cm³}	unknown	sewage treatment plant (STP)	intermittent r lease			
Ethanol	64-17-5	PNEC	0,63 ^{mg} / _{cm³}	unknown	soil	intermittent r lease			
Ethanol	64-17-5	PNEC	0,96 ^{mg} / _{cm³}	unknown	freshwater	intermittent r lease			
2-Propanol	67-63-0	PNEC	140,9 ^{mg} / _l	aquatic organ- isms	freshwater	short-term (sin instance)			
2-Propanol	67-63-0	PNEC	140,9 ^{mg} / _l	aquatic organ- isms	marine water	short-term (sin instance)			
2-Propanol	67-63-0	PNEC	2.251 ^{mg} / _l	aquatic organ- isms	sewage treatment plant (STP)	short-term (sin instance)			
2-Propanol	67-63-0	PNEC	552 ^{mg} / _{kg}	aquatic organ- isms	freshwater sedi- ment	short-term (sin instance)			
2-Propanol	67-63-0	PNEC	552 ^{mg} / _{kg}	aquatic organ- isms	marine sediment	short-term (sin instance)			
2-Propanol	67-63-0	PNEC	28 ^{mg} / _{kg}	terrestrial organ- isms	soil	short-term (sin instance)			
Methanol	67-56-1	PNEC	20,8 ^{mg} / _l	aquatic organ- isms	freshwater	short-term (sin instance)			
Methanol	67-56-1	PNEC	2,08 ^{mg} / _l	aquatic organ- isms	marine water	short-term (sin instance)			
Methanol	67-56-1	PNEC	100 ^{mg} / _l	aquatic organ- isms	sewage treatment plant (STP)	short-term (sin instance)			
Methanol	67-56-1	PNEC	77 ^{mg} / _{kg}	aquatic organ- isms	freshwater sedi- ment	short-term (sin instance)			
Methanol	67-56-1	PNEC	7,7 ^{mg} / _{kg}	aquatic organ- isms	marine sediment	short-term (sin instance)			
Methanol	67-56-1	PNEC	100 ^{mg} / _{kg}	terrestrial organ- isms	soil	short-term (sin instance)			

Malta (en) Page 9 / 28

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

Name of sub- stance	CAS No	End- point	Threshol d level	Organism	Environmental compartment	Exposure time
Ethylene glycol	107-21-1	PNEC	10 ^{mg} / _l	aquatic organ- isms	freshwater	short-term (single instance)
Ethylene glycol	107-21-1	PNEC	1 ^{mg} / _l	aquatic organ- isms	marine water	short-term (single instance)
Ethylene glycol	107-21-1	PNEC	199,5 ^{mg} / _l	aquatic organ- isms	sewage treatment plant (STP)	short-term (single instance)
Ethylene glycol	107-21-1	PNEC	37 ^{mg} / _{kg}	aquatic organ- isms	freshwater sedi- ment	short-term (single instance)
Ethylene glycol	107-21-1	PNEC	3,7 ^{mg} / _{kg}	aquatic organ- isms	marine sediment	short-term (single instance)
Ethylene glycol	107-21-1	PNEC	1,53 ^{mg} / _{kg}	terrestrial organ- isms	soil	short-term (single instance)
Sodium azide	26628-22-8	PNEC	0,35 ^{µg} / _l	aquatic organ- isms	freshwater	short-term (single instance)
Sodium azide	26628-22-8	PNEC	30 ^{µg} / _I	aquatic organ- isms	sewage treatment plant (STP)	short-term (single instance)
Sodium azide	26628-22-8	PNEC	16,7 ^{µg} / _{kg}	aquatic organ- isms	freshwater sedi- ment	short-term (single instance)
Sodium azide	26628-22-8	PNEC	0,72 ^{µg} / _{kg}	aquatic organ- isms	marine sediment	short-term (single instance)

8.2 Exposure controls

Individual protection measures (personal protective equipment)

Eye/face protection





Use safety goggle with side protection.

Skin protection





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

Malta (en) Page 10 / 28

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

NBR (Nitrile rubber)

material thickness

>0,11 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 (against organic gases and vapours with a boiling point of > 65 °C , colour code: Brown). Usually no personal respirative protection necessary.

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 fruity - floral odor

Melting point/freezing point ~0 °C

Boiling point or initial boiling point and boiling ~100 °C

range

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) 5-5,2 (20 °C)

Kinematic viscosity 3,448 mm²/s at 20 °C

Dynamic viscosity 3,5 mPa s at 20 °C

Solubility(ies)

Water solubility miscible in any proportion

Partition coefficient

Partition coefficient n-octanol/water (log value): this information is not available

Malta (en) Page 11 / 28

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

ROTH

ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

Vapour pressure 23 hPa at 20 °C

Density and/or relative density

Density $1,015 \, \mathrm{g/_{cm^3}}$ 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

This material is not reactive under normal ambient conditions.

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

No known hazardous reactions.

10.4 Conditions to avoid

UV-radiation/sunlight.

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

Shall not be classified as acutely toxic.

Malta (en) Page 12 / 28

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

Acute toxicity estimate (ATE) of components of the mixture

Name of substance	CAS No	Exposure route	ATE
Ammonium chloride	12125-02-9	oral	1.410 ^{mg} / _{kg}
Methanol	67-56-1	oral	100 ^{mg} / _{kg}
Methanol	67-56-1	dermal	300 ^{mg} / _{kg}
Methanol	67-56-1	inhalation: vapour	3 ^{mg} / _l /4h
Ethylene glycol	107-21-1	oral	500 ^{mg} / _{kg}
Sodium azide	26628-22-8	oral	27 ^{mg} / _{kg}
Sodium azide	26628-22-8	dermal	20 ^{mg} / _{kg}
Sodium azide	26628-22-8	inhalation: dust/mist	>0,054 ^{mg} / _l /4h

Acute toxicity of components of the mixture

Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Hexamethylene tetramine	100-97-0	oral	LD50	>20.000 ^{mg} / _{kg}	rat
Hexamethylene tetramine	100-97-0	dermal	LD50	>2.000 ^{mg} / _{kg}	rat
Citric acid	77-92-9	oral	LD50	5.400 ^{mg} / _{kg}	mouse
Citric acid	77-92-9	dermal	LD50	>2.000 ^{mg} / _{kg}	rat
Glycerine	56-81-5	dermal	LD50	>10.000 ^{mg} / _{kg}	rabbit
Glycerine	56-81-5	oral	LD50	27.200 ^{mg} / _{kg}	rat
Glycerine	56-81-5	inhalation: dust/mist	LC50	>5.850 ^{mg} / _{m³} / 4h	rat
Ethanol	64-17-5	inhalation: va- pour	LC50	95,6 ^{mg} / _l /4h	rat
Ethanol	64-17-5	oral	LD50	7.060 ^{mg} / _{kg}	rat
2-Propanol	67-63-0	inhalation: va- pour	LC50	37,5 ^{mg} / _l /4h	rat
2-Propanol	67-63-0	oral	LD50	5.045 ^{mg} / _{kg}	rat
2-Propanol	67-63-0	dermal	LD50	12.800 ^{mg} / _{kg}	rabbit
Ammonium chloride	12125-02-9	oral	LD50	1.410 ^{mg} / _{kg}	rat
Ammonium chloride	12125-02-9	dermal	LD50	>2.000 ^{mg} / _{kg}	rat
Methanol	67-56-1	inhalation: va- pour	LC50	131 ^{mg} / _l /4h	rat
Methanol	67-56-1	oral	LD50	5.628 ^{mg} / _{kg}	rat
Methanol	67-56-1	oral	LDLo	143 ^{mg} / _{kg}	human
Methanol	67-56-1	dermal	LD50	15.800 ^{mg} / _{kg}	rabbit
Ethylene glycol	107-21-1	dermal	LD50	>3.500 ^{mg} / _{kg}	mouse

Malta (en) Page 13 / 28

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

Acute toxicit	y of com	ponents of	the mixture
---------------	----------	------------	-------------

Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Ethylene glycol	107-21-1	oral	LD50	4.700 ^{mg} / _{kg}	rat
DL-Lactic acid	598-82-3	oral	LD50	3.543 ^{mg} / _{kg}	rat
DL-Lactic acid	598-82-3	inhalation: dust/mist	LC50	>7,94 ^{mg} / _l /4h	rat
DL-Lactic acid	598-82-3	dermal	LD50	>2.000 ^{mg} / _{kg}	rabbit
Sodium azide	26628-22-8	inhalation: dust/mist	LC50	>0,054 - <0,52 ^{mg} / _l /4h	rat
Sodium azide	26628-22-8	oral	LD50	27 ^{mg} / _{kg}	rat
Sodium azide	26628-22-8	dermal	LD50	20 ^{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

May cause an allergic skin 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.

Symptoms related to the physical, chemical and toxicological characteristics

If swallowed

Data are not available.

• If in eyes

Data are not available.

• If inhaled

Data are not available.

• If on skin

Malta (en) Page 14 / 28

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

May produce an allergic reaction, pruritis, localised redness

• 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

Shall not be classified as hazardous to the aquatic environment.

Aquatic toxicity (acute) of components of the mixture

Name of sub- stance	CAS No	Endpoint	Value	Species	Exposure time
Hexamethylene tetra- mine	100-97-0	EC50	36 ^{mg} / _I	daphnia magna	48 h
Hexamethylene tetra- mine	100-97-0	LC50	41 ^g / _l	fish	96 h
Citric acid	77-92-9	LC50	440 ^{mg} / _l	fish	48 h
Glycerine	56-81-5	LC50	54.000 ^{mg} / _l	fish	96 h
Ethanol	64-17-5	LC50	8.140 ^{mg} / _l	orfe (Leuciscus idus)	96 h
Ethanol	64-17-5	EC50	9.000 – 14.000 ^{mg} / _l	daphnia magna	48 h
2-Propanol	67-63-0	LC50	9.640 ^{mg} / _l	Pimephales promelas	96 h
Ammonium chloride	12125-02-9	LC50	42,91 ^{mg} / _l	fish	96 h
Ammonium chloride	12125-02-9	EC50	101 ^{mg} / _l	aquatic invertebrates	48 h
Methanol	67-56-1	LC50	15.400 ^{mg} / _l	fish	96 h
Methanol	67-56-1	ErC50	22.000 ^{mg} / _l	algae	96 h
Ethylene glycol	107-21-1	LC50	>72.860 ^{mg} / _l	fish	96 h
Ethylene glycol	107-21-1	EC50	>100 ^{mg} / _l	daphnia magna	48 h
Ethylene glycol	107-21-1	ErC50	<13.000 ^{mg} / _l	algae	96 h
DL-Lactic acid	598-82-3	EC50	250 ^{mg} / _l	aquatic invertebrates	48 h
DL-Lactic acid	598-82-3	ErC50	3,5 ^g / _l	algae	72 h
Sodium azide	26628-22-8	LC50	2,75 ^{mg} / _l	fish	96 h
Sodium azide	26628-22-8	EC50	0,35 ^{mg} / _l	algae	96 h

Malta (en) Page 15 / 28

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

Aquatic toxicity (chronic) of components of the mixture						
Name of sub- stance	CAS No	Endpoint	Value	Species	Exposure time	
Hexamethylene tetra- mine	100-97-0	ErC50	3 ^g / _l	algae	14 d	
Hexamethylene tetra- mine	100-97-0	EC50	>5.000 ^{mg} / _l	microorganisms	30 min	
2-Propanol	67-63-0	LC50	>10.000 ^{mg} / _I	aquatic invertebrates	24 h	
Ammonium chloride	12125-02-9	ErC50	1.300 ^{mg} / _l	algae	5 d	
Ammonium chloride	12125-02-9	EC50	2.700 ^{mg} / _l	algae	18 d	
Ethylene glycol	107-21-1	LC50	>1.500 ^{mg} / _I	fish	28 d	
Ethylene glycol	107-21-1	EC50	>15.000 ^{mg} / _l	aquatic invertebrates	21 d	
DL-Lactic acid	598-82-3	EC50	>88,2 ^{mg} / _l	microorganisms	3 h	
Sodium azide	26628-22-8	EC50	79,3 ^{mg} / _l	microorganisms	3 h	

Biodegradation

The relevant substances of the mixture are readily biodegradable.

12.2 Process of degradability

Degradability of components of the mixture Name of substance Degrada-tion rate **CAS No Process** Time Method Source Hexamethyl-100-97-0 biotic/abiotic 45 % 28 d MITI-Test ene tetramine 100-97-0 oxygen deple-35 % 28 d **ECHA** Hexamethylene tetramine tion Hexamethyl-100-97-0 DOC removal 39 % 28 d **ECHA** ene tetramine Citric acid 77-92-9 biotic/abiotic 98 % 2 d Glycerine 56-81-5 biotic/abiotic 63 % 14 d Ethanol 64-17-5 biotic/abiotic 94 % d 2-Propanol 67-63-0 biotic/abiotic 95 % 21 d modifizierter OECD Screening Test 2-Propanol 67-63-0 oxygen deple-53 % 5 d **ECHA** tion 67-56-1 biotic/abiotic 99 % Methanol 30 d oxygen deple-Methanol 67-56-1 69 % 5 d **ECHA** tion Ethylene glycol 107-21-1 biotic/abiotic 83 - 96 % 14 d Ethylene glycol 107-21-1 DOC removal 90 - 100 % 10 d **ECHA**

12.3 Bioaccumulative potential

Data are not available.

Malta (en) Page 16 / 28

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

Name of substance	CAS No	BCF	Log KOW	BOD5/COD
Hexamethylene tetramine	100-97-0		-2,18 (20 °C)	
Citric acid	77-92-9		-1,64	
Glycerine	56-81-5		-1,75 (pH value: 7,4, 25 °C)	
Ethanol	64-17-5		-0,31	
2-Propanol	67-63-0		0,05	
Ammonium chloride	12125-02-9		-4,37	
Methanol	67-56-1		-0,77	
Ethylene glycol	107-21-1		-1,36	
DL-Lactic acid	598-82-3		-0,54 (25 °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.

13.2 Relevant provisions relating to waste

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

13.3 Remarks

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

Malta (en) Page 17 / 28

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

SECTION 14: Transport information

14.1 UN number or ID number not subject to transport regulations

14.2 UN proper shipping name not assigned

14.3 Transport hazard class(es) none

14.4 Packing group not assigned

14.5 Environmental hazards non-environmentally hazardous acc. to the dan-

gerous 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.

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

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 informationNot 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
ROTI®Histofix ECO Plus	this product meets the criteria for classification in accordance with Reg- ulation No 1272/2008/EC		R3	3
Hexamethylene tetramine	flammable / pyrophoric		R40	40
Hexamethylene tetramine	substances in tattoo inks and permanent make-up		R75	75
Ammonium chloride	inorganic ammonium salts		R65	65
Ammonium chloride	substances in tattoo inks and permanent make-up		R75	75
DL-Lactic acid	substances in tattoo inks and permanent make-up		R75	75
Ethanol	flammable / pyrophoric		R40	40
Ethanol	substances in tattoo inks and permanent make-up		R75	75

Malta (en) Page 18 / 28

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

Dangerous substances with restrictions (REACH, Annex XVII)

Name of substance	Name acc. to inventory	CAS No	Restriction	No
Methanol	methanol	67-56-1	R69	69
Methanol	flammable / pyrophoric		R40	40
2-Propanol	flammable / pyrophoric		R40	40
2-Propanol	substances in tattoo inks and perman- ent make-up		R75	75
Citric acid	substances in tattoo inks and perman- ent 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:
- ments 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.';

 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 expert signed and supply to the general public or extended and supply to the general public are packaged in black or extended and supply to the general public or extended and supply to the g

R40 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.

Page 19 / 28 Malta (en)

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

Legend

R65

1. Shall not be placed on the market, or used, in cellulose insulation mixtures or cellulose insulation articles after 14 July 2018 unless the emission of ammonia from those mixtures or articles results in a concentration of less than 3 ppm by volume (2,12 mg/m3) under the test conditions specified in paragraph 4.

A supplier of a cellulose insulation mixture containing inorganic ammonium salts shall inform the recipient or consumer of the maximum permissible loading rate of the cellulose insulation mixture, expressed in thickness and dens-

A downstream user of a cellulose insulation mixture containing inorganic ammonium salts shall ensure that the maximum permissible loading rate communicated by the supplier is not exceeded.

2. By way of derogation, paragraph 1 shall not apply to placing on the market of cellulose insulation mixtures intended to be used solely for the production of cellulose insulation articles, or to the use of those mixtures in the production of cellulose insulation articles.

tion of cellulose insulation articles.

3. In the case of a Member State that, on 14 July 2016, has national provisional measures in place that have been authorised by the Commission pursuant to Article 129(2)(a), the provisions of paragraphs 1 and 2 shall apply from that

4. Compliance with the emission limit specified in the first subparagraph of paragraph 1 shall be demonstrated in accordance with Technical Specification CEN/TS 16516, adapted as follows:(a) the duration of the test shall be at least 14 days instead of 28 days;

(b) the ammonia gas emission shall be measured at least once per day throughout the test;

(c) the emission limit shall not be reached or exceeded in any measurement taken during the test; (d) the relative humidity shall be 90 % instead of 50 %; (e) an appropriate method to measure the ammonia gas emission shall be used;

(f) the loading rate, expressed in thickness and density, shall be recorded during the sampling of the cellulose insulation mixtures or articles to be tested.

Shall not be placed on the market to the general public after 9 May 2019 in windscreen washing or defrosting fluids, in a concentration equal to or greater than 0,6 % by weight. R69

Page 20 / 28 Malta (en)

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

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

(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

(ií) 0,01 % by weight, in all other cases;

(f) (o, 1 % 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";

(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 concen-

(n) 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.

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,

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";

(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;

tion limit specified in Appendix 13

(f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below

the concentration limit specified in Appendix 13; (g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.

The information shall be clearly visible, easily legible and marked in a way that is indelible.

The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use.

Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph. 8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for

tattooing purposes.

Page 21 / 28 Malta (en)

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

Legend

9. This entry does not apply to substances that are gases at temperature of 20 $^{\circ}$ C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 $^{\circ}$ 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/	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	3 - <10 % 909,4 ⁹ / _I

Industrial Emissions Directive (IED)

VOC content	3 - <10 %
VOC content (Water content was discounted)	909,4 ^g / _I

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	
Hexamethylene tetramine	Substances and preparations, or the breakdown products of such, which have been proved to pos- sess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine- related functions in or via the aquatic environment		a)		
Ammonium chloride	Substances which contribute to eutrophication (in particular, nitrates and phosphates)		a)		
Sodium azide	Metals and their compounds		a)		

Malta (en) Page 22 / 28

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

List of pollutants (WFD)				
Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Ethanol	Substances and preparations, or the breakdown products of such, which have been proved to pos- sess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine- related functions in or via the aquatic environment		a)	
Methanol	Substances and preparations, or the breakdown products of such, which have been proved to pos- sess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine- related functions in or via the aquatic environment		a)	
2-Propanol	Substances and preparations, or the breakdown products of such, which have been proved to pos- sess 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

Explosives precursors which are subject to restrictions						
Name of substance	CAS No	Wt%	Type of registration	Re- marks	Limit value	Upper limit value for the purpose of licensing under Article 5(3)
Hexamethylene tetramine	100-97-0	2,4	Annex II			

Legend

annex II Substances on their own or in mixtures or in substances for which suspicious transactions shall be reported

Additional statements

If the product is passed on to third parties, in accordance with Article 7 "Notification of the supply chain" of Regulation EU 2019/1148, the information obligation is subject to the entire supply chain and all other provisions mentioned in Article 7 on restricted and regulated raw materials.

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

Malta (en) Page 23 / 28

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

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	not 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.	not all ingredients are listed
JP	CSCL-ENCS	not all ingredients are listed
JP	ISHA-ENCS	not all ingredients are listed
KR	KECI	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	all ingredients are listed
US	TSCA	not all ingredients are listed

Legend

AIIC CICR

Australian Inventory of Industrial Chemicals Chemical Inventory and Control Regulation List of Existing and New Chemical Substances (CSCL-ENCS) CSCL-ENCS DSL ECSI IECSC

Domestic Substances List (DSL)
EC Substance Inventory (EINECS, ELINCS, NLP)
Inventory of Existing Chemical Substances Produced or Imported in China National Inventory of Chemical Substances
Inventory of Existing and New Chemical Substances (ISHA-ENCS)
Korea Existing Chemicals Inventory
New Zealand Inventory of Chemicals

INSQ ISHA-ENCS

NZIOC New Zealand Inventory of Chemicals
PICCS Philippine Inventory of Chemicals and Chemical Substances (PICCS)
REACH Reg. REACH registered substances

TCSI TSCA Taiwan Chemical Substance Inventory Toxic Substance Control Act

15.2 Chemical Safety Assessment

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

Malta (en) Page 24 / 28

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

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- relev- ant
2.1	Classification according to Regulation (EC) No 1272/2008 (CLP): This mixture does not meet the criteria for clas- sification in accordance with Regulation No 1272/2008/EC.	Classification according to Regulation (EC) No 1272/2008 (CLP)	yes
2.1		Classification according to Regulation (EC) No 1272/2008 (CLP): change in the listing (table)	yes
2.2	Labelling according to Regulation (EC) No 1272/ 2008 (CLP): not required	Labelling according to Regulation (EC) No 1272/ 2008 (CLP)	yes
2.2		Signal word: Warning	yes
2.2		Pictograms	yes
2.2		Pictograms: change in the listing (table)	yes
2.2		Hazard statements	yes
2.2		Hazard statements: change in the listing (table)	yes
2.2		Precautionary statements	yes
2.2		Precautionary statements - prevention	yes
2.2		Precautionary statements - prevention: change in the listing (table)	yes
2.2		Precautionary statements - response	yes
2.2		Precautionary statements - response: change in the listing (table)	yes
2.2		Labelling of packages where the contents do not exceed 125 ml: Signal word: Warning	yes
2.2		Labelling of packages where the contents do not exceed 125 ml: 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
2.2		Labelling of packages where the contents do not exceed 125 ml: change in the listing (table)	yes
2.2		contains: Hexamethylene tetramine	yes

Malta (en) Page 25 / 28

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
2000/39/EC	Commission Directive establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC
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
Acute Tox.	Acute toxicity
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de naviga- tion intérieures (European Agreement concerning the International Carriage of Dangerous Goods by In- land 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
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BOD	Biochemical Oxygen Demand
CAP. 424	Occupational Health and Safety Authority Act (CAP. 424)
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
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
Flam. Liq.	Flammable liquid
Flam. Sol.	Flammable solid
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)

Malta (en) Page 26 / 28

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

Abbr.	Descriptions of used abbreviations
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
IOELV	Indicative occupational exposure limit value
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
log KOW	n-Octanol/water
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
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
STOT SE	Specific target organ toxicity - single 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).

Malta (en) Page 27 / 28

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



ROTI®Histofix ECO Plus SOLVAGREEN® ready-to-use, formalin-free

article number: 8907

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

Code	Text
H225	Highly flammable liquid and vapour.
H228	Flammable solid.
H300	Fatal if swallowed.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H310	Fatal in contact with skin.
H311	Toxic in contact with skin.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H331	Toxic if inhaled.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H370	Causes damage to organs.
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.

Disclaimer

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

Malta (en) Page 28 / 28