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



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#### D/E Neutralizing Agar for microbiology

article number: **8850** Version: **2.0 en** Replaces version of: 2015-05-21 Version: (1)

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

1.1 Product identifier

Identification of the substance

Article number

Registration number (REACH)

D/E Neutralizing Agar for microbiology

8850

B, not relevant (mixture), The substance does not require registration according to Regulation (EC) No 1907/2006 [REACH].

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

Relevant identified uses:

Uses advised against:

Laboratory chemical Laboratory and analytical use

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

Name	Street	Postal code/city	Telephone	Website
National Poisons Information Centre Beaumont Hospital	Beaumont Road	Dublin 9	01 809 2166	https:// www.poisons.ie/

# **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
3.4S	Skin sensitisation	1	Skin Sens. 1	H317

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



## D/E Neutralizing Agar for microbiology

#### article number: 8850

Suppleme	ental hazard information
Code	Supplemental hazard information
EUH031	contact with acids liberates toxic gas

For full text of abbreviations: see SECTION 16

#### 2.2 Label elements

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

Signal word	Warning
	5

Pictograms

GHS07



#### **Hazard statements**

H317	May cause an allergic skin reaction

#### Precautionary statements

#### **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

#### Supplemental hazard information

EUH031 Contact with acids liberates toxic gas.

Hazardous ingredients for labelling: Sodium thioglycolate

#### Labelling of packages where the contents do not exceed 125 ml

Signal word: Warning

Symbol(s)



H317	May cause an allergic skin reaction.
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
EUH031	Contact with acids liberates toxic gas.
contains:	Sodium thioglycolate

## 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.

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



## D/E Neutralizing Agar for microbiology

#### article number: 8850

# **SECTION 3: Composition/information on ingredients**

#### 3.1 **Substances**

not relevant (mixture)

**REACH Reg. No** 

В

#### 3.2 Mixtures

### Description of the mixture

Name of sub- stance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
Sodium hydrogen- sulphite%	CAS No 7631-90-5 EC No 231-548-0 Index No 016-064-00-8 REACH Reg. No 01-2119524563- 42-xxxx	2-<10	Acute Tox. 4 / H302 EUH031	<b>(!)</b>	B(a) GHS-HC
Sodium thioglycolate	CAS No 367-51-1 EC No 206-696-4 REACH Reg. No 01-2119968564- 24-xxxx	1-<2	Met. Corr. 1 / H290 Acute Tox. 3 / H301 Acute Tox. 4 / H312 Skin Sens. 1 / H317		

#### Notes

B(a): The classification refers to an aqueous solution GHS-HC: Harmonised classification (the classification of the substance corresponds to the entry in the list according to 1272/ 2008/EC, Annex VI)

Name of sub- stance	Identifier	Specific Conc. Limits	<b>M-Factors</b>	ΑΤΕ	Exposure route
Sodium hydro- gensulphite%	CAS No 7631-90-5 EC No 231-548-0 Index No 016-064-00-8	-	-	500 <sup>mg</sup> / <sub>kg</sub>	oral
Sodium thiogly- colate	CAS No 367-51-1 EC No 206-696-4	-	-	200 <sup>mg</sup> / <sub>kg</sub> 1.500 <sup>mg</sup> / <sub>kg</sub>	oral dermal

For full text of abbreviations: see SECTION 16

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



#### D/E Neutralizing Agar for microbiology

article number: 8850

# **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

Allergic reactions, Irritant effects, Gastrointestinal complaints, Diarrhoea, Vomiting

## 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, foam, alcohol resistant foam, dry extinguishing powder, ABC-powder

#### Unsuitable extinguishing media

water jet

#### 5.2 Special hazards arising from the substance or mixture

Combustible.

#### Hazardous combustion products

Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>)

#### 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.

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



## D/E Neutralizing Agar for microbiology

article number: 8850

# **SECTION 6: Accidental release measures**

6.1 Personal precautions, protective equipment and emergency procedures



#### For non-emergency personnel

Do not breathe dust. Prevent skin contact.

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. Take up mechanically.

#### Advice on how to clean up a spill

Take up mechanically. Control of dust.

#### 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

Avoid dust formation. Do not mix with acids.

#### Measures to prevent fire as well as aerosol and dust generation

Removal of dust deposits.

#### 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 in a cool place.

#### Incompatible substances or mixtures

Observe hints for combined storage.

#### Consideration of other advice:

#### **Ventilation requirements**

Use local and general ventilation.

#### Specific designs for storage rooms or vessels

Recommended storage temperature: 2 - 8 °C

#### 7.3 Specific end use(s)

No information available.

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



## D/E Neutralizing Agar for microbiology

#### article number: 8850

# **SECTION 8: Exposure controls/personal protection**

#### 8.1 **Control parameters**

#### National limit values

#### **Occupational exposure limit values (Workplace Exposure Limits)**

Coun try	Name of agent	CAS No	Identifi- er	TWA [mg/ m³]	STEL [mg/ m³]	Ceil- ing-C [mg/ m <sup>3</sup> ]	Nota- tion	Source
IE	dusts non-specific		OELV	10			i	S.I. No. 619 of 2001
IE	dusts non-specific		OELV	4			r	S.I. No. 619 of 2001
IE	sodium bisulfite	7631-90-5	OELV	5				S.I. No. 619 of 2001

#### Notation

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

Inhalable fraction Respirable fraction 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) 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 sub- stance	CAS No	End- point	Threshol d level	Protection goal, route of exposure	Used in	Exposure time			
Sodium hydrogen- sulphite%	7631-90-5	DNEL	246 mg/m <sup>3</sup>	human, inhalat- ory	worker (industry)	chronic - systemic effects			
Sodium thioglycol- ate	367-51-1	DNEL	1,41 mg/ m³	human, inhalat- ory	worker (industry)	chronic - systemic effects			
Sodium thioglycol- ate	367-51-1	DNEL	2,06 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects			

#### **Relevant PNECs of components of the mixture**

Name of sub- stance	CAS No	End- point	Threshol d level	Organism	Environmental compartment	Exposure time
Sodium hydrogen- sulphite%	7631-90-5	PNEC	1,09 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	freshwater	short-term (single instance)
Sodium hydrogen- sulphite%	7631-90-5	PNEC	0,11 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	marine water	short-term (single instance)
Sodium hydrogen- sulphite%	7631-90-5	PNEC	10,71 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	sewage treatment plant (STP)	short-term (single instance)
Sodium thioglycol- ate	367-51-1	PNEC	ا <sup>روىر</sup> 380	aquatic organ- isms	water	intermittent re- lease
Sodium thioglycol- ate	367-51-1	PNEC	38 <sup>µg</sup> /I	aquatic organ- isms	freshwater	short-term (single instance)
Sodium thioglycol- ate	367-51-1	PNEC	3,8 <sup>µg</sup> / <sub>I</sub>	aquatic organ- isms	marine water	short-term (single instance)

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



## D/E Neutralizing Agar for microbiology

article number: 8850

Relevant PNECs	Relevant PNECs of components of the mixture					
Name of sub- stance	CAS No	End- point	Threshol d level	Organism	Environmental compartment	Exposure time
Sodium thioglycol- ate	367-51-1	PNEC	3,2 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	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 consider-able reduction of the breakthrough time. If in doubt, contact manufacturer. At an approx. 1.5 times larger / smaller layer thickness, the respective breakthrough time is doubled / halved. The data apply only to the pure substance. When transferred to substance mixtures, they may only be considered as a guide.

#### • type of material

NBR (Nitrile rubber)

#### material thickness

>0,11 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: Dust formation. Particulate filter device (EN 143). P1 (filters at least 80 % of airborne particles, colour code: White).

#### **Environmental exposure controls**

Keep away from drains, surface and ground water.

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



## D/E Neutralizing Agar for microbiology

## article number: 8850

# **SECTION 9: Physical and chemical properties**

9.1	Information on basic physical and chemical pro	operties
	Physical state	solid
	Form	powder, crystalline
	Colour	violet
	Odour	characteristic
	Melting point/freezing point	not determined
	Boiling point or initial boiling point and boiling range	not determined
	Flammability	this material is combustible, but will not ignite readily
	Lower and upper explosion limit	not determined
	Flash point	not applicable
	Auto-ignition temperature	not determined
	Decomposition temperature	not relevant
	pH (value)	7,4 – 7,8 (in aqueous solution: 54 <sup>g</sup> / <sub>l</sub> , 25 °C)
	Kinematic viscosity	not relevant
	Solubility(ies)	
	Water solubility	54 <sup>g</sup> / <sub>l</sub> at 100 °C
	Partition coefficient	
	Partition coefficient n-octanol/water (log value):	this information is not available
	Vapour pressure	not determined
	Density	not determined
	Relative vapour density	information on this property is not available
	Particle characteristics	No data available.
	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:	There is no additional information.

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



#### D/E Neutralizing Agar for microbiology

#### article number: 8850

# **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

#### 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

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

#### **10.5** Incompatible materials

There is no additional information.

Release of toxic materials with

Acids.

#### 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.

cute toxicity estimate (ATE) of components of the mixture				
Name of substance         CAS No         Exposure route         ATE				
Sodium hydrogensulphite%	7631-90-5	oral	500 <sup>mg</sup> / <sub>kg</sub>	
Sodium thioglycolate	367-51-1	oral	200 <sup>mg</sup> / <sub>kg</sub>	
Sodium thioglycolate	367-51-1	dermal	1.500 <sup>mg</sup> / <sub>kg</sub>	

#### Acute toxicity of components of the mixture

Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Sodium hydrogensulphite%	7631-90-5	inhalation: dust/mist	LC50	>5,5 <sup>mg</sup> / <sub>l</sub> /4h	rat
Sodium hydrogensulphite%	7631-90-5	dermal	LD50	>2.000 <sup>mg</sup> / <sub>kg</sub>	rat
Sodium thioglycolate	367-51-1	oral	LD50	50 – 200 <sup>mg</sup> / <sub>kg</sub>	rat

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



# D/E Neutralizing Agar for microbiology

#### article number: 8850

Acu	Acute toxicity of components of the mixture					
	Name of substance	CAS No	Exposure route	Endpoint	Value	Species
	Sodium thioglycolate	367-51-1	dermal	LD50	>1.000 - ≤2.00 0 <sup>mg</sup> / <sub>kg</sub>	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

diarrhoea, vomiting, gastrointestinal complaints

### • If in eyes

Data are not available.

#### • If inhaled

Inhalation of dust may cause irritation of the respiratory system

#### • If on skin

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.

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



## D/E Neutralizing Agar for microbiology

## article number: 8850

# **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
Sodium hydrogen- sulphite%	7631-90-5	LC50	62,3 <sup>mg</sup> / <sub>l</sub>	fish	96 h
Sodium hydrogen- sulphite%	7631-90-5	EC50	89 <sup>mg</sup> / <sub>l</sub>	aquatic invertebrates	48 h
Sodium hydrogen- sulphite%	7631-90-5	ErC50	43,8 <sup>mg</sup> / <sub>l</sub>	algae	72 h
Sodium thioglycolate	367-51-1	LC50	>100 <sup>mg</sup> / <sub>l</sub>	fish	96 h
Sodium thioglycolate	367-51-1	EC50	>100 <sup>mg</sup> / <sub>l</sub>	aquatic invertebrates	48 h
Sodium thioglycolate	367-51-1	ErC50	>100 <sup>mg</sup> / <sub>l</sub>	algae	72 h

#### Aquatic toxicity (chronic) of components of the mixture

Name of sub- stance	CAS No	Endpoint	Value	Species	Exposure time
Sodium hydrogen- sulphite%	7631-90-5	EC50	>1.000 <sup>mg</sup> / <sub>l</sub>	microorganisms	3 h
Sodium thioglycolate	367-51-1	EC50	530 <sup>mg</sup> / <sub>l</sub>	microorganisms	3 h

### Biodegradation

Data are not available.

#### 12.2 Process of degradability

Data are not available.

#### 12.3 Bioaccumulative potential

Data are not available.

E	Bioaccumulative potential of components of the mixture					
	Name of substance         CAS No         BCF         Log KOW         BOD5/COD					
	Sodium thioglycolate	367-51-1		-2,99 (pH value: 7, 22 °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

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



## D/E Neutralizing Agar for microbiology

article number: 8850

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. 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**

14.1UN number or ID numbernot subject to transport regulations14.2UN proper shipping namenot assigned14.3Transport hazard class(es)none14.4Packing groupnot assigned14.5Environmental hazardsnon-environmentally hazardous acc. to the dan-<br/>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 information** Not subject to ICAO-IATA.

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



## D/E Neutralizing Agar for microbiology

#### article number: 8850

# SECTION 15: Regulatory information

#### Safety, health and environmental regulations/legislation specific for the substance or mixture 15.1

**Relevant provisions of the European Union (EU)** 

#### **Restrictions according to REACH, Annex XVII**

Dangerous substances with restrictions (REACH, Annex XVII)					
Name of substanceName acc. to inventoryCAS NoRestriction					
Sodium thioglycolate	substances in tattoo inks and perman- ent make-up		R75	75	
Sodium hydrogensulphite%	this product meets the criteria for classification in accordance with Reg- ulation No 1272/2008/EC		R3	3	

#### 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

a 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 on a containers not exceeding 1 litre by 1 December 2010;

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

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

## D/E Neutralizing Agar for microbiology



#### article number: 8850

# Legend 1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such sub-stances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or R75 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 cat-egory 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 cat-egory 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; (e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (\*1), the substance is present in the (f) in the case of a substance in 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; (ii) "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. (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 strictest in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the 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. A. 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 the paragraph 1 or substance then paragraph 1 or substance to paragraph 1 or substance then paragraph 1 or substance to paragraph 1 or su plication of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, para-graph 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 affect 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"; (b) a reference number to uniquely identify the barch: (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.

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



# D/E Neutralizing Agar for microbiology

#### article number: 8850

#### Legend

9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).

10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device or an accessory to a medical device, 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. (Or Concentration of the substance in a mixture: <0.1 % Mass concentration)

#### **Seveso Directive**

2012/18/EU (Seveso III)					
Νο	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the ap- plication of lower and upper-tier re- quirements	Notes		
	not assigned				

#### **Deco-Paint Directive**

VOC content	9,26 %
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#### **Industrial Emissions Directive (IED)**

VOC content	9,26 %
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# Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

none of the ingredients are listed

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

none of the ingredients are listed

#### Water Framework Directive (WFD)

#### List of pollutants (WFD)

Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Sodium thioglycolate	Metals and their compounds		A)	
Sodium hydrogensulphite%	Metals and their compounds		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

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



#### D/E Neutralizing Agar for microbiology

#### article number: 8850

#### Regulation concerning the export and import of hazardous chemicals (PIC)

none of the ingredients are listed

#### **Regulation on persistent organic pollutants (POP)**

none of the ingredients are listed

#### **Other information**

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

#### **National inventories**

Country	Inventory	Status	
AU	AICS	not all ingredients are listed	
CA	DSL	not all ingredients are listed	
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	not all ingredients are listed	
MX	INSQ	not 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	not all ingredients are listed	

#### Legend

DSL ECSI IECSC INSQ ISHA-ENCS KECI NZIOC PICCS REACH Reg.	Australian Inventory of Chemical Substances Chemical Inventory and Control Regulation List of Existing and New Chemical Substances (CSCL-ENCS) 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 Philippine Inventory of Chemicals and Chemical Substances (PICCS) REACH registered Substances
REACH Reg. TCSI TSCA	REACH registered substances 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.

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



## D/E Neutralizing Agar for microbiology

#### article number: 8850

# **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): GHS chapter - Hazard class and category - Hazard statement code(s)	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
2.1	Remarks: For full text of H-phrases: see SECTION 16.		yes
2.1		Supplemental hazard information: change in the listing (table)	yes
2.1	Classification according to Directive 1999/45/EC (DPD): Indication(s) of danger - Symbol codes - R- Phrases		yes
2.1		Classification according to Directive 1999/45/EC (DPD): change in the listing (table)	yes
2.1	Remarks: For full text of R-phrases: see SECTION 16.		yes
2.2		Pictograms: change in the listing (table)	yes
2.2		Precautionary statements - response: change in the listing (table)	yes
2.2		Supplemental hazard information	yes
2.2	Hazardous ingredients for labelling: sodium mercaptoacetate	Hazardous ingredients for labelling: Sodium thioglycolate	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: Sodium mercaptoacetate	contains: Sodium thioglycolate	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

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



## D/E Neutralizing Agar for microbiology

# article number: 8850

## Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations		
Acute Tox.	Acute toxicity		
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de 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 conce ing the International Carriage of Dangerous Goods by Road)		
ATE	Acute Toxicity Estimate		
BCF	Bioconcentration factor		
BOD	Biochemical Oxygen Demand		
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances		
Ceiling-C	Ceiling value		
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures		
COD	Chemical oxygen demand		
DGR	Dangerous Goods Regulations (see IATA/DGR)		
DNEL	Derived No-Effect Level		
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval		
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an iden fier of substances commercially available within the EU (European Union)		
EINECS	European Inventory of Existing Commercial Chemical Substances		
ELINCS	European List of Notified Chemical Substances		
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control		
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations		
IATA	International Air Transport Association		
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)		
ICAO	International Civil Aviation Organization		
IMDG	International Maritime Dangerous Goods Code		
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008		
LC50	50 Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 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		
Met. Corr.	Substance or mixture corrosive to metals		
NLP	No-Longer Polymer		
PBT	Persistent, Bioaccumulative and Toxic		
PNEC	Predicted No-Effect Concentration		

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



# D/E Neutralizing Agar for microbiology

#### article number: 8850

Abbr.	Descriptions of used abbreviations	
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals	
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regula- tions concerning the International carriage of Dangerous goods by Rail)	
S.I. No. 619 of 2001	Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001	
Skin Sens.	Skin sensitisation	
STEL	Short-term exposure limit	
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.

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

#### **Classification procedure**

Physical and chemical properties. The classification is based on tested mixture. Health hazards. Environmental hazards. The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

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

Code	Text
H290	May be corrosive to metals.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H317	May cause an allergic skin reaction.

#### Disclaimer

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