

# Material Safety Data Sheet

## Cetrimide Agar acc. to harm. EP/USP/JP



According to Regulation (EC) No. 1907/2006  
Version 2.0, Issue Date: 2014-10-20, Replaces version: 2011-03-28

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

#### 1.1 Product Identifier

**Article number**

TN 1024

**Trade name**

Cetrimide Agar acc. to harm. EP/USP/JP

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

**Intended use:**

Used to detect *Pseudomonas aeruginosa*. Culture medium for testing non-sterile products. This medium is based on the recommendations of the harmonised method according to EP/USP/JP (2006).

**Uses advised against: -**

#### 1.3 Details of the supplier of the Safety data sheet

**Name of supplier**

sifin diagnostics gmbh  
Berliner Allee 317-321  
13088 Berlin, Germany

**Contact for technical information**

Telefon: +49 (0)30 927030-0 (Head of Department Culture Media)  
Telefax: +49 (0)30 927030-30  
E-Mail: [info@sifin.de](mailto:info@sifin.de)

**E-Mail, competent person**

[msds@conceptec.de](mailto:msds@conceptec.de)

#### 1.4 Emergency telephone number

Phone: +49 (0)30-927030-0, Safety Officer for Medical Devices  
Mo. – Th. 7.30 a.m. - 4.15 p.m., Fr. 7.30 a.m. - 3.00 p.m.

### SECTION 2: Hazards Identification

#### 2.1 Classification of the mixture

**Classification according to Regulation (EC) 1272/2008 (CLP)**

Acute Aquatic Toxicity, Category 2, H411

**Classification according to Directive 1999/45/EG (DPD)**

N, Dangerous for the environment, R51-53

#### 2.2 Label elements

**Labelling according to Regulation (EC) 1272/2008 (CLP)**


Hazard elements for labelling, contains	Cetrimide
Hazard pictogramme(s)	
Signal word	Warning
Hazard statements (H-statement)	H411: Toxic to aquatic life with long lasting effects.
Precautionary Statements (P-statement)	P273: Avoid release to the environment. P501: Dispose of contents/container to local / regional / national

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	regulations.
<b>Additional Labelling elements:</b>	None.
<b>Labelling according to Directive 1999/45/EG (DPD)</b>	
<b>Hazard elements for labelling, contains</b>	Cetrimide
<b>Hazard symbols</b>	
<b>Risk phrases (R-phrases)</b>	R51/53: Toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment
<b>Safety phrases (S-phrases)</b>	S61: Avoid release to the environment. Refer to special instructions/material safety data sheet.
<b>Additional Labelling elements:</b>	None.

### 2.3 Other hazards

None known. Minimum standards for protection measures (TRGS 500) as common in the chemical industry should be followed.



## SECTION 3: Composition/Information on Ingredients

### 3.2 Mixtures

#### Description

Mixture of the following hazardous substances with non-hazardous additives

#### Hazardous ingredients

Substance name	CAS-No.	EC-No.	REACH-No.
Cetrimid	57-09-0	200-311-3	-
Conc. (w/w %)	Classification acc. to DSD	Classification acc. to CLP	Note
≥ 90 – < 100 %	 Xn, R22 Xi, R36/37/38 N, R 50-53	 Acute Tox. 4, H302 Skin Irrit.. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 Aqua. Acute. 1, H400, Aqua. Chron. 1, H410 M-Factor:100	[1]

[1] = Hazardous or environmentally harmful substance; [2] = substance with a Community workplace exposure limit; [3] = PBT substance; [4] = vPvB substance; [5] = SVHC-candidate (substance of very high concern).  
For the full text of the R-phrases / H-Statements mentioned in this section, see section 16.

## SECTION 4: First-Aid-Measures

### 4.1 Description of First-Aid-Measures

General Advice: Immediately remove any clothing soiled by the product.

Inhalation: Fresh air. If breathing stops: immediately apply artificial breathing, if necessary oxygen. Call a physician immediately.

Skin contact: Wash off with water and soap. Call a physician immediately.

Eye contact: Give water to drink (two glasses at most). Seek medical advice immediately.

### 4.2 Most important symptoms and effects, both acute and delayed

No information available.

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### 4.3 Indications of any immediate medical attention and special treatment

Treat symptomatically.

## SECTION 5: Fire-fighting measures

### 5.1 Extinguishing media

Suitable extinguishing media: Water spray jet, carbon dioxide (CO<sub>2</sub>), foam, extinguishing powder.

Unsuitable extinguishing media: Water full jet

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

Combustible. Hazardous combustion products: hydrogen bromide, nitrogen oxides

### 5.3 Advice for fire fighters

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing (see Section 8).

Prevent fire extinguishing water from contaminating surface water or the ground water system.

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures:

Avoid inhalation of dusts. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area. Wear appropriate protective equipment (see Section 8).

### 6.2 Environmental precautions

Do not empty into drains.

### 6.3 Methods and material for containment and cleaning up:

Cover drains. Collect, bind and pump off spills. Observe possible material restrictions (see Section 7.2 and 10.5). Take up dry. Dispose of properly. Clean up affected area. Avoid formation of dusts.

### 6.4 Reference to other sections

See Section 7 for Handling and Storage, Section 8 for appropriate personal protective equipment and Section 13 for disposal considerations.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid generation of dusts. In case of formation of dusts: ensure adequate ventilation.

Precautions against fire and explosion: No special measures necessary.

### 7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storing conditions:

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Recommended storage temperature: light-protected, at 10...25 °C.

Packaging materials: Keep only in the original container.

Conditions for storage rooms and vessels: No special measures necessary.

Hints for joint storage: Store separate from products of the following storage classes: 1, 5.1A, 6.2, 7.

Joint storage with products of storage classes 2.1, 3, 4.1A, 4.2, 4.3, 5.1B-C, 5.2, 6.1A-B allowed, if specific conditions are kept (for further information: see Section 7.2 TRGS 510).

Storage class: 10-13

### 7.3 Specific end use(s)

None known.

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### SECTION 8: Exposure controls / Personal protective equipment

#### 8.1 Control parameters

##### Exposure limits

Substance	CAS-No.	Value	Limit value	Source
-	-	-	-	-

Control- and monitoring procedures: see for example "NIOSH Manual of Analytical Methods", National Institute for Occupational Safety and Health.

##### DNEL- / DMEL-Value

Substance	Cetrimide	-
EC-No.	200-311-3	-
CAS-No.	57-09-0	-

Exposure Route	Species	Time of exposure / Effect	Value	Note
Inhalation	Worker	Acute / local	0,05 mg/kg	-
Dermal	Worker	Longterm / systemic	0,4 mg/kg body weight	-
Dermal	Worker	Langterm / local	0,05 mg/cm <sup>2</sup>	-
Dermal	Worker	Acut / local	0,25 mg/cm <sup>2</sup>	-

##### PNEC-Value

Substance	Cetrimide	-
EC-No.	200-311-3	-
CAS-No.	57-09-0	-

Environmental compartment	Species / Time of exposure / Effect	Value
Fresh water	-	0,022 µg/l
Marine water	-	0,0022 µg/l
STP	-	0,19 mg/l
Soil	-	0,21 mg/kg

#### 8.2 Exposure controls

Appropriate engineering controls: Technical measures and appropriate working procedures should be given priority over the use of personal protective equipment:

Individual protection measures, such as personal protective equipment: Do not breathe dusts. Avoid skin and eye contact.

Hygienic measures	Keep away from food and feeding stuff. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work. Separate storage of protective clothes.
Skin protection	Protective clothes

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<b>Hand protection</b>	Nitrile rubber (reference substance: potassium tellurite)	
	Full contact:	Splash contact:
<b>Glove material</b>	Nitrile rubber	Nitrile rubber
<b>Glove thickness (mm)</b>	≥ 0.11	≥ 0.11
<b>Break through time (min)</b>	≥ 480	≥ 480
	<p>The glove material has to be impermeable and resistant to the product. Due to missing tests no recommendation to the glove material can be given for the product.</p> <p>Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation. The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.</p> <p>The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.</p>	
<b>Respiratory protection</b>	Respiratory protection in case of dust formation. Filtering device: Filter Type P1.	
<b>Eye/ face protection</b>	Goggles.	
<b>Thermal hazards</b>	None known.	
<b>Others</b>	None known.	
<b>Environmental Exposure controls</b>	- Do not empty into drains.	

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

<b>Appearance</b>	Solid
<b>Form</b>	powder
<b>Particle size</b>	Not applicable
<b>Colour</b>	Bright beige.
<b>Odour</b>	Not applicable
<b>Odour threshold</b>	Not applicable
<b>pH</b>	Final pH at 25°C: 7.0 ± 0.2
<b>Melting point / freezing point</b>	No data available
<b>Initial boiling point and boiling range</b>	No data available
<b>Flash point</b>	No data available
<b>Evaporation rate</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Lower flammability or explosive Limits</b>	No data available
<b>Upper flammability or explosive Limits</b>	No data available
<b>Minimum ignition energy</b>	No data available

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Vapour pressure	Not applicable
Relative density	No data available
Solubility(ies)	No data available
Partition coefficient; n-octanol/water	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Thermal decomposition	No data available
Viscosity	No data available
Explosive properties	The product itself is not explosive.
Oxidising properties	The product itself is not oxidizing.

### 9.2 Other Information

Density	No data available
Bulk density	No data available
Further information	Not applicable

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Dangerous reactions are not expected handling the product according to the intended use.

### 10.2 Chemical Stability

The product is chemically stable under standards ambient conditions (room temperature).

### 10.3 Possibility of hazardous reactions

See 10.1.

### 10.4 Conditions to avoid

Strong heating.

### 10.5 Incompatible materials

No data available.

### 10.6 Hazardous decomposition products

Hazardous combustion products: hydrogen bromide, nitrogen oxides.

## SECTION 11: Toxicological Information

### 11.1 Information on toxicological effects

#### Acute Toxicity

Exposition	LD50/LC50-Value	Species/test system	Source
Oral	> 2000 mg/kg (ATE)	Calculation method	

#### Skin irritation

No data available.

#### Eye irritation

No data available.

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Sensitisation: No data available.  
Repeated dose toxicity: No data available.  
Mutagenicity: No data available.  
Carcinogenicity: No data available.  
Toxic for reproduction: No data available.  
STOT – single exposure: No data available.  
STOT – repeated exposure: No data available.

### 11.2 Further Information

Symptoms related to the physical, chemical and toxicological characteristics:  
Systemic effects: No data available.  
Delayed and immediate effects as well as chronic effects from short and long-term exposure: No data available.  
Further toxicological information: No data available.

#### Components: Cetrimide Acute Toxicity

Exposition	LD50/LC50-Value	Species/test system	Source
Oral	410 mg/kg	rat	Supplier MSDS

#### Skin Irritation

Causes skin irritation.

#### Eye Irritation

Rabbit, result: severe irritations (RTECS). Causes serious eye irritation.  
STOT – single exposure: May cause sensitization by inhalation.

## SECTION 12: Ecological information

### 12.1 Toxicity

Toxicity	Species/test system	Value
-	-	-

### 12.2 Persistence and degradability Biodegradation

Method	Elimination rate	Classification	Source
-	-	-	-

Biodegradation/Further Information: No data available.  
Further Information: No data available.

### 12.3 Bioaccumulative potential

No data available.

### 12.4 Mobility in soil

No data available.

### 12.5 Results of der PBT & vPvB assessment

Product does not contain substances which meet the PBT/vPvB criteria of REACH, annex XIII.

### 12.6 Other adverse effects

Biological effects: No data available.  
Further information on ecology: Discharge in the environment must be avoided.

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### Components: Cetrimide

#### Acute Toxicity

Toxicity	Species/test system	Value
<i>Toxicity to fish</i>		
LC50	Danio rerio (zebra fish, OECD 203, 96 h (ECHA))	0,2 mg/l
<i>Toxicity to daphnia and other aquatic invertebrates</i>		
EC50	Daphnia magna (great water flea), OECD 202, 48 h (ECHA)	0,037 mg/l
<i>Toxicity to algae</i>		
ErC50	Desmodesmus subspicatus (green algae), 72 h (ECHA)	0,004 mg/l
<i>Toxicity to bacteriae</i>		
EC50	Photobacterium phosphoreum, 5 min (Lit.)	9,8 mg/l

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product: Recommendation: Waste can be disposed of in appropriate and approved facilities in compliance with applicable technical regulations following consultation with approved waste disposal management companies and authorities in charge.

Uncleaned Packaging: Recommendation: Completely emptied packages can be recycled. Packing which cannot be properly cleaned must be disposed of. Observe local/state/federal regulations.

Cleaned Packaging: Non-contaminated packages must be recycled or disposed of.

Waste codes / waste designations according to EWC / AVV: The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

## SECTION 14: Transport information

	ADR	RID	ADNR	IMDG	IATA
14.1 UN-Number	UN3077				
14.2 Proper shipping name	Environmentally hazardous substance, solid, n.o.s (cont. Cetrimide)				
14.3 Hazard class	9				
14.4 Packing group	III				
Tunnel code	E				
EmS	F-A, S-F				

14.5 Environmental Hazards: Marine pollutant

14.6 Special precautions for user: -

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IPBC code: -

## SECTION 15: Regulatory information

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

National and local regulations must be observed. For information on labelling please refer to section 2 of this document.

EU legislations: Subject to Directive 96/82/EG: not applicable.

National Regulations: -

Restrictions to occupation: Observe employment restrictions for pregnant and nursing mothers according to the



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'mother protection guideline' (92/85/EEC). Observe restrictions to employment for juveniles according to the 'protection of young people at work directive' (94/33/EC).

### TA Air

CAS-No.	Substance	Number	Class
-	-	-	-

**Water hazard class:** 3(classification according to Annex 4 VwVWS (Deutschland)).

### 15.2 Chemical safety assessment

For this product a chemical assessment was not carried out.

### SECTION 16: Other Information

Further Information: None.

Full text of R-phrases referred to under Sections 2 and 3

R-phrases	Text
22	Harmful if swallowed.
36/37/38	Irritating to eyes, respiratory system and skin.
50-53	Very toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment.
51-53	Toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment.

Full text of H-Statements referred to under Sections 2 and 3

H-statements	Text
302	Harmful if swallowed.
315	Causes skin irritation.
319	Causes serious eye irritation.
335	May cause respiratory irritation.
400	Very toxic to aquatic life.
410	Very toxic to aquatic life with long lasting effects.
H411	Very toxic to aquatic life with long lasting effects.

**Further Information:** The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

The information is based on present level of our knowledge. It does not, however, give assurances of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

**Changes:** The present MSDS is a completely revised MSDS fulfilling the requirements of Annex II of Regulation (EC) 1907/2006 and Annex II of Regulation (EC) 453/2010.