Material Safety Data Sheet
MacConkey Broth acc. to harm. EP/USP/JP

According to Regulation (EC) No. 1907/2006
Version 2.1, Issue Date: : 2020-04-22, Replaces version: 2015-04-22

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

1.1 Product Identifier

Article number
TN1027

Trade name
MacConkey Broth acc. to harm. EP/USP/JP

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

Intended use
Test for *Escherichia coli*. Culture medium for testing non-sterile products. The medium fulfils the requirements of the harmonised methods according to EP/USP/JP. No IVD - The laboratory diagnostic examination of human samples has not been evaluated.

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)30 700 144-0 (Head of Department Culture Media)
Telefax: +49 (0)30 700 144-30
E-Mail: info@sifin.de

E-Mail, competent person
msds@sifin.de

1.4 Emergency telephone number

Phone: +49 (0)30 700 144-0, 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)



Skin Irritation, Category 2, H315
Eye Irritation, Category 2, H319

Classification according to Directive 1999/45/EG (DPD)
This product is classified as not hazardous according to Directive 1999/45/EG.

2.2 Label elements

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

Hazard elements for labelling, contains	Ox bile
Hazard piktogramme(s)	
Signal word	Warning
Hazard statements (H-statement)	H315: Causes skin irritation. H319: Causes serious eye irritation..
Precautionary Statements (P-statement)	P280: Wear protective gloves/protective clothing/eye protection/face protection.

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	P302 + P352: IF ON SKIN: Wash with plenty of soap and water. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Additional Labelling Elements:	None

Labelling according to Directive 1999/45/EG (DPD)
The product does not need to be labelled in accordance with Directive 1999/45/EC.

Additional Labelling elements:
Safety data sheet available on request for professional users.

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.
Ox bile	8008-63-7	232-369-0	-
Conc. (w/w %)	**Classification acc. to DSD**	**Classification acc. to CLP**	**Note**
≥ 10 – < 20 %	 Xi, R36/37/38	 Skin Irrit.. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335	[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: Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician immediately.
Ingestion: Give water to drink (two glasses at most). If symptoms persist, seek medical advice.

4.2 Most important symptoms and effects, both acute and delayed
No information available.

4.3 Indications of any immediate medical attention and special treatment
Treat symptomatically.

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SECTION 5: Fire-fighting measures

5.1 Extinguishing media
Suitable extinguishing media: Water spray jet, carbon dioxide (CO_2), foam, extinguishing powder.
Unsuitable extinguishing media: Water full jet

5.2 Special Hazards arising from the substance or mixture
Hazardous combustion products: CO, CO_2.

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 appropiate 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 incompatabilities
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 Spezific 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	-	-	
EC-No.	-	-	
CAS-No.	-	-	

Exposure Route	Species	Time of exposure / Effect	Value	Note
-	-	-	-	-

PNEC-Value

Substance	-	-	
EC-No.	-	-	
CAS-No.	-	-	

Environmental compartment	Species / Time of exposure / Effect	Value
-	-	-

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	
Hand protection	Nitrile rubber	
	Full contact:	Splash contact:
Glove material	Nitrile rubber	Nitrile rubber
Glove thickness (mm)	≥ 0.11	≥ 0.11
Break through time (min)	≥ 480	≥ 480
	The glove material has to be impermeable and resistant to the product. Due to	

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	missing tests no recommendation to the glove material can be given for the product. 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. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
Respiratory protection	Respiratory protection in case of dust formation. Filtering device: Filter Type P1.
Eye/ face protection	Goggles.
Thermal hazards	None known.
Others	None known.
Environmental Exposure controls -	Do not empty into drains.

SECTION 9: Physical and chemical porperties

9.1 Information on basic physical and chemical properties

Appearence	Solid
Form	powder
Particle size	Not applicable
Colour	Greenish
Odour	Not applicable
Odour threshold	Not applicable
pH	Final pH at 25 °C: 7.3 ± 0.2
Melting point / freezing point	No data available
Initial boiling point and boiling range	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Lower flammability or explosive Limits	No data available
Upper flammability or explosive Limits	No data available
Minimum ignition energy	No data available
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

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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
No data available.

10.5 Incompatible materials
Strong oxidants.

10.6 Hazardous decomposition products
Hazardous combustion products: CO, CO_2.

SECTION 11: Toxicological Information

11.1 Information on toxicological effects
Acute Toxicity

Exposition	LD50/LC50-Value	Species/test system	Source
-	-	-	-

Skin irritation
No data available.

Eye irritation
No data available.

Sensitation: 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.

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11.2 Further Information

Symptoms related to the physical, chemical and toxicological characteristics: 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.

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.

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

Not classified as dangerous in the meaning of transport regulations.

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: -

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Restrictions to occupation: Observe employment restrictions for pregnant and nursing mothers according to the '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: 1 (classificcation according to Annex 4 VwVwS (Deutschland)).

15.2 Chemical safety assessment

For this product a chemical assessment was not carried out.

SECTION 16: Other Informations

Further Informations: None.
Full text of R-phrases referred to under Sections 2 and 3

R-phrases	Text
36/37/38	Irritating to eyes, respiratory system and skin.

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

H-statement	Text
315	Causes skin irritation.
319	Causes serious eye irritation.
335	May cause respiratory irritation.

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.

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