

Safety Data Sheet dated 12/3/2019, version 4

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

1.1. Product identifier

Mixture identification:

Trade name: FecalSwab

FecalSwab 2 ml green cap + rectal with plastic ring

Trade code: 4E048S

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

Recommended use:

The Copan FecalSwab Collection, Transport and Preservation System is intended for the collection of rectal swabs and fecal specimens and to preserve the viability of enteric pathogenic bacteria during transport from the collection site to the testing laboratory. In the laboratory, FecalSwab specimens are processed using standard clinical laboratory operating procedures for culture.

1.3. Details of the supplier of the safety data sheet

Company:

COPAN ITALIA SPA

VIA PEROTTI, 10 – 25125 BRESCIA

Phone : +39 0302687211

Competent person responsible for the safety data sheet:

msds@copangroup.com

Legal Manufacturer:

Copan Italia SpA - Italia

Phone : +39 0302687211

1.4. Emergency telephone number

Phone : +390266101029 (Centro antiveneni Niguarda ca' Grande - Milano)

Phone : +390881732326 (Az. Osp. Univ. - Foggia)

Phone : +390817472870 (Az. Osp. " A. Caldarelli " Napoli)

Phone : +390649978000 (Policlinico "Umberto I " Roma)

Phone : +39063054343 (Policlinico "A. Gemelli" Roma)

Phone : +862131765555 (Institute SHANGHAI)

Phone : +862131015117 (Institute SHANGHAI)

Phone: +39-055-6120735 (technical Support Hours : 9:00-13:00, 14:00-18:00 GMT+1:00)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

EC regulation criteria 1272/2008 (CLP)

The product is not classified as dangerous according to Regulation EC 1272/2008 (CLP).

Adverse physicochemical, human health and environmental effects:

No other hazards

2.2. Label elements

The product is not classified as dangerous according to Regulation EC 1272/2008 (CLP).

Hazard pictograms:

None

Hazard statements:

None

Precautionary statements:

None

Special Provisions:

None

Special provisions according to Annex XVII of REACH and subsequent amendments:

None

Safety Data Sheet
4E048S

- 2.3. Other hazards
vPvB Substances: None - PBT Substances: None
Other Hazards:
No other hazards

SECTION 3: Composition/information on ingredients

- 3.1. Substances
N.A.
3.2. Mixtures
Hazardous components within the meaning of the CLP regulation and related classification:

Qty	Name	Ident. Number	Classification
236 ppm	Sodio Thioglicolato PURO 100%	CAS: 367-51-1 EC: 206-696-4	⚠ 3.1/4/Oral Acute Tox. 4 H302 ⚠ 3.1/4/Dermal Acute Tox. 4 H312 ⚠ 3.4.2/1 Skin Sens. 1 H317

SECTION 4: First aid measures

- 4.1. Description of first aid measures
In case of skin contact:
Wash with plenty of water and soap.
In case of eyes contact:
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
In case of Ingestion:
Do not under any circumstances induce vomiting. OBTAIN A MEDICAL EXAMINATION IMMEDIATELY.
In case of Inhalation:
Remove casualty to fresh air and keep warm and at rest.
4.2. Most important symptoms and effects, both acute and delayed
None
4.3. Indication of any immediate medical attention and special treatment needed
Treatment:
None

SECTION 5: Firefighting measures

- 5.1. Extinguishing media
Suitable extinguishing media:
Water.
Carbon dioxide (CO₂).
Extinguishing media which must not be used for safety reasons:
None in particular.
5.2. Special hazards arising from the substance or mixture
Do not inhale explosion and combustion gases.
Burning produces heavy smoke.
5.3. Advice for firefighters
Use suitable breathing apparatus .
Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Move undamaged containers from immediate hazard area if it can be done safely.

SECTION 6: Accidental release measures

- 6.1. Personal precautions, protective equipment and emergency procedures
Wear personal protection equipment.
Remove persons to safety.
See protective measures under point 7 and 8.
6.2. Environmental precautions

Safety Data Sheet
4E048S

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains. Retain contaminated washing water and dispose it.

In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

Suitable material for taking up: absorbing material, organic, sand

6.3. Methods and material for containment and cleaning up

Wash with plenty of water.

6.4. Reference to other sections

See also section 8 and 13

SECTION 7: Handling and storage
7.1. Precautions for safe handling

Avoid contact with skin and eyes, inhalation of vapours and mists.

Do not eat or drink while working.

See also section 8 for recommended protective equipment.

7.2. Conditions for safe storage, including any incompatibilities

Keep away from food, drink and feed.

Incompatible materials:

None in particular.

Instructions as regards storage premises:

Adequately ventilated premises.

7.3. Specific end use(s)

Product Pack Insert may be available, ask to legal manufacturer

SECTION 8: Exposure controls/personal protection
8.1. Control parameters

No occupational exposure limit available

DNEL Exposure Limit Values

N.A.

PNEC Exposure Limit Values

N.A.

8.2. Exposure controls

Eye protection:

Not needed for normal use. Anyway, operate according good working practices.

Protection for skin:

No special precaution must be adopted for normal use.

Protection for hands:

Not needed for normal use.

Respiratory protection:

Not needed for normal use.

Thermal Hazards:

None

Environmental exposure controls:

None

Appropriate engineering controls:

None

SECTION 9: Physical and chemical properties
9.1. Information on basic physical and chemical properties

Properties	Value	Method:	Notes
Color:	colourless	--	--
Appearance:	transparent	--	--
Odour:	N.A.	--	--

Safety Data Sheet
4E048S

Odour threshold:	N.A.	--	--
pH:	7,20 +/- 0,30	--	--
Melting point / freezing point:	N.A.	--	--
Initial boiling point and boiling range:	N.A.	--	--
Flash point:	N.A.	--	--
Evaporation rate:	N.A.	--	--
Solid/gas flammability:	N.A.	--	--
Upper/lower flammability or explosive limits:	N.A.	--	--
Vapour pressure:	N.A.	--	--
Vapour density:	N.A.	--	--
Relative density:	N.A.	--	--
Solubility in water:	N.A.	--	--
Solubility in oil:	N.A.	--	--
Partition coefficient (n-octanol/water):	N.A.	--	--
Auto-ignition temperature:	N.A.	--	--
Decomposition temperature:	N.A.	--	--
Viscosity:	N.A.	--	--
Explosive properties:	N.A.	--	--
Oxidizing properties:	N.A.	--	--

9.2. Other information

Properties	Value	Method:	Notes
Miscibility:	N.A.	--	--
Fat Solubility:	N.A.	--	--
Conductivity:	N.A.	--	--
Substance Groups relevant properties	N.A.	--	--

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions

Safety Data Sheet
4E048S

- 10.2. Chemical stability
Stable under normal conditions
- 10.3. Possibility of hazardous reactions
None
- 10.4. Conditions to avoid
Stable under normal conditions.
- 10.5. Incompatible materials
None in particular.
- 10.6. Hazardous decomposition products
None.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicological information of the product:

FecalSwab

FecalSwab 2 ml green cap + rectal with plastic ring

a) acute toxicity

Not classified

Based on available data, the classification criteria are not met

b) skin corrosion/irritation

Not classified

Based on available data, the classification criteria are not met

c) serious eye damage/irritation

Not classified

Based on available data, the classification criteria are not met

d) respiratory or skin sensitisation

Not classified

Based on available data, the classification criteria are not met

e) germ cell mutagenicity

Not classified

Based on available data, the classification criteria are not met

f) carcinogenicity

Not classified

Based on available data, the classification criteria are not met

g) reproductive toxicity

Not classified

Based on available data, the classification criteria are not met

h) STOT-single exposure

Not classified

Based on available data, the classification criteria are not met

i) STOT-repeated exposure

Not classified

Based on available data, the classification criteria are not met

j) aspiration hazard

Not classified

Based on available data, the classification criteria are not met

Toxicological information of the main substances found in the product:

Sodio Thioglicolato PURO 100% - CAS: 367-51-1

a) acute toxicity:

Test: LD50 - Route: Oral - Species: Mouse = 504 mg/kg

SECTION 12: Ecological information

12.1. Toxicity

Adopt good working practices, so that the product is not released into the environment.

FecalSwab

FecalSwab 2 ml green cap + rectal with plastic ring

Not classified for environmental hazards

Based on available data, the classification criteria are not met

Safety Data Sheet
4E048S

- 12.2. Persistence and degradability
N.A.
- 12.3. Bioaccumulative potential
N.A.
- 12.4. Mobility in soil
N.A.
- 12.5. Results of PBT and vPvB assessment
vPvB Substances: None - PBT Substances: None
- 12.6. Other adverse effects
None

SECTION 13: Disposal considerations

- 13.1. Waste treatment methods
Recover if possible. In so doing, comply with the local and national regulations currently in force.

SECTION 14: Transport information

- 14.1. UN number
Not classified as dangerous in the meaning of transport regulations.
- 14.2. UN proper shipping name
N.A.
- 14.3. Transport hazard class(es)
N.A.
- 14.4. Packing group
N.A.
- 14.5. Environmental hazards
ADR-Environmental Pollutant: No
IMDG-Marine pollutant: No
- 14.6. Special precautions for user
N.A.
- 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code
N.A.

SECTION 15: Regulatory information

- 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
 - Dir. 98/24/EC (Risks related to chemical agents at work)
 - Dir. 2000/39/EC (Occupational exposure limit values)
 - Regulation (EC) n. 1907/2006 (REACH)
 - Regulation (EC) n. 1272/2008 (CLP)
 - Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013
 - Regulation (EU) 2015/830
 - Regulation (EU) n. 286/2011 (ATP 2 CLP)
 - Regulation (EU) n. 618/2012 (ATP 3 CLP)
 - Regulation (EU) n. 487/2013 (ATP 4 CLP)
 - Regulation (EU) n. 944/2013 (ATP 5 CLP)
 - Regulation (EU) n. 605/2014 (ATP 6 CLP)
 - Regulation (EU) n. 2015/1221 (ATP 7 CLP)
 - Regulation (EU) n. 2016/918 (ATP 8 CLP)
 - Regulation (EU) n. 2016/1179 (ATP 9 CLP)
 - Regulation (EU) n. 2017/776 (ATP 10 CLP)
- Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006 (REACH) and subsequent modifications:
 - Restrictions related to the product:
No restriction.
 - Restrictions related to the substances contained:
No restriction.

Safety Data Sheet
4E048S

Where applicable, refer to the following regulatory provisions :

Directive 2012/18/EU (Seveso III)
 Regulation (EC) nr 648/2004 (detergents).
 Dir. 2004/42/EC (VOC directive)

Provisions related to directive EU 2012/18 (Seveso III):

Seveso III category according to Annex 1, part 1
 None

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for the mixture.
 Substances for which a Chemical Safety Assessment has been carried out:
 None

SECTION 16: Other information

Full text of phrases referred to in Section 3:

H302 Harmful if swallowed.
 H312 Harmful in contact with skin.
 H317 May cause an allergic skin reaction.

Hazard class and hazard category	Code	Description
Acute Tox. 4	3.1/4/Dermal	Acute toxicity (dermal), Category 4
Acute Tox. 4	3.1/4/Oral	Acute toxicity (oral), Category 4
Skin Sens. 1	3.4.2/1	Skin Sensitisation, Category 1

Paragraphs modified from the previous revision:

SECTION 2: Hazards identification
 SECTION 3: Composition/information on ingredients
 SECTION 9: Physical and chemical properties

This document was prepared by a competent person who has received appropriate training.

Main bibliographic sources:

ECDIN - Environmental Chemicals Data and Information Network - Joint Research Centre,
 Commission of the European Communities
 SAX's DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS - Eight Edition - Van
 Nostrand Reinold

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality.

It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

This MSDS cancels and replaces any preceding release.

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
 ATE: Acute Toxicity Estimate
 ATEmix: Acute toxicity Estimate (Mixtures)
 CAS: Chemical Abstracts Service (division of the American Chemical Society).
 CLP: Classification, Labeling, Packaging.
 DNEL: Derived No Effect Level.
 EINECS: European Inventory of Existing Commercial Chemical Substances.
 GefStoffVO: Ordinance on Hazardous Substances, Germany.

Safety Data Sheet
4E048S

GHS:	Globally Harmonized System of Classification and Labeling of Chemicals.
IATA:	International Air Transport Association.
IATA-DGR:	Dangerous Goods Regulation by the "International Air Transport Association" (IATA).
ICAO:	International Civil Aviation Organization.
ICAO-TI:	Technical Instructions by the "International Civil Aviation Organization" (ICAO).
IMDG:	International Maritime Code for Dangerous Goods.
INCI:	International Nomenclature of Cosmetic Ingredients.
KSt:	Explosion coefficient.
LC50:	Lethal concentration, for 50 percent of test population.
LD50:	Lethal dose, for 50 percent of test population.
PNEC:	Predicted No Effect Concentration.
RID:	Regulation Concerning the International Transport of Dangerous Goods by Rail.
STEL:	Short Term Exposure limit.
STOT:	Specific Target Organ Toxicity.
TLV:	Threshold Limiting Value.
TWA:	Time-weighted average
WGK:	German Water Hazard Class.