

Safety Data Sheet dated 29/3/2023, version 6

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

1.1. Product identifier

Mixture identification:

Trade name:

Transystem Amies W/O CH Plastic Applicator Rayon Tipped

Trade code:

108C.USE

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

Recommended use:

Copan Transystem™ are sterile ready-to-use systems intended for the collection, transport and preservation of clinical specimens for bacteriological examinations.

Uses advised against:

Not suitable for any other application other than its intended use

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

City Hospital, Birmingham B187QH, United Kingdom Phone: +44 121 507 4123

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

2.3. Other hazards

No PBT, vPvB or endocrine disruptor substances present in concentration $\geq 0.1\%$

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
241 ppm	Sodium Thioglycolate	CAS: 367-51-1 EC: 206-696-4 REACH No.: 01-2119968564-24-0010	⚠ 2.16/1 Met. Corr. 1 H290 ⚠ 3.1/3/Oral Acute Tox. 3 H301 ⚠ 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
 - 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.
 - See also section 8 for recommended protective equipment.
 - Advice on general occupational hygiene:
 - Do not eat or drink while working.
- 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
Physical state:	Liquid	--	--
Colour:	N.A.	--	--

Odour:	Not applicable	--	--
Odour threshold:	Not applicable	--	--
Melting point/freezing point:	N.A.	--	--
Boiling point or initial boiling point and boiling range:	N.A.	--	--
Flammability:	N.A.	--	--
Lower and upper explosion limit:	N.A.	--	--
Flash point:	N.A.	--	--
Auto-ignition temperature:	N.A.	--	--
Decomposition temperature:	N.A.	--	--
pH:	7,3	--	--
Kinematic viscosity:	N.A.	--	--
Solubility in water:	N.A.	--	--
Solubility in oil:	N.A.	--	--
Partition coefficient n-octanol/water (log value):	N.A.	--	--
Vapour pressure:	N.A.	--	--
Density and/or relative density:	N.A.	--	--
Relative vapour density:	N.A.	--	--
Particle characteristics:			
Particle size:	N.A.	--	--

9.2. Other information
 No other relevant information

SECTION 10: Stability and reactivity

- 10.1. Reactivity
 Stable under normal conditions
- 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 hazard classes as defined in Regulation (EC) No 1272/2008

Toxicological information of the product:

Transystem Amies W/O CH Plastic Applicator Rayon Tipped

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:

Sodium Thioglycolate - CAS: 367-51-1

a) acute toxicity:

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

11.2. Information on other hazards

Endocrine disrupting properties:

No endocrine disruptor substances present in concentration $\geq 0.1\%$

SECTION 12: Ecological information

12.1. Toxicity

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

Transystem Amies W/O CH Plastic Applicator Rayon Tipped

Not classified for environmental hazards

Based on available data, the classification criteria are not met

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. Endocrine disrupting properties
No endocrine disruptor substances present in concentration $\geq 0.1\%$
- 12.7. Other adverse effects
None

SECTION 13: Disposal considerations

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

SECTION 14: Transport information

- 14.1. UN number or ID 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. Maritime transport in bulk according to IMO instruments
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) n. 2020/878
 - 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)
 - Regulation (EU) n. 2018/669 (ATP 11 CLP)
 - Regulation (EU) n. 2018/1480 (ATP 13 CLP)
 - Regulation (EU) n. 2019/521 (ATP 12 CLP)

Regulation (EU) n. 2020/217 (ATP 14 CLP)
 Regulation (EU) n. 2020/1182 (ATP 15 CLP)
 Regulation (EU) n. 2021/643 (ATP 16 CLP)
 Regulation (EU) n. 2021/849 (ATP 17 CLP)
 Regulation (EU) n. 2022/692 (ATP 18 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:

Restriction 75

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:

H290 May be corrosive to metals.

H301 Toxic if swallowed.

H312 Harmful in contact with skin.

H317 May cause an allergic skin reaction.

Hazard class and hazard category	Code	Description
Met. Corr. 1	2.16/1	Substance or mixture corrosive to metals, Category 1
Acute Tox. 3	3.1/3/Oral	Acute toxicity (oral), Category 3
Acute Tox. 4	3.1/4/Dermal	Acute toxicity (dermal), Category 4
Skin Sens. 1	3.4.2/1	Skin Sensitisation, Category 1

This safety data sheet has been completely updated in compliance to Regulation 2020/878.

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.
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.