

Information document of 29/11/2021, version 8

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

1.1. Product identifier

Mixture identification:

Trade name: Self-vaginal swab, marked breakpoint.

Trade code: 552C.80

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

Recommended use:

The swabs 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. Information on the provider of the information document

Company:

COPAN ITALIA SPA

VIA PEROTTI, 10 – 25125 BRESCIA

Phone : +39 0302687211

Competent person responsible for the information document:

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

THE ARTICLE IN QUESTION IS NOT SUBJECT TO REACH REGULATION AND THE CLASSIFICATION IS PROVIDED ON VOLUNTARY BASIS

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

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

Identification of the substance:

Trade code: 552C.80

None.

3.2. Mixtures

N.A.

SECTION 4: First aid measures

4.1. Description of first aid measures

In case of skin contact:

None in particular.

In case of eyes contact:

None in particular.

In case of Ingestion:

None in particular.

In case of Inhalation:

None in particular.

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

None in particular

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.

Extinguishing media which must not be used for safety reasons:

None in particular.

5.2. Special hazards arising from the substance or mixture

None in particular.

5.3. Advice for firefighters

Use suitable breathing apparatus .

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

None in particular.

See protective measures under point 7 and 8.

6.2. Environmental precautions

None in particular.

6.3. Methods and material for containment and cleaning up

None in particular.

6.4. Reference to other sections

See also section 8 and 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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:	Solid	--	--
Colour:	N.A.	--	--
Odour:	odorless	--	--
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:	N.A.	--	--
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 substance:

Self-vaginal swab, marked breakpoint.

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

- 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.
Self-vaginal swab, marked breakpoint.
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)
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.
- 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 substance.

SECTION 16: Other information

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.