

MicroSwab, MicroSwabPlus MicroPelletRT, MicroPelletRTPlus, MicroPelletRT10

SDS according to Annex of Commission Regulation (EU) No 830/2015 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning REACH.

Version 1.3

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SECTION 1: IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product identifier

Product name: MicroSwab, MicroSwabPlus, MicroPelletRT, MicroPelletRTPlus, MicroPelletRT10

Product codes: MS-XXXX, MS2-XXXX, MPRT-XXXX, MPRTP-XXXX, MPRT10-XXXX

XXXX –number characteristic for a given microorganism.

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

Identified uses: Lyophilized pellets containing live, potentially pathogenic microorganisms, intended for

professional use in microbiological laboratories.

Uses advised against: None identified.

1.3 Details of the supplier of the safety data sheet

Manufacturer:

Mecconti S.A.R.L Sp. z o. o. Rakowiecka Str. 36, 02-532 Warsaw, Poland tel. +48 22 397 45 33, fax +48 22 504 72 13 **Contact person:** e-mail: sales@mecconti.com

1.4 Emergency telephone number

- 112 Cell phone and landline; 998 State Fire Brigade; Medical emergency 999
- +48 667 609 607 (Mecconti 24 hour Emergency Number English language)
- +48 22 397 45 33 (office hours of Mecconti: 8-16 English language)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Product is not classified as hazardous according to Regulation EC 1272/2008 (CLP)

Health hazards The preparations contain live microorganisms that can potentially cause infections and diseases.

Physiocochemical hazards Not applicable

Environmental hazards Not applicable

The full texts of H phrases are given in Section 16 of SDS.

2.2 Label elements

Label elements according to Regulation EC 1272/2008 (CLP)

Pictogram:

Type of hazard





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Signal word: Does not occur.

Hazard statements indicating type of danger: Does not occur.

Precautionary statements indicating conditions of safe use: Does not occur.

Additional remarks:

The preparation contains live microorganisms that can potentially cause infections and diseases characteristic for a given strain described on the product label.

2.3. Other hazards:

This mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0,1% or higher, and they are not included in Annex XVII of Regulation (EC) No 1907/2006.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances: Not applicable

3.2 Mixtures:

Composition: Lyophilized pellets containing live, potentially pathogenic microorganisms, that can cause infections and diseases characteristic of the strain described on the label.

Microorganisms belonging to the Biosafety level 1 or 2 in accordance with the recommendations of WHO (World Health Organization).

The full texts of H phrases, hazard classes are given in Section 16 of SDS.

Pellet/composition of the medium:

Name of the component	CAS number	% content in the mixture	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Gelatin	(CAS-No.) 9000-70-8 (EC-No.) 232-554-6	5 - 60	Not classified
Sucrose	(CAS-No.) 57-50-1 (EC-No.) 200-334-9	0 - 60	Not classified
Glucose	(CAS-No.) 50-99-7 (EC-No.) 200-075-1	0 - 60	Not classified
Phosphoric acid, potassium salt (1:1)	(CAS-No.) 7778-77-0 (EC-No.) 231-913-4	5 - 35	Not classified
Albumins, blood serum	(CAS-No.) 9048-46-8 (EC-No.) 232-936-2	10 - 30	Not classified
Skim milk (Bovine)	None	2 - 20	Not classified
Water	(CAS-No.) 7732-18-5 (EC-No.) 231-791-2	1 - 10	Not classified
L-Ascorbic acid	(CAS-No.) 50-81-7 (EC-No.) 200-066-2	1-5	Not classified
Carbon	(CAS-No.) 7440-44-0 (EC-No.) 231-153-3	0-5	Not classified

Ingredients according to the requirements of Regulation (EC) No. 648/2004 on detergents:

- not present in the formulation



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SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General Advice: Immediately remove contaminated clothing, rinse with water, never give anything by mouth to an unconscious person.

Inhalation: Remove person to fresh air, keep at rest, consult doctor mentioning the name of the microorganism.

Skin contact: Rinse with plenty of water with soap, then disinfect with an antiseptic solution.

Eye contact: Remove contact lenses, wash immediately with plenty of water or eye liquid for at least 15 minutes, keeping eyelids open, consult a doctor immediately mentioning the name of the microorganism.

Ingestion: Rinse mouth with water, consult a doctor immediately mentioning the name of the microorganism.

4.2 Most important symptoms and effects, both acute and delayed

Characteristic for the strain of the microorganism described on the product label. Inhalation of infectious materials may result in infection. Inhalation of infectious materials may result in infection. May be harmful if swallowed.

4.3 Indication of any immediate medical attention and special treatment needed

Symptomatic treatment indicated, **immediately mention the name of the microorganism to your health care provider.**

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:

Fire extinguishing agents should be appropriate to the size of the fire and burning media.

In case of fire, you can use the following extinguishing media: dry chemical, water, foam and carbon dioxide.

Unsuitable extinguishing media: undefined

5.2 Special hazards arising from the substance or mixture

Combustion can result in: carbon oxides.

5.3 Advice for firefighters

Use personal protective equipment, depending on the size of the fire and suitable for burning materials. Dispose of fire debris and contaminated water in accordance with waste regulations.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Avoid direct contact with eyes and skin, keep careful.

Wear personal protective equipment, use suitable protective clothing, gloves, eye protection/face protection.

Do not drink, eat, or smoke while working.

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and materials for containment and cleaning up

In the event of damage to the vial or swab with pellet, isolate the hazard zone, and inform nearby personnel.

Stop the leak if it concerns the solution (place the damaged container in a protective container), collect small amounts of spilled liquid with disposable towels/paper cleaners, collect it into a closed container. Send for utilization - treat as a biologically hazardous material.

Disinfect the hazard zone in accordance with the recommendations of the preparation manufacturer, to allow the preparation to work effectively (disinfectants based on hypochlorite used in accordance with the instructions are effective in combating all strains of microorganisms offered by MECCONTI).

Sterilized vials and swabs pose no further risk to the environment.



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6.4 Reference to other sections

Dispose of in accordance with the recommendations set out in Section 13 Information regarding personal protective equipment specified in Section 8

7: HANDLING AND STORAGE

7.1 Precautions for safe handling

CAUTION!: The preparations contain live microorganisms and should be used only by qualified microbiological personnel.

CAUTION !: It is recommended to use the preparations only in rooms of at Biosafety level category appropriate for the microorrganism.

Handling of the product: use as directed, keep careful, do not eat or drink and do not smoke while using mixture.

Avoid contact with eyes, avoid prolonged contact with skin.

Detailed information on the use of the product can be found on the label and leaflet.

Wash hands during breaks and after finishing work. Keep away from food, drink and animal feeding.

Remove outer working clothes before entering the dining area.

Immediately remove contaminated clothing and wash before re-wearing.

Handle in accordance with good industrial hygiene and safety advice.

7.2 Conditions for safe storage, including any incompatibilities

Keep out of reach of unauthorized persons.

Store in original, properly labeled, tightly closed containers in a separate storage room with good ventilation. Store at 2-8°C or according to a specification on the label.

CAUTION!: Respect the expiry date of the product specified on the packaging.

7.3 Specific end use(s)

No information about the applications other than those listed in section 1.2.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Ingredients harmful to health that require monitoring at the workplace and their limits:

-not present in the mixture formulation

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Provide good room ventilation. Restrict access to the area of use.

8.2.2 Individual protection measures, such as personal protective equipment

Handle in accordance with good laboratory and hygiene practice when handling biological hazardous material. Wash hands before breaks and after work. Do not store together with food, drink and animal feed.

Eye/Face Protection: safety glasses or face shield (EN 166).

Skin/Hand protection: hand protection: wear protective gloves resistant to chemicals made of materials such as latex,

chloroprene, nitrile / chloroprene, fluoro rubber (EN 374). Use of hand protective cream is recommended.

Skin protection: footwear and protective clothing - laboratory clothing

Respiratory protection: use a face mask is recommended in case of any irritation experienced.

CAUTION!: If possible, work in biological safety cabinets.

8.2.3 Environmental exposure controls

Prevent penetration into the water and sewage system

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties



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Solid, convex discs 6 mm in diameter and 5 mm thick, grey colour. a) Appearance:

b) Odour: odourless

c) Odour threshold: No data available d) pH-value (temp. 25°C): No data available e) Melting / freezing point: No data available

f) Initial boiling point and boiling range: Not applicable

g) Flash point: No data available h) Evaporation rate: No data available i) Flammability: No data available

j) Upper / lower flammability or upper / lower explosive limit: No data available

k) Vapour pressure: No data available I) Vapour density: No data available m) Density: No data available

n) Water solubility: Soluble, when dissolved, the microorganisms form a suspension in solution

o) Partition coefficient: Not applicable.

p) Autoignition temperature: No data available g) Decomposition temperature: No data available

r) Viscosity: No data available

s) Explosive properties: No data available t) Oxidising properties: No data available

9.2 Other Information

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Under conditions of storage and use as intended - no reactivity.

10.2 Chemical stability

Product is stable under the typical use and storage conditions.

10.3 Possibility of hazardous reactions

Under normal conditions of use, hazardous reactions do not occur.

10.4 Conditions to avoid

No data available. See also section 7.

10.5 Incompatible materials

No dangerous reactions are known with other materials.

10.6 Hazardous decomposition products

Under normal conditions of use no hazardous decomposition products are liberated.

See also Subsection 5.2.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Products are not classified in regards to acute toxicity (oral, dermal, inhalation)

Mixture components LD50 oral ratinformation:

Water (7732-18-5) -> 90 ml/kg

Glucose (50-99-7) – 25800 mg/kg

Phosphoric acid, potassium salt (1:1) (7778-77-0) – 29700 mg/kg

Sucrose (57-50-1) - 29700 mg/kg



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Carbon (7440-44-0) - > 10000 mg/kg L-ascorbic acid (50-81-7) – 11900 mg/kg

Product and mixture components are not classified in regards to skin corrosion/irritation, serious eye damage/irritation, respiratory or skin sensitization, germ cell mutagenicity, carcinogenicity, reproductive toxicity, specific target organ toxicity – single and repeated exposure, and aspiration hazard.

11.2 Information on other hazards

There are no additional information available on endocrine disrupting properties nor potential adverse human health effects symptoms.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Products are not classified in regard to aquatic acute and chronic toxicity.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

The mixture does not meet the criteria for PBT and vPvB.

12.6 Other adverse effects

No other available information.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Comply with the provisions of the Waste Act and the Act on packaging and packaging waste.

Appropriate laboratory procedures exist for the destruction of these types of products.

Biohazard can be eliminated by incineration, autoclaving at 121 °C for 30 minutes, or the use of an appropriate disinfectant. Dispose according to local regulations.

SECTION 14: TRANSPORT INFORMATION

Transport by road ADR/RID

14.1 UN number UN 3373

14.2 UN proper shipping name: Biological Substance category B (Diagnostic specimens).

14.3 Transport hazard class(es): 6.2. **14.4 Packing group:** not applicable

14.5 Environmental hazards: not applicable

14.6 Special precautions for users: packing instructions: P650

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable.

Air transport (IATA)

14.1 UN number UN 3373

14.2 UN proper shipping name: Biological Substance category B (Diagnostic specimens).

14.3 Transport hazard class(es): 6.2.



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14.4 Packing group: not applicable

14.5 Environmental hazards: not applicable

14.6 Special precautions for users: packing instructions: P650

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable.

Sea transport (IMDG)

14.1 UN number UN 3373

14.2 UN proper shipping name: Biological Substance category B (Diagnostic specimens).

14.3 Transport hazard class(es): 6.2. **14.4 Packing group:** not applicable

14.5 Environmental hazards: not applicable

14.6 Special precautions for users: packing instructions: P650

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable.

SECTION 15: REGULATORY INFORMATION

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

EU-Regulations

-Regulation (EC) **1907/2006** of 18 December 2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing European Chemicals Agency, amending Directive 1999/45/EC and repealing Regulation (EC) No 793/93 and Regulation (EC) No 1488/94 as well as Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ EU L 396 of 30 December 2006, as amended).

-Regulation (EC) No **1272/2008** of 16 December 2008. on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ EU No L 353 of 31 December 2008) (CLP).

-COMMISSION REGULATION (EU) **2015/830** of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ EU L 132 of 29 May 2015)

-Regulation (EC) No 648/2004 of 31 March 2004 on detergents, Acts. EU Laws, 104/1, 04.08.2004.

National Regulations - follow local regulations/legislation

15.2 Chemical Safety Assessment

Has not been made.

SECTION 16: OTHER INFORMATION

H-phrases (indicating type of hazard) and hazard class used in Sections 2 and 3 of Safety Data Sheet:

The necessary training.

All persons involved in the sale and use of the product should be trained in hygiene and safe handling and use of biohazardous substances.

The information contained in this data sheet are based on literature data and Internet, raw material safety data sheets and safety data sheets of similar products. The manufacturer is not liable for any damage, loss, damage resulting from misuse of the product or omissions appropriate action.

The above information is based on current state of art and apply to product as it is used. Data concerning this product are presented in order to take into account the security requirements and not to guarantee its special properties.

This product is intended for professional use, detailed information on the use of the product is preset on the label and leaflet. Read label before use.



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List of abbreviations used in this document:

ADR - European Agreement concerning the international carriage of dangerous goods by road.

CAS - Chemical Abstract Service.

CLP - Classification Labeling Packaging - simplified reference to EC Regulation 1272/2008.

ECHA - European Chemical Agency.

EN - European Norms.

OECD - Organisation for Economic Co-operation and Developement

PBT - Persistent, bioaccumulative and toxic.

vPvB - very persistent and very bioaccumulative.

Changes compared to the previous version:

- section 3: update
- section 11: update