

# SAFETY DATA SHEET



In accordance with Commission Regulation (EU) 2020/878 as currently in force

Product name: **BMIC, FMIC, RMIC, TMIC**

Version 2:

Revision date: 01/02/2024

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## 1. Identification of the substance/ mixture and the company

**1.1. Product name:** BMIC, FMIC, RMIC, TMIC

**Cat. no:** XXXXB05, XXXXB10, XXXXB30  
XXXXF05, XXXXF10, XXXXF30  
XXXXR05, XXXXR10, XXXXR30  
XXXXT05, XXXXT10, XXXXT30

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

Strips for determination of Antibacterial Minimum Inhibitory Concentration, dedicated for professional studies for in vitro diagnostics

### 1.3. Details of the supplier of the safety data

#### Company

BioMaxima S.A. ul. Vetterów 5, 20-277 Lublin, Poland, tel.: +48 (81) 745 51 40, fax.: + 48 ( 81) 744 29 15, email: info@biomaxima.com

### 1.4. Emergency phone:

112, 998 (fire)

Pomeranian Center of Toxicology, 4/6 Kartuska Street, 80-104 Gdańsk, tel. +48 (53) 682 04 04 and 512 069 737  
Department of Toxicological Information and Laboratory Analysis of the Jagiellonian University - Collegium Medicum, 2 Jakubowskiego Street, Department of Toxicology, 30-688 Kraków, tel.: +48 (12) 411 99 99

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## 2. Hazards identification

### 2.1. Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008

### 2.2. Label elements

The product does not need to be labeled in accordance with (EC) No. 1272/2008 or respective national laws.

### 2.3. Other hazards – none

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## 3. Composition / Information on ingredients

Component
The product does not contain any ingredients that require to be mentioned according to Regulation EC No 1272/2008, means substance with estimated maximum concentration or substance that might be a concern in the quantities exceeding the limits.

For the full text of the H-Statements mentioned in this Section, see Section 16

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## 4. First aid measures

### 4.1. Description of first aid measures

#### General advice

Consult a physician. Show this safety data sheet to the doctor in attendance

#### If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician

#### In case of skin contact

Wash off with soap and plenty of water. Consult a physician

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## In case of eye contact

Flush eyes with water as a precaution

## If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician

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

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated

## 4.3. Indication of any immediate medical attention and special treatment needed

No data available

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## 5. Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media: use water spray, alcohol-resistant foam, dry chemical or carbon dioxide

**5.2. Special hazards arising from the substance or mixture:** carbon oxides. Oxides of phosphorus. Sodium oxides

**5.3. Advice for firefighters:** wear self contained breathing apparatus for the fighting if necessary

**5.4. Further information:** no data available

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## 6. Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Avoid breathing dust.

### 6.2. Environmental precaution

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

### 6.3. Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal

### 6.4. Reference to other section

For disposal see section 13.

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## 7. Handling and storage

**7.1. Precautions for safe handling:** provide appropriate exhaust ventilation at places where dust is formed

**7.2. Condition of safe storage:** store in dry place at -20°C ....+8°C

**7.3. Specific and uses:** moisture sensitive

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## 8. Exposure control / personal protection

### 8.1. Control parameter

Components with workplace control parameters

### 8.2. Exposure control

#### Appropriate engineering controls

Handle in accordance with good laboratory hygiene and safety practice. Wash hands before breaks and at the end of workday.

#### Personal protective equipment

##### Eye / face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH or EN 166 (EU).

##### Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching gloves outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specification of EU Directive 89/686/EEC and the standard EN 374 derived from it.

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## Body protection

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific work-place.

## Respiratory protection

Respiratory protection is not required. Where protection from nuisance levels of dusts are desired use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOCH (US) or CEN (EU).

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## 9. Physical and chemical properties

### 9.1. Information on basis physical and chemical properties

a) Physical state:	solid
b) Colour:	white
c) Odour:	no data available
d) Melting point/freezing point:	no data available
e) Initial boiling point and boiling range:	no data available
f) Flammability:	no data available
g) Lower and upper explosion limit:	no data available
h) Flash point:	no data available
i) Auto-ignition temperature:	no data available
j) Decomposition temperature:	no data available
k) pH:	no data available
l) Kinematic viscosity:	no data available
m) Water solubility:	no data available
n) Partition coefficient n-octanol/water	no data available
o) Vapor pressure	no data available
p) Density and/or relative density	no data available
q) Relative vapor	no data available
r) Particle characteristic:	no data available
s) Explosive properties:	Not classified as explosive
t) Oxidizing properties :	none

**9.2. Other safety information:** no data available

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## 10. Stability and reactivity

<b>10.1. Reactivity</b>	no data available
<b>10.2. Chemical stability</b>	no data available
<b>10.3 Possibility of hazardous reactions</b>	no data available
<b>10.4. Condition to avoid</b>	no data available
<b>10.5. Incompatible materials</b>	no data available
<b>10.6. Hazardous decomposition products</b>	other decomposition products - no data available

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## 11. Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity	no data available
LD50 Oral- mouse- 96 mg/kg	
LD50 Oral- rabbit-150 mg/kg	
LD50 Intraperitoneal- rat- 8,9 mg/kg	
LD50 Intraperitoneal- mouse- 5,1 mg/kg	
LD50 Intraperitoneal- rabbit- 5 mg/kg	
LD50 Intradoudenal- rabbit – 160 mg/kg	

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Skin corrosion/ irritation	skin- human-irritating to skin- 3d
Skin corrosion/ irritation	no data available
Serious eye damage/eye irritation	no data available
Respiratory or skin sensitization	no data available
Germ cell mutagenicity	no data available

## Carcinogenity

IARC: No component of this product present at levels greater than or equal to 0,1% is identified as probable, possible or confirmed human carcinogen by IARC

Reproductive toxicity	no data available
Specific target organ toxicity – single exposure	no data available
Specific target organ toxicity – repeated exposure	no data available
Aspiration hazard	no data available

## Potential health effects

<b>Inhalation</b>	May be harmful if inhaled. May cause respiratory tract irritation
<b>Ingestion</b>	May be harmful if swallowed
<b>Skin</b>	May be harmful if absorbed through skin. May cause skin irritation
<b>Eye</b>	May cause eye irritation

## 11.2. Additional Information

### Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine.

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## 12. Ecological information

**12.1.Toxicity** no data available  
to daphnia and other aquatic invertebrates: EC50 Daphnia magna (Water flea)-0,24-5 mg/l- 48 h. Method: OECD Test Guidelin 202  
Toxicity to algae - Pseudokirchneriella subcapitata – 0,025 – 0,8 mg/l – 72 h. Method: OECD Test Guidelin 201

**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 an vPvB assessment

The product does not contain substances that meet the criteria for PBT or vPvB substances according to Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as currently in force.

### 12.6.Endocrine disrupting properties

The mixture does not contain substances with endocrine-disrupting properties according to the criteria defined in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

**12.7. Other adverse effects:** no data available

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## 13. Disposal considerations

### 13.1. Waste treatment methods

Product: offer surplus and non-recyclable solutions to a licensed disposal company.  
Contaminated packaging: dispose of as unused product

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## 14. Transport information

### 14.1. UN number

ADR/RID:- IMDG:- IATA:-

### 14.2.UN proper shipping name

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ADR/RID: not dangerous goods

IMDG: not dangerous goods

IATA: not dangerous goods

### 14.3. Transport hazard class(es)

ADR/RID:- IMDG:- IATA:-

### 14.4. Packaging group

ADR/RID:- IMDG:- IATA:-

### 14.5. Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6. Special precaution for user: no data available

14.7. Maritime transport in bulk according to IMO instruments: no data available

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## 15. Regulatory information

### 15.1. Safety, health and environmental regulation / legislation specific for the substance or mixture

Public Health Act. Announcement of the Marshal of the Sejm of the Republic of Poland of December 1, 2022 regarding the publication of the consolidated text of the Act - Environmental Protection Law (Journal of Laws of 2022, item 2556). Regulation (EC) No 1907/2006 of the European Parliament and of the Council of December 18, 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC in the current wording. Regulation (EC) No 1272/2008 of the European Parliament and of the Council in the current wording. Regulation (EU) No 649/2012 of the European Parliament and of the Council of July 4, 2012 concerning the export and import of hazardous chemicals. Act of February 25, 2011 on Chemical Substances and Their Mixtures (consolidated text Journal of Laws of 2022, item 1816). Act of May 28, 2020 amending the Act on Chemical Substances and Their Mixtures and certain other acts (Journal of Laws of 2020, item 1337). Act of January 23, 2020 amending the Act on Waste and certain other acts (Journal of Laws of January 23, 2020, item 150). Act of July 13, 2023 amending the Act on Packaging and Packaging Waste Management and certain other acts (Journal of Laws of 2023, item 1852). Regulation of the Minister of Family, Labour and Social Policy of June 12, 2018 concerning the maximum permissible concentrations and intensities of harmful factors for health in the workplace environment (Journal of Laws of 2018, item 1286, as amended). Commission Regulation (EU) 2020/878 of June 18, 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).

### 15.2. Chemical Safety Assessment

No data available

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## 16. Other information

### Information important for safety and human health protection:

The product may not be used for purposes other than those stated in section 1 without special permission from the manufacturer/importer. The user is responsible for complying with all relevant health protection regulations.

### Explanation of abbreviations and acronyms used in the safety data sheet:

ADR European Agreement concerning the International Carriage of Dangerous Goods by Road

BCF Bioconcentration Factor

CAS Chemical Abstracts Service

CLP Regulation (EC) No 1272/2008 on classification, labelling, and packaging of substances and mixtures

EINECS European Inventory of Existing Commercial Chemical Substances

EmS Emergency Plan

EuPCS European Product Classification System

IATA International Air Transport Association

IBC International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk

ICAO International Civil Aviation Organization

IMDG International Maritime Dangerous Goods Code

IMO International Maritime Organization

INCI International Nomenclature of Cosmetic Ingredients

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ISO International Organization for Standardization

IUPAC International Union of Pure and Applied Chemistry

LD<sub>50</sub> Lethal Dose 50%

log Kow Octanol-water partition coefficient

LZO Volatile Organic Compounds

NDS Maximum Allowable Concentration

NDSch Short-term Maximum Allowable Concentration

NDSP Peak Maximum Allowable Concentration

OEL Occupational Exposure Limits

PBT Persistent, Bioaccumulative, and Toxic

ppm Parts per million

REACH Registration, Evaluation, Authorization, and Restriction of Chemicals

RID Regulations Concerning the International Carriage of Dangerous Goods by Rail

EU European Union

UN United Nations four-digit material identification number

UVCB Substances of Unknown or Variable Composition, Complex Reaction Products, or Biological Materials

vPvB Very Persistent and Very Bioaccumulative

WE Identification Code for each substance listed in EINECS

Eye Dam. Serious Eye Damage

Skin Corr. Skin Corrosion

### Training Recommendations

Familiarize employees with recommended methods of use, mandatory protective measures, first aid procedures, and prohibited handling methods for the product.

### Recommended Use Restrictions

No data available

### Information on Data Sources Used to Compile the Safety Data Sheet

Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH) as currently in force.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council as currently in force. Manufacturer data for substance/mixture - data from registration documentation.

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*The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product.*

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