

PRODUCT: Top-Gut<sup>®</sup>

DATE: February, 2023

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**1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY /UNDERTAKING****1.1. PRODUCT IDENTIFIER**

<i>Trade name:</i>	Top-Gut <sup>®</sup>
<i>Characterisation of the active substance:</i>	Viable spores of <i>Clostridium butyricum</i> FERM BP-2789.
<i>CAS Number:</i>	Not applicable.
<i>Structural formula:</i>	Not applicable.
<i>Molecular formula:</i>	Not applicable.
<i>Molecular weight:</i>	Not applicable.

**1.2. RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR THE MIXTURE AND USES ADVISED AGAINST**

<i>Identified uses:</i>	Complementary feed.
<i>Uses advised against:</i>	None known.

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### 1.3. DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

EU distributor

EU distributor: Huvepharma N.V.  
Certification number: α BE2280  
Contact person: Monita Vereecken  
Technical Manager Europe  
Huvepharma N.V.  
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[customerservice@huvepharma.com](mailto:customerservice@huvepharma.com)

Manufacturer:

BIOVET Joint Stock Company  
39, Petar Rakov Str.  
4550 Peshtera - Bulgaria  
Tel.: +359 350 65619  
Fax: +359 350 65636  
E-mail: [biovet@biovet.com](mailto:biovet@biovet.com)  
Identification No α BG 13 1 0069.

### 1.4. EMERGENCY TELEPHONE NUMBERS

+359 887 939420.

## 2. HAZARDS IDENTIFICATION

### 2.1. CLASSIFICATION OF THE MIXTURE

This preparation is not classified as dangerous according to Regulation (EC) No 1271/2008.

**Health hazards**

Respiratory sensitisation	Category 1	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
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## 2.2. LABEL ELEMENTS

**Labeling according to Regulation (EC) No 1272/2008 of December 2008 as amended**

**Signal words:**



**Danger**

**Hazard statements:**

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Precautionary Statements**

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P284	In case of inadequate ventilation wear respiratory protection.
P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P342 + P311	If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

## 2.3 OTHER HAZARDS

None.

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### **3. COMPOSITION/INFORMATION ON INGREDIENTS**

#### **3.2. MIXTURES**

##### **General information:**

Chemical Name	% content	CAS No/EC No	REACH registration No	INDEX No	CLP classification
Preparation of <i>Clostridium butyricum</i> MIYAIRI 588 <sup>®</sup> (FERM BP-2789)	< 10	EU Identification number 4b1830	-	-	H334
Lactose monohydrate	30 – 40	5989-81-1	-	-	H315; H319 H335
Dextrose	40 – 50	5996-10-1	-	-	H319; H335

##### **Composition comments:**

The full text for H-phrases is displayed in section 16.

### **4. FIRST AID MEASURES**

#### **4.1. DESCRIPTION OF FIRST AID MEASURES**

##### General

Top-Gut<sup>®</sup> is a dry, inert powder that may be handled and stored as for any proteinaceous, non-toxic food or feed ingredient.

##### Inhalation

If Top-Gut<sup>®</sup> is inhaled, remove the subject to a well-ventilated environment and allow to breathe normally.

##### Skin exposure

If Top-Gut<sup>®</sup> is spilt on skin, rinse the skin with clean water and dry.

##### Eye exposure

If Top-Gut<sup>®</sup> comes in contact with the eyes, rinse out the eyes with sterile saline or a proprietary eye wash.

##### Ingestion

If Top-Gut<sup>®</sup> is accidentally swallowed, allow the subject to drink a glass of potable water.

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**4.2. MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED**

In sensitive and allergized individuals may cause allergy or asthma symptoms or breathing difficulties if inhaled.

**4.3. INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED**

No immediate medical attention is necessary. Contact with Top-Gut<sup>®</sup> is unlikely to require medical attention.

**5. FIREFIGHTING MEASURES****5.1. EXTINGUISHING MEDIA**

Water, foam, powders.

**5.2. SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE**

None reasonably foreseeable.

**5.3. ADVICE FOR FIREFIGHTERS**

Standard fire-fighting measures, extinguishing equipment and apparatus may be used. Wear a self-contained breathing apparatus and full protective gear.

**6. ACCIDENTAL RELEASE MEASURES****6.1. PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES**

Wear appropriate personal protective clothing and devices (i.e. safety glasses, face mask, long-sleeved overalls and closed footwear). Light gloves may be also be worn.  
Refer to Section 8 (Exposure Controls/Personal Protection) for minimum personal protective equipment.

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## **6.2. ENVIRONMENTAL PRECAUTIONS**

Accidental spillage should be treated as non-hazardous biological waste and cleaned up accordingly.

## **6.3. METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP**

First sweeping, then mopping or scrubbing floors with standard household or industrial cleaning agents.

When picked up, treat the material as prescribed under heading “Disposal”.

## **7. HANDLING AND STORAGE**

### **7.1. PRECAUTIONS FOR SAFE HANDLING**

Top-Gut<sup>®</sup> is recommended to be used in a well-ventilated environment with standard protective clothing (safety glasses, face mask, overalls and closed footwear).

### **7.2. CONDITIONS FOR SAFE STORAGE INCLUDING ANY INCOMPATIBILITIES**

#### *Incompatibilities*

No data available.

#### *Further information on storage conditions*

Simple custodial procedures (e.g. store in closed, original containers in a clean, dry storeroom). Top-Gut<sup>®</sup> retains its activity for at least 1 year when stored in original, closed packaging on a cool (<25°C) and dry place.

#### *Storage class:*

Not applicable.

### **7.3. SPECIFIC END USE(S)**

For detailed information about the use of Top-Gut<sup>®</sup>, see identified use(s) referred to in Subsection 1.2.

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## **8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### **8.1. CONTROL PARAMETERS**

There are no exposure limit values. Monitoring procedures are those stipulated in the EU Feed Hygiene Regulation (Regulation EC N° 183/2005) in relation to traceability and monitoring of product or service complaints.

### **8.2. EXPOSURE CONTROLS**

Users are advised to handle Top-Gut<sup>®</sup> in a well-ventilated environment and to adopt appropriate personal protective clothing and devices (i.e. safety glasses, face mask, long-sleeved overalls and closed footwear). Light gloves may be also be worn.

#### *Hygienic measures*

Do not eat or drink during work time.

Wash hands before breaks and after work.

Keep away from foodstuffs and beverages.

#### *Respiratory protection*

Use barrier ventilation systems or a face mask CE certified to EN 149:2001, marked FFFP3-S for solids, protection factor 20.

#### *Hand protection*

Light cotton, latex or rubber gloves may be worn to prevent skin contact.

#### *Eye protection*

Safety glasses conforming to European Standard EN 166:2002.

#### *Skin protection*

Light weight, long-sleeved overalls and closed footwear.

#### *Environmental exposure controls*

Standard feed mill procedures for non-toxic, non-hazardous biological waste.

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## **9. PHYSICAL AND CHEMICAL PROPERTIES**

### **9.1. INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES**

a) Appearance:	White to greyish-white powder.
b) Odour:	Characteristic faint, yeasty smell.
c) Odour threshold:	NDA
d) pH:	NDA
e) Melting point/freezing point:	NDA
f) Initial boiling point and boiling range:	NDA
g) Flash point:	NDA
h) Evaporation rate:	Not applicable
i) Flammability (solid, gas):	NDA
j) Upper/lower flammability or explosive limits:	NDA
k) Vapour pressure:	NDA
l) Vapour density:	Not applicable
m) Relative density:	NDA
n) Solubility:	NDA
o) Partition coefficient n-octanol/water:	NDA
p) Auto-ignition temperature:	NDA
q) Decomposition temperature:	NDA
r) Viscosity:	Not applicable
s) Explosive properties:	NDA
t) Oxidising properties:	NDA

### **9.2. OTHER INFORMATION**

No other specific data are available.

## **10. STABILITY AND REACTIVITY**

### **10.1. REACTIVITY**

Top-Gut<sup>®</sup> is a non-reactive dry powder.

### **10.2. CHEMICAL STABILITY**

Top-Gut<sup>®</sup> is a stable dry powder.

### **10.3. POSSIBILITY OF HAZARDOUS REACTIONS**

None.



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Users should store Top-Gut<sup>®</sup> in closed, original containers and avoid generating environmental dust from the product.

**10.5. INCOMPATIBLE MATERIALS**

None.

**10.6. HAZARDOUS DECOMPOSITION PRODUCTS**

None.

**11. TOXICOLOGICAL INFORMATION****11.1. INFORMATION ON HAZARD CLASSES AS DEFINED IN REGULATION (EC) 1272/2008**

a) acute toxicity:

<b>Product</b>		<b>Species</b>	<b>Test results</b>
<i>Clostridium butyricum</i> (EU Identification number 4b1830)	Acute Oral LD <sub>50</sub>	Rat	> 5 g/kg b.w.
Dextrose (CAS 5996-10-1)	Acute Oral LD <sub>50</sub>	Rat	25.8 g/kg b.w.
	Acute i.v. LD <sub>50</sub>	Mouse	9 g/kg b.w.
Lactose monnohydrate (CAS 5989-81-1)	Acute IP LD <sub>50</sub>	Rat	> 10 g/kg b.w.
	Acute Oral LD <sub>50</sub>	Rat	> 10 g/kg b.w.
	Acute s.c. LD <sub>50</sub>	Rat	> 5 g/kg b.w.

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- b) skin corrosion/irritation: NDA.
- c) serious eye damage/irritation: NDA.
- d) respiratory or skin sensitization: NDA.  
Top-Gut<sup>®</sup> contains proteinaceous material and so has the potential to cause respiratory irritation and allergic reactions in sensitive individuals.
- e) germ cell mutagenicity (Lysate of the producing strain *Clostridium butyricum* CBM 588):
- |                 |  |          |
|-----------------|--|----------|
| <i>In Vitro</i> | Bacterial Reverse Mutation Test                  | Negative |
| <i>In Vitro</i> | Chromosomal aberrations assay in mammalian cells | Negative |
- f) carcinogenicity:  
The available data indicate that FERM BP-2789 (MIYARI CBM) does not induce any toxicological effect.
- g) reproductive toxicity:  
The available data indicate that FERM BP-2789 (MIYARI CBM) does not induce any toxicological effect.
- h) STOT-single exposure: NDA
- i) STOT-repeated exposure: NDA
- j) aspiration hazard: NDA

## 11.2. INFORMATION ON OTHER HAZARDS

11.2.1. Endocrine disrupting properties NDA.

11.2.2. Other information NDA.

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**12. ECOLOGICAL INFORMATION****12.1. TOXICITY**

*Clostridium butyricum* is a natural soil organism and its use as Top-Gut<sup>®</sup> in animal feeding would not be expected to pose a risk for the environment.

**12.2. PERSISTENCE AND DEGRADABILITY**

Top-Gut<sup>®</sup> degrades rapidly through biodegradation.

**12.3. BIOACCUMULATIVE POTENTIAL**

Top-Gut<sup>®</sup> does not persist in the environment and degrades rapidly through biodegradation.

**12.4. MOBILITY IN SOIL**

Not applicable.

**12.5. RESULTS OF PBT AND VPVB ASSESSMENT**

Not applicable.

**12.6. ENDOCRINE DISRUPTING PROPERTIES**

NDA.

**12.7. OTHER ADVERSE EFFECTS**

None.

**13. DISPOSAL CONSIDERATIONS****13.1. WASTE TREATMENT METHODS**

Dispose of as non-hazardous biological waste.

Packaging that cannot be cleaned should be disposed of as product waste.

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## **14. TRANSPORT INFORMATION**

### **14.1. UN NUMBER**

Not applicable as this product is not regulated by IMDG/IMO, ADR/RID, IATA/ICAO.

### **14.2. UN PROPER SHIPPING NAME**

Not applicable as this product is not regulated by IMDG/IMO, ADR/RID, IATA/ICAO.

### **14.3. TRANSPORT HAZARD CLASS(ES)**

Not applicable as this product is not regulated by IMDG/IMO, ADR/RID, IATA/ICAO.

### **14.4. PACKING GROUP**

Not applicable as this product is not regulated by IMDG/IMO, ADR/RID, IATA/ICAO.

### **14.5. ENVIRONMENTAL HAZARDS**

Not applicable as this product is not regulated by IMDG/IMO, ADR/RID, IATA/ICAO.

### **14.6. SPECIAL PRECAUTIONS FOR USER**

Not applicable as this product is not regulated by IMDG/IMO, ADR/RID, IATA/ICAO.

### **14.7. MARITIME TRANSPORT IN BULK ACCORDING TO IMO INSTRUMENTS**

Not applicable as this product is not regulated by IMDG/IMO, ADR/RID, IATA/ICAO.

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**15. REGULATORY INFORMATION****15.1. SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE****EU regulations**

- **Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I**  
Not listed.
- **Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II**  
Not listed.
- **Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended**  
Not listed.
- **Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA**  
Not listed.

**Authorisations**

- **Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended**  
Not listed.

**Restrictions on use**

- **Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended**  
Not listed.
- **Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work**  
Not listed.

**Other EU regulations**

- **Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances**  
Not listed.
- **Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work**  
Not listed.

**Other regulations**

- The product is classified and labelled in accordance with EC directives or respective national laws.
- This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

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- Young people under 18 years old are not allowed to work with this product according to the EU Directive 94/33/EC on the protection of young people at work.

**15.2. CHEMICAL SAFETY ASSESSMENT**

A chemical safety assessment according to REACH-regulation has not been carried out.

**16. OTHER INFORMATION**

The data and information reported in this Safety Data Sheet are based on information and studies made with Top-Gut<sup>®</sup>, and are only a guide for the user. They respect the actual level of the scientific and technical state of the art. In any case they cannot involve a responsibility of HUVEPHARMA if they are not respected, in particular for the aspects not considered.

**LIST OF ABBREVIATIONS IN THE MSDS**

<b>ADR</b>	International Carriage of Dangerous Goods by Road;
<b>CAS Number</b>	Chemical Abstract Service Registry Number;
<b>EC</b>	European Community;
<b>ICAO/IATA</b>	International Civil Aviation Organization/International Air Transport Association;
<b>IMDG</b>	International Maritime Dangerous Goods;
<b>IMO</b>	International Maritime Organisation;
<b>NDA</b>	No specific data available;
<b>RID</b>	International Carriage of Dangerous Goods by Rail;
<b>vPvB</b>	Very Persistent, very Bioaccumulative substance.

**FULL TEXT OF H STATEMENTS UNDER SECTION 3**

H302:	Harmful if swallowed.
H315:	Causes skin irritation.
H319:	Causes serious eye irritation.
H332:	Harmful if inhaled.
H334:	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335:	May cause respiratory irritation.