SAFETY DATA SHEET

Based upon Regulation (EC) No 1907/2006, as amended by Regulation (EU) No 2015/830

Mucilago Carbomeri FTM-TMF

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

1.1. Product identifier

Product name : Mucilago Carbomeri FTM-TMF
Synonyms : Carbomeergel TMF
Registration number REACH : Not applicable (mixture)
Product type REACH : Mixture

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

1.2.1 Relevant identified uses

This raw material is purchased by a pharmacist and after distribution will be delivered to the patient as such or processed in a magistral or officinal preparation

External use

1.2.2 Uses advised against

No uses advised against known

1.3. Details of the supplier of the safety data sheet

Supplier of the safety data sheet

Pannoc NV/SA
Lammerdries-oost 23
B-2250 Olen
☎ +32 14 21 70 18
info@pannoc.eu

1.4. Emergency telephone number

During business hours, 8:00-16:30 (CET) :
+32 14 21 70 18

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Not classified as dangerous according to the criteria of Regulation (EC) No 1272/2008

2.2. Label elements

Not classified as dangerous according to the criteria of Regulation (EC) No 1272/2008

Supplemental information

EUH210 Safety data sheet available on request.

2.3. Other hazards

No other hazards known

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name REACH Registration No	CAS No EC No	Conc. (C)	Classification according to CLP	Note	Remark
propane-1,2-diol 01-2119456809-23	57-55-6 200-338-0	C=10 %		(2)	Constituent

(2) Substance with a Community workplace exposure limit

SECTION 4: First aid measures

4.1. Description of first aid measures

General:

If you feel unwell, seek medical advice.

After inhalation:

Remove the victim into fresh air. Respiratory problems: consult a doctor/medical service.

After skin contact:

Rinse with water. Do not apply (chemical) neutralizing agents without medical advice. Take victim to a doctor if irritation persists.

After eye contact:

Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing. Do not apply (chemical) neutralizing agents without medical advice. Take victim to an ophthalmologist if irritation persists.

After ingestion:

Rinse mouth with water. Do not apply (chemical) neutralizing agents without medical advice. Consult a doctor/medical service if you feel unwell.

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

4.2.1 Acute symptoms

After inhalation:

No effects known.

After skin contact:

No effects known.

After eye contact:

No effects known.

After ingestion:

No effects known.

4.2.2 Delayed symptoms

No effects known.

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

If applicable and available it will be listed below.

SECTION 5: Firefighting measures

5.1. Extinguishing media

5.1.1 Suitable extinguishing media:

Small fire: Quick-acting ABC powder extinguisher, Quick-acting BC powder extinguisher, Quick-acting class B foam extinguisher, Quick-acting CO2 extinguisher.

Major fire: Class B foam (not alcohol-resistant).

5.1.2 Unsuitable extinguishing media:

Small fire: Water (quick-acting extinguisher, reel); risk of puddle expansion.

Major fire: Water; risk of puddle expansion.

5.2. Special hazards arising from the substance or mixture

Upon combustion: formation of CO, CO2 and small quantities of nitrous vapours.

5.3. Advice for firefighters

5.3.1 Instructions:

No specific fire-fighting instructions required.

5.3.2 Special protective equipment for fire-fighters:

Gloves (EN 374). Protective clothing (EN 14605 or EN 13034). Heat/fire exposure: compressed air apparatus (EN 136 + EN 137).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

No naked flames.

6.1.1 Protective equipment for non-emergency personnel

See heading 8.2

6.1.2 Protective equipment for emergency responders

Gloves (EN 374). Protective clothing (EN 14605 or EN 13034).

Suitable protective clothing

See heading 8.2

6.2. Environmental precautions

Contain released product.

6.3. Methods and material for containment and cleaning up

Scoop solid spill into closing containers. Clean contaminated surfaces with an excess of water. Wash clothing and equipment after handling.

6.4. Reference to other sections

See heading 13.

SECTION 7: Handling and storage

The information in this section is a general description. If applicable and available, exposure scenarios are attached in annex. Always use the relevant exposure scenarios that correspond to your identified use.

7.1. Precautions for safe handling

Keep away from naked flames/heat. Observe strict hygiene. Keep container tightly closed.

7.2. Conditions for safe storage, including any incompatibilities

7.2.1 Safe storage requirements:

Storage temperature: 15 °C - 25 °C. Store in a dark area. Meet the legal requirements.

7.2.2 Keep away from:
Heat sources.

7.2.3 Suitable packaging material:
Polypropylene.

7.2.4 Non suitable packaging material:
No data available

7.3. Specific end use(s)

If applicable and available, exposure scenarios are attached in annex. See information supplied by the manufacturer.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 Occupational exposure

a) Occupational exposure limit values

If limit values are applicable and available these will be listed below.

UK

Propane-1,2-diol particulates	Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005))	10 mg/m³
Propane-1,2-diol total vapour and particulates	Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005))	150 ppm
	Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005))	474 mg/m³

b) National biological limit values

If limit values are applicable and available these will be listed below.

8.1.2 Sampling methods

Product name	Test	Number
Propylene Glycol	NIOSH	5523
Propylene Glycol	OSHA	2051

8.1.3 Applicable limit values when using the substance or mixture as intended

If limit values are applicable and available these will be listed below.

8.1.4 Threshold values

DNEL/DMEL - Workers

propane-1,2-diol

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects inhalation	168 mg/m³	
	Long-term local effects inhalation	10 mg/m³	

DNEL/DMEL - General population

propane-1,2-diol

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects inhalation	50 mg/m³	
	Long-term local effects inhalation	10 mg/m³	

PNEC

propane-1,2-diol

Compartments	Value	Remark
Fresh water	260 mg/l	
Marine water	26 mg/l	
Aqua (intermittent releases)	183 mg/l	
STP	20000 mg/l	
Fresh water sediment	572 mg/kg sediment dw	
Marine water sediment	57.2 mg/kg sediment dw	
Soil	50 mg/kg soil dw	

8.1.5 Control banding

If applicable and available it will be listed below.

8.2. Exposure controls

The information in this section is a general description. If applicable and available, exposure scenarios are attached in annex. Always use the relevant exposure scenarios that correspond to your identified use.

8.2.1 Appropriate engineering controls

Keep away from naked flames/heat. Measure the concentration in the air regularly.

8.2.2 Individual protection measures, such as personal protective equipment

Observe strict hygiene. Do not eat, drink or smoke during work.

a) Respiratory protection:

Full face mask with filter type A at conc. in air > exposure limit.

b) Hand protection:

Protective gloves against chemicals (EN 374).

c) Eye protection:

Eye protection not required in normal conditions.

d) Skin protection:

Protective clothing (EN 14605 or EN 13034).

8.2.3 Environmental exposure controls:

See headings 6.2, 6.3 and 13

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical form	Gel
Odour	Characteristic odour
Odour threshold	No data available in the literature
Colour	Colourless
Translucency	Clear
Particle size	No data available in the literature
Explosion limits	No data available in the literature
Flammability	Not classified as flammable
Log Kow	Not applicable (mixture)
Dynamic viscosity	650000 mPa.s - 850000 mPa.s ; 0.5 rpm
	350000 mPa.s - 550000 mPa.s ; 1 rpm
Kinematic viscosity	No data available in the literature
Melting point	No data available in the literature
Boiling point	No data available in the literature
Evaporation rate	No data available in the literature
Relative vapour density	No data available in the literature
Vapour pressure	No data available in the literature
Solubility	No data available in the literature
Relative density	No data available in the literature
Decomposition temperature	No data available in the literature
Auto-ignition temperature	No data available in the literature
Flash point	No data available in the literature
Explosive properties	No chemical group associated with explosive properties
Oxidising properties	No chemical group associated with oxidising properties
pH	6.0 - 8.0

9.2. Other information

Surface tension	No data available in the literature
Absolute density	No data available in the literature

SECTION 10: Stability and reactivity

10.1. Reactivity

Heating increases the fire hazard.

10.2. Chemical stability

No data available.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Precautionary measures

Keep away from naked flames/heat.

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

Upon combustion: formation of CO, CO2 and small quantities of nitrous vapours.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

11.1.1 Test results

Acute toxicity

Mucilago Carbomeri FTM-TMF

No (test)data on the mixture available

Judgement is based on the relevant ingredients

propane-1,2-diol

Route of exposure	Parameter	Method	Value	Exposure time	Species	Value determination	Remark
Oral	LD50		22000 mg/kg		Rat	Experimental value	
Dermal	LD50		> 2000 mg/kg bw	24 h	Rabbit	Experimental value	
Inhalation						Data waiving	

Conclusion

Not classified for acute toxicity

Corrosion/irritation

Mucilago Carbomeri FTM-TMF

No (test)data on the mixture available

Judgement is based on the relevant ingredients

propane-1,2-diol

Route of exposure	Result	Method	Exposure time	Time point	Species	Value determination	Remark
Eye	Not irritating	OECD 405		24; 48; 72 hours	Rabbit	Experimental value	Single treatment
Skin	Not irritating	OECD 404	4 h	24; 48; 72 hours	Rabbit	Experimental value	

Conclusion

Not classified as irritating to the skin

Not classified as irritating to the eyes

Not classified as irritating to the respiratory system

Respiratory or skin sensitisation

Mucilago Carbomeri FTM-TMF

No (test)data on the mixture available

Judgement is based on the relevant ingredients

propane-1,2-diol

Route of exposure	Result	Method	Exposure time	Observation time point	Species	Value determination	Remark
Skin	Not sensitizing	Equivalent to OECD 429			Mouse	Experimental value	
Inhalation						Data waiving	

Conclusion

Not classified as sensitizing for skin

Not classified as sensitizing for inhalation

Specific target organ toxicity

Mucilago Carbomeri FTM-TMF

No (test)data on the mixture available

Judgement is based on the relevant ingredients

propane-1,2-diol

Route of exposure	Parameter	Method	Value	Organ	Effect	Exposure time	Species	Value determination
Oral (diet)	NOAEL	Subchronic toxicity test	443 mg/kg bw/day			283 week(s)	Cat (male)	Experimental value
Dermal	NOAEL		0.02 ml		No effect		Mouse (female)	Experimental value
Inhalation (aerosol)	LOEC	Subchronic toxicity test	160 mg/m³ air	Nose	Nasal bleeding	13 weeks (6h / day, 5 days / week)	Rat (male / female)	Experimental value

Conclusion

Not classified for subchronic toxicity

Mutagenicity (in vitro)

Mucilago Carbomeri FTM-TMF

No (test)data on the mixture available

Judgement is based on the relevant ingredients

propane-1,2-diol

Result	Method	Test substrate	Effect	Value determination	Remark
Negative with metabolic activation, negative without metabolic activation	Equivalent to OECD 471	Bacteria (S.typhimurium)		Experimental value	
Negative with metabolic activation, negative without metabolic activation	OECD 473	Human lymphocytes		Experimental value	

Mutagenicity (in vivo)

Mucilago Carbomeri FTM-TMF

No (test)data on the mixture available

Judgement is based on the relevant ingredients

propane-1,2-diol

Result	Method	Exposure time	Test substrate	Organ	Value determination
Negative	Chromosome aberration assay	5 day(s)	Rat (male)		Experimental value

Conclusion

Not classified for mutagenic or genotoxic toxicity

Carcinogenicity

Mucilago Carbomeri FTM-TMF

No (test)data on the mixture available

Judgement is based on the relevant ingredients

propane-1,2-diol

Route of exposure	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Oral (repeated exposure)	NOAEL	Carcinogenic toxicity study	1700 mg/kg bw/day - 2100 mg/kg bw/day	104 weeks (daily)	Rat (male / female)	No carcinogenic effect		Experimental value

Conclusion

Not classified for carcinogenicity

Reproductive toxicity

Mucilago Carbomeri FTM-TMF

No (test)data on the mixture available

Judgement is based on the relevant ingredients

propane-1,2-diol

	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Developmental toxicity	NOAEC	Equivalent to OECD 414	1040 mg/kg bw/day	10 day(s)	Mouse	No effect	Foetus	Experimental value
Maternal toxicity	NOAEL	Equivalent to OECD 414	520 mg/kg bw/day	10 day(s)	Mouse	No effect		Experimental value
Effects on fertility	NOAEL	NTP continuous breeding protocol	10100 mg/kg bw/day		Mouse (male / female)	No effect		Experimental value

Conclusion

Not classified for reprotoxic or developmental toxicity

Toxicity other effects

Mucilago Carbomeri FTM-TMF

No (test)data on the mixture available

Chronic effects from short and long-term exposure

Mucilago Carbomeri FTM-TMF

No effects known.

SECTION 12: Ecological information

12.1. Toxicity

Mucilago Carbomeri FTM-TMF

No (test)data on the mixture available

Judgement of the mixture is based on the relevant ingredients

propane-1,2-diol

	Parameter	Method	Value	Duration	Species	Test design	Fresh/salt water	Value determination
Acute toxicity fishes	LC50	OECD 203	51600 mg/l	96 h	Oncorhynchus mykiss			Experimental value
	LC50	Other	40613 mg/l	96 h	Oncorhynchus mykiss	Static system	Fresh water	Experimental value
Acute toxicity crustacea	LC50	EPA 600/4-90/027	18340 mg/l	48 h	Ceriodaphnia dubia	Static system	Fresh water	Experimental value
Toxicity algae and other aquatic plants	ErC50	OECD 201	24200 mg/l	72 h	Pseudokirchneriella subcapitata	Static system	Fresh water	Experimental value; GLP
Long-term toxicity fish								Data waiving
Long-term toxicity aquatic crustacea	NOEC	EPA 600/4-89/001	13020 mg/l	7 day(s)	Ceriodaphnia sp.	Semi-static system	Fresh water	Experimental value; Reproduction
Toxicity aquatic micro-organisms	NOEC	Other	> 20000 mg/l	18 h	Pseudomonas putida		Fresh water	Experimental value; Growth inhibition

Conclusion

Not classified as dangerous for the environment according to the criteria of Regulation (EC) No 1272/2008

12.2. Persistence and degradability

propane-1,2-diol

Biodegradation water

Method	Value	Duration	Value determination
OECD 301F: Manometric Respirometry Test	81.7 %; Carbon dioxide	28 day(s)	Experimental value

Phototransformation air (DT50 air)

Method	Value	Conc. OH-radicals	Value determination
AOPWIN v1.92	0.83 day(s)	1500000 /cm³	QSAR

Half-life water (t1/2 water)

Method	Value	Primary degradation/mineralisation	Value determination
			Data waiving

Conclusion

Contains non readily biodegradable component(s)

12.3. Bioaccumulative potential

Mucilago Carbomeri FTM-TMF

Log Kow

Method	Remark	Value	Temperature	Value determination
	Not applicable (mixture)			

propane-1,2-diol

BCF other aquatic organisms

Parameter	Method	Value	Duration	Species	Value determination
BCF		0.09			

Log Kow

Method	Remark	Value	Temperature	Value determination
EU Method A.8		-1.07	20.5 °C	Experimental value

Conclusion

No straightforward conclusion can be drawn based upon the available numerical values

12.4. Mobility in soil

propane-1,2-diol

(log) Koc

Parameter	Method	Value	Value determination
log Koc		0.46	Calculated value

Volatility (Henry's Law constant H)

Value	Method	Temperature	Remark	Value determination
1.29E-8 atm m³/mol		25 °C		Estimated value
0.0012 Pa.m³/mol				Experimental value

Conclusion

Contains component(s) with potential for mobility in the soil

12.5. Results of PBT and vPvB assessment

Due to insufficient data no statement can be made whether the component(s) fulfil(s) the criteria of PBT and vPvB according to Annex XIII of Regulation (EC) No 1907/2006.

12.6. Other adverse effects

Mucilago Carbomeri FTM-TMF

Greenhouse gases

None of the known components is included in the list of fluorinated greenhouse gases (Regulation (EU) No 517/2014)

Ozone-depleting potential (ODP)

Not classified as dangerous for the ozone layer (Regulation (EC) No 1005/2009)

propane-1,2-diol

Groundwater

Groundwater pollutant

SECTION 13: Disposal considerations

The information in this section is a general description. If applicable and available, exposure scenarios are attached in annex. Always use the relevant exposure scenarios that correspond to your identified use.

13.1. Waste treatment methods

13.1.1 Provisions relating to waste

European Union

Can be considered as non hazardous waste according to Directive 2008/98/EC, as amended by Regulation (EU) No 1357/2014 and Regulation (EU) No 2017/997.

Waste material code (Directive 2008/98/EC, Decision 2000/0532/EC).

07 05 99 (wastes from the MFSU of pharmaceuticals: wastes not otherwise specified). Depending on branch of industry and production process, also other waste codes may be applicable.

13.1.2 Disposal methods

Remove waste in accordance with local and/or national regulations. Do not discharge into drains or the environment. Dispose of at authorized waste collection point.

13.1.3 Packaging/Container

European Union

Waste material code packaging (Directive 2008/98/EC).

15 01 02 (plastic packaging).

SECTION 14: Transport information

Road (ADR), Rail (RID), Inland waterways (ADN), Sea (IMDG/IMSBC), Air (ICAO-TI/IATA-DGR)

14.1. UN number

Transport	Not subject

14.2. UN proper shipping name

14.3. Transport hazard class(es)

Hazard identification number	
Class	
Classification code	

14.4. Packing group

Packing group	
Labels	

14.5. Environmental hazards

Environmentally hazardous substance mark	no

14.6. Special precautions for user

Special provisions	
Limited quantities	

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Annex II of MARPOL 73/78	Not applicable, based on available data

SECTION 15: Regulatory information

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

European legislation:

VOC content Directive 2010/75/EU

VOC content	Remark
≥ 10 %	

National legislation Belgium

Mucilago Carbomeri FTM-TMF

No data available

National legislation The Netherlands

Mucilago Carbomeri FTM-TMF

Waterbezwaarlijkheid	B (4); Algemene Beoordelingsmethodiek (ABM)

National legislation France

Mucilago Carbomeri FTM-TMF

No data available

National legislation Germany

Mucilago Carbomeri FTM-TMF

WGK	1; Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (AwSV) - 18. April 2017

propane-1,2-diol

TA-Luft	5.2.5

National legislation United Kingdom

Mucilago Carbomeri FTM-TMF

No data available

Other relevant data

Mucilago Carbomeri FTM-TMF

No data available

15.2. Chemical safety assessment

No chemical safety assessment has been conducted for the mixture.

SECTION 16: Other information

(*)	INTERNAL CLASSIFICATION BY BIG
ADI	Acceptable daily intake
AOEL	Acceptable operator exposure level
CLP (EU-GHS)	Classification, labelling and packaging (Globally Harmonised System in Europe)
DMEL	Derived Minimal Effect Level
DNEL	Derived No Effect Level
EC50	Effect Concentration 50 %
ErC50	EC50 in terms of reduction of growth rate
LC50	Lethal Concentration 50 %
LD50	Lethal Dose 50 %
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative & Toxic
PNEC	Predicted No Effect Concentration
STP	Sludge Treatment Process
vPvB	very Persistent & very Bioaccumulative

The information in this safety data sheet is based on data and samples provided to BIG. The sheet was written to the best of our ability and according to the state of knowledge at that time. The safety data sheet only constitutes a guideline for the safe handling, use, consumption, storage, transport and disposal of the substances/preparations/mixtures mentioned under point 1. New safety data sheets are written from time to time. Only the most recent versions may be used. Unless indicated otherwise word for word on the safety data sheet, the information does not apply to substances/preparations/mixtures in purer form, mixed with other substances or in processes. The safety data sheet offers no quality specification for the substances/preparations/mixtures in question. Compliance with the instructions in this safety data sheet does not release the user from the obligation to take all measures dictated by common sense, regulations and recommendations or which are necessary and/or useful based on the real applicable circumstances. BIG does not guarantee the accuracy or exhaustiveness of the information provided and cannot be held liable for any changes by third parties. This safety data sheet is only to be used within the European Union, Switzerland, Iceland, Norway and Liechtenstein. Any use outside of this area is at your own risk. Use of this safety data sheet is subject to the licence and liability limiting conditions as stated in your BIG licence agreement or when this is failing the general conditions of BIG. All intellectual property rights to this sheet are the property of BIG and its distribution and reproduction are limited. Consult the mentioned agreement/conditions for details.