

According to EC-Regulation 1907/2006 (REACH)

SAFETY DATA SHEET

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

1.1. Product identifier

Trade name

GUARDIAN MEDICAL SURFACE

Product no.

505500, 500001, 500005

REACH registration number

Not applicable

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

Relevant identified uses of the substance or mixture

Disinfection

Uses advised against

Avoid digestion and inhaling aerosol from the product

The full text of any mentioned and identified use categories are given in section 16

1.3. Details of the supplier of the safety data sheet

Company and address

APPEARTEX AB

Sofierogatan 3A

412 51 GÖTEBORG

SWEDEN

Tel: +46 31 703 59 50

Fax: +46 31 703 59 51

Contact person

E-mail

SDS date

2016-04-01

SDS Version

3.0

1.4. Emergency telephone number

Use your national or local emergency number

See section 4 "First aid measures"

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Aquatic Chronic 2; H411

See full text of H-phrases in section 2.2.

2.2. Label elements

Hazard pictogram(s)



Signal word

-

Hazard statement(s)

According to EC-Regulation 1907/2006 (REACH)

Toxic to aquatic life with long lasting effects. (H411)

Safety statement(s)	General	If medical advice is needed, have product container or label at hand. (P101). Keep out of reach of children. (P102).
	Prevention	Avoid release to the environment. (P273).
	Response	Collect spillage. (P391).
	Storage	-
	Disposal	Dispose of contents/container to an approved waste disposal plant. (P501).

Identity of the substances primarily responsible for the major health hazards

Active substance: PHMBG 0,9 %

2.3. Other hazards

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Additional labelling

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Additional warnings

PHMBG is sensitizing as a pure substance (100%). Tests (OECD 406 Guinea Pig) show that PHMBG is **not sensitizing** at concentrations below 21%.

VOC

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SECTION 3: Composition/information on ingredients

3.1/3.2. Substances/Mixtures

NAME:	Polyhexamethylene biguanide Guanidine (PHMBG). Poly(iminocarbonimidoyliminocarbonimidoylimino- 1,6-hexanediy), hydrochloride (9Cl) and cyanamide, N-cyano-, compound with 1,6- hexanediamine (2:1), polymer with 1,6-hexanediamine hydrochloride (1:2)
IDENTIFICATION NOS.:	CAS-no: 1802181-67-4 and 32289-58-0
CONTENT:	<1%
CLP CLASSIFICATION:	Acute Tox cat.4, H302, ATI cat.2, H330, STOT RE 3, H335, Eye Dam.cat.1,H318, Skin Sens cat.1,H317 Aquatic Acute cat.1,H400 (M=10) Aquatic Chron. cat.1,H410 (M=10)
NAME:	Betaines, C12-14-alkyldimethyl
IDENTIFICATION NOS.:	CAS-no: 66455-29-6 EC-no: 266-368-1
CONTENT:	<1%
CLP CLASSIFICATION:	Skin Irrit. 2, Eye Irrit. 2, Aquatic Chronic 3 H315, H319, H412
NAME:	Modified Polyethylenimine (M-PEI)
IDENTIFICATION NOS.:	CAS-no: 1003006-64-1
CONTENT:	<0.1%
CLP CLASSIFICATION:	Acute Tox. 4, Eye Dam. 1, Skin Sens. 1, Aquatic Acute 1, Aquatic Chronic 1 H302, H317, H318, H400, H410

(*) See full text of H-phrases in chapter 16. Occupational exposure limits are listed in section 8, if these are available.

Other informations

ATEmix(inhale, vapour) > 20
 ATEmix(inhale, dust/mist) > 20
 ATEmix(oral) > 2000
 $N \text{ chronic (CAT 2) Sum} = \text{Sum}(\text{Ci}/\text{M}(\text{chronic})^i * 25 * 0.1 * 10^{\wedge} \text{CAT}_i) = 2,88 - 4,32$
 PHMBG not found to be sensitizing at concentrations below 21% (Concentration in this product is 0,9%)

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

In the case of accident: Contact a doctor or casualty department – take the label or this safety data sheet. Contact a doctor, if in doubt about the injured person's condition or if the symptoms continue. Never give an unconscious person water or similar.

According to EC-Regulation 1907/2006 (REACH)

Inhalation

Get the person into fresh air and stay with them.

Skin contact

In case of skin discomfort rinse contact area with clean water .

Eye contact

Upon irritation, remove contact lenses. Flush eyes immediately with plenty of water (20-30°C) for at least 15 minutes and continue until irritation stops. Make sure you flush under the upper and lower eyelids. If irritation continues, contact a doctor.

Ingestion

Give the person plenty to drink and stay with the person. If the person feels unwell, contact a doctor immediately and take this safety data sheet or the label from the product with you. Do not induce vomiting unless recommended by the doctor. Hold head facing down so that no vomit runs back into the mouth and throat.

Burns

Not applicable

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

This product contains substances that may cause an allergic reaction in people who are already so disposed.

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

No special

Information to medics

Bring this safety data sheet.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Recommended: alcohol-resistant foam, carbonic acid, powder, water mist. Water jets should not be used, since they can spread the fire.

5.2. Special hazards arising from the substance or mixture

No special

5.3. Advice for firefighters

Wear self-contained breathing apparatus and protective clothing to prevent contact.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

No specific requirements.

6.2. Environmental precautions

Avoid discharge to lakes, streams, sewers, etc. In the event of a leakage to the surroundings, contact the local environmental authorities. Consider putting up waste collecting trays/basins to prevent leakage to the surroundings.

6.3. Methods and material for containment and cleaning up

Use sand, sawdust, earth, vermiculite, diatomaceous earth to contain and collect non-combustible absorbent materials and place in container for disposal, according to local regulations. Cleaning should be done as far as possible using normal cleaning agents. Solvents should be avoided.

6.4. Reference to other sections

See section on "Disposal considerations " with regard to the handling of waste. See section on 'Exposure controls/personal protection' for protective measures.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Smoking, consumption of food or liquid, and storage of tobacco, food or liquids are not allowed in the workrooms. Consider putting up waste collecting trays/basins to prevent leakage to the surroundings. See section on 'Exposure controls/personal protection' for information on personal protection.

7.2. Conditions for safe storage, including any incompatibilities

According to EC-Regulation 1907/2006 (REACH)

Always store in containers of the same material as the original. Containers that have been opened must be carefully resealed and kept upright to prevent leakage.

Storage temperature

Room temperature 18 to 23°C

7.3. Specific end use(s)

This product should only be used for applications described in Section 1.2

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

OEL

No substances listed.

DNEL / PNEC

PNEC (PHMBG): 0,279 ug/L
Exposure: Freshwater

PNEC (PHMBG): 1,22 mg/kg wet wt
Exposure: Freshwater sediment

PNEC (PHMBG): 0,0279 ug/L
Exposure: Marine water

PNEC (PHMBG): 0,122 mg/kg wet wt
Exposure: Marine water sediment

PNEC (PHMBG): 0,323 mg/L
Exposure: Sewage Treatment Plant

PNEC (PHMBG): 0,83 ug/kg wet wt
Exposure: Soil

8.2. Exposure controls

No control is necessary if the product is used in a normal way.

General recommendations

Observe general occupational hygiene.

Exposure scenarios

If there is an appendix to this safety data sheet, the indicated exposure scenarios must be complied.

Exposure limits

There are no maximum exposure limits for the substances contained in this product.

Appropriate technical measures

Take ordinary precautions when using the product. Avoid inhalation of gas or dust.

Hygiene measures

This is a hygienic biocidal product. Optional: Use clean water and soap for hands, forearms and/or face after work to remove the product if so desired.

Measures to avoid environmental exposure

No specific requirements.

Individual protection measures, such as personal protective equipment

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Generally

Use only CE marked protective equipment.

Respiratory Equipment

No specific requirements.

Skin protection

No specific requirements.

Hand protection

No specific requirements.

Eye protection

No specific requirements.



According to EC-Regulation 1907/2006 (REACH)

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Form	Liquid
Colour	Clear
Odour	Faint
pH	5-6
Viscosity	No data available.
Density (g/cm ³)	No data available.

Phase changes

Melting point (°C)	No data available.
Boiling point (°C)	No data available.
Vapour pressure	No data available.

Data on fire and explosion hazards

Flashpoint (°C)	No data available.
Ignition (°C)	No data available.
Self ignition (°C)	No data available.
Explosion limits (Vol %)	No data available.

Solubility

Solubility in water	Soluble
n-octanol/water coefficient	No data available.

9.2. Other information

Solubility in fat (g/L)	No data available.
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SECTION 10: Stability and reactivity

10.1. Reactivity

No data available

10.2. Chemical stability

The product is stable under the conditions, noted in the section on "Handling and storage".

10.3. Possibility of hazardous reactions

No special

10.4. Conditions to avoid

Avoid mixing with Chlorine containing compounds/formulations

10.5. Incompatible materials

Strong acids, strong bases, strong oxidizing agents, and strong reducing agents.

10.6. Hazardous decomposition products

The product is not degraded when used as specified in section 1.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Substance	Species	Test	Route of exposure	Result
Modified Polyethylenimine (M...	Rat	LD50	Oral	500 mg/kg
Modified Polyethylenimine (M...	Rat	LD50	Dermal	>2000 mg/kg
Betaines, C12-14-alkyldimethyl	Rat	LD50	Oral	>2000 mg/kg
PHMBG	Rat	LD50	Oral	>2000 mg/kg
PHMBG	Rat	LD50	Dermal	>2000 mg/kg
PHMBG	Rat	LC50	Inhalation	1,61 mg/L/4h

Skin corrosion/irritation

Data on substance: PHMBG
 Test: OECD Guideline 404
 Organism: Rabbit
 Result: Slightly skin irritant not classified

Serious eye damage/irritation

According to EC-Regulation 1907/2006 (REACH)

Data on substance: PHMBG
 Test: OECD Guideline 405
 Organism: Rabbit
 Result: Very irritant for the eye

Respiratory or skin sensitisation

No data available. Data on substance: PHMBG
 Test: OECD Guideline 406
 Organism: Guinea pig
 Result: not sensitizing <21% w/w

Sensitivity effects: This product contains substances which can give an allergic reaction on contact with skin. The allergic reaction will typically set in 12-72 hours after exposure.

Germ cell mutagenicity

Data on substance: PHMBG
 Test: OECD Guideline 471
 No adverse effect observed.

Data on substance: PHMBG
 Test: OECD Guideline 473
 No adverse effect observed.

Data on substance: PHMBG
 Test: OECD Guideline 476
 No adverse effect observed.

Carcinogenicity

Data on substance: PHMBG
 Test: OECD Guideline 453
 Organism: Rat
 Result: NOAEL 500 mg/L 2-y oral
 Benign neoplastic activity liver. Tested as pure active substance in water

Reproductive toxicity

Data on substance: PHMBG
 Test: OECD 414
 Result: up to 1000 ppm
 No adverse effect observed.

Data on substance: PHMBG
 Test: OECD TG 416
 Organism: Rat
 Result: multi generation no toxicity
 No adverse effect observed.

STOT-single exposure

No data available.

STOT-repeated exposure

No data available.

Aspiration hazard

No data available.

Long term effects

No special

SECTION 12: Ecological information

12.1. Toxicity

Substance	Species	Test	Test duration	Result
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According to EC-Regulation 1907/2006 (REACH)

	Daphnia			
	Fish			
	Fish			
Modified Polyethylenimine (M...	Algae	EC50	48h	0,37mg/L
Modified Polyethylenimine (M...	Algae	NOEC	96h	0,10 mg/L
Modified Polyethylenimine (M...	Algae	LC50		0,15mg/L
Modified Polyethylenimine (M...	Daphnia	NOEC	72h	0,40 mg/L
Modified Polyethylenimine (M...	Daphnia	ErC50		1,5mg/L
PHMBG	Oncorhynchus	NOEC	21d	5,44ug/L
PHMBG	mykiss (rainbow	EC50	48h	0,156mg/L
PHMBG	trout)	LC50	96h	0,321 mg/L
PHMBG	Pimephales promelas	NOEC	28d	4,98ug/L
PHMBG	(fathead minnow)	EC10	72h	2,79ug/L
PHMBG	Pseudokirchneriella	ErC50	72h	20,6ug/L
PHMBG	subcapitala algae			
	Pseudokirchneriella			
	subcapitala algae			

12.2. Persistence and degradability

Substance	Biodegradability	Test	Result
PHMBG and PEI	Not easy biodegradable (biocide)	No data available	No data available

12.3. Bioaccumulative potential

Substance	Potential bioaccumulation	LogPow	BCF
PHMB and PEI	No	No data available	No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

No data available

12.6. Other adverse effects

This product contains ecotoxic substances which can have damaging effects on water-organisms. This product contains substances which can cause undesirable long-term effects in the water environment, due to its poor biodegradability.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

The product is covered by the regulations on dangerous waste.

Waste

EWC code
070704

Specific labelling

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Contaminated packing

Packaging which contains leftovers from the product must be disposed of in the same way as the product.

SECTION 14: Transport information

14.1 – 14.4

This product is covered by the conventions on dangerous goods.

ADR/RID

14.1. UN number	3082
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
14.3. Transport hazard class(es)	9
14.4. Packing group	III
Notes	-
Tunnel restriction code	E

IMDG

UN-no.	3082
Proper Shipping Name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
Class	9

According to EC-Regulation 1907/2006 (REACH)

PG*	III
EmS	F-A, S-B
MP**	Yes
Hazardous constituent	PHMBG
IATA/ICAO	
UN-no.	3082
Proper Shipping Name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
Class	9
PG*	III

14.5. Environmental hazards

This product contains substances which can cause undesirable long-term effects in the water environment, due to its poor biodegradability.

14.6. Special precautions for user

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14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

No data available

(*) Packing group

(**) Marine pollutant

14.8. Other information

When transported in single or combination packagings containing a net quantity per single or inner packaging of 5 L or less for liquids or having a net mass of 5 kg or less for solids, are not classified as dangerous goods for the environment provided the packagings meet the general regulations.

SECTION 15: Regulatory information

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

Restrictions for application

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Demands for specific education

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Additional information

Sources

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (CLP).
EC regulation 1907/2006 (REACH).

15.2. Chemical safety assessment

No

SECTION 16: Other information

Full text of H-phrases as mentioned in section 3

According to EC-Regulation 1907/2006 (REACH)

H302 - Harmful if swallowed.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H319 - Causes serious eye irritation.
H332 - Harmful if inhaled.
H335 - May cause respiratory irritation.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.
H412 - Harmful to aquatic life with long lasting effects.

The full text of identified uses as mentioned in section 1

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Other symbols mentioned in section 2

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Other

It is recommended to hand over this safety data sheet to the actual user of the product. Information in this safety data sheet cannot be used as a product specification.

The information in this safety data sheet applies only to this specific product (mentioned in section 1) and is not necessarily correct for use with other chemicals/products.

A change (in proportion to the last essential change (first cipher in SDS version)) is marked with a blue triangle.

The safety data sheet is validated by

**Date of last essential change
(First cipher in SDS version)**

-

**Date of last minor change
(Last cipher in SDS version)**

-