

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

#### 1.1. Product identifier

Trade name : AquaHy

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

##### 1.2.1. Relevant identified uses

Use of the substance/mixture : Medical device  
disinfectants  
Cleaning agent

##### 1.2.2. Uses advised against

No additional information available

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

##### Supplier

Alfred Becht GmbH  
Carl-Zeiss-Str. 16  
P.O. Box 1145  
77656 Offenburg  
T +49 781 60586-0 - F +49 781 60586-40

##### Email competent person

sds@kft.de

#### 1.4. Emergency telephone number

Emergency number : National Poison Information Service (NPIS)  
24 hour national number professionals only  
0844 892 0111  
  
National Health Service (NHS)  
24 hour national number consumer  
England and Scotland: 111  
Wales: 0845 46 47  
Northern Ireland: call your local General Practitioner  
  
Call 999 if there is a life-threatening incident.

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Hazardous to the aquatic environment — Chronic Hazard, Category 3 H412  
Full text of H statements : see section 16

##### Adverse physicochemical, human health and environmental effects

Harmful to aquatic life with long lasting effects.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Signal word (CLP) : -  
Hazard statements (CLP) : H412 - Harmful to aquatic life with long lasting effects.  
EUH-statements : EUH208 - Contains polyhexamethylene biguanide hydrochloride; PHMB. May produce an allergic reaction.  
Extra phrases : INCI Name.  
POLYAMINOPROPYL BIGUANIDE.

#### 2.3. Other hazards

No additional information available

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Not applicable

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according to Regulation (EC) No. 1907/2006 (REACH)

### 3.2. Mixtures

Comments : Aqueous solution

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
polyhexamethylene biguanide hydrochloride; PHMB	(CAS-No.) 27083-27-8 (EC-No.) 608-042-7 (EC Index-No.) 616-207-00-X	>=0.1 - <1	Carc. 2, H351 Acute Tox. 2 (Inhalation), H330 Acute Tox. 4 (Oral), H302 STOT RE 1, H372 Eye Dam. 1, H318 Skin Sens. 1B, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=10)

Full text of H-statements: see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.  
First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.  
First-aid measures after skin contact : Wash skin with plenty of water. If skin irritation or rash occurs: Get medical advice/attention.  
First-aid measures after eye contact : Rinse eyes with water as a precaution. If eye irritation persists: Get medical advice/attention.  
First-aid measures after ingestion : Rinse mouth out with water. Spit. Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects after skin contact : May cause sensitisation of susceptible persons.

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

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam. Carbon dioxide.  
Unsuitable extinguishing media : Strong water jet.

### 5.2. Special hazards arising from the substance or mixture

Fire hazard : Non flammable.  
Hazardous decomposition products in case of fire : Toxic fumes may be released. Carbon dioxide. Carbon monoxide. Hydrogen chloride. Nitrogen oxides.

### 5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.  
Other information : Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

## SECTION 6: Accidental release measures

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

#### 6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

#### 6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

### 6.2. Environmental precautions

Notify authorities if product enters sewers or public waters. Avoid sub-soil penetration. Prevent entry to sewers and public waters.

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according to Regulation (EC) No. 1907/2006 (REACH)

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

Methods for cleaning up : Take up liquid spill into absorbent material. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.

Other information : Disposal must be done according to official regulations.

### 6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station.

#### Hand protection:

In case of repeated or prolonged contact wear gloves. EN 374. Nitrile rubber. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

#### Eye protection:

Use splash goggles when eye contact due to splashing is possible. EN 166

#### Skin and body protection:

Wear suitable protective clothing. EN 340. EN 13034

#### Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. EN 143. Short term exposure. Breathing apparatus with filter. A-P2. Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust

#### Environmental exposure controls:

Avoid release to the environment.

#### Other information:

Do not eat, drink or smoke when using this product. Avoid contact with skin and eyes. Always wash hands after handling the product.

## SECTION 9: Physical and chemical properties

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

Physical state : Liquid

Appearance : clear.

Colour : colourless.

Odour : odourless.

Odour threshold : No data available

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according to Regulation (EC) No. 1907/2006 (REACH)

pH	: 6.5 - 7.5
Relative evaporation rate (butylacetate=1)	: Not relevant   (Water)
Melting point	: Not applicable
Freezing point	: ≈ 0 °C (Water)
Boiling point	: ≈ 100 °C (Water)
Flash point	: Not applicable
Auto-ignition temperature	: Not self-igniting
Decomposition temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 1.02 g/cm <sup>3</sup>
Solubility	: Water: completely miscible
Log Pow	: Not applicable
Viscosity, kinematic	: Not relevant   (Water)
Viscosity, dynamic	: Not relevant   (Water)
Explosive properties	: Product is not explosive.
Oxidising properties	: Non oxidizing.
Explosive limits	: Not applicable

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

No additional information available

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)

### polyhexamethylene biguanide hydrochloride; PHMB (27083-27-8)

LC50 inhalation rat (Dust/Mist - mg/l/4h)	0.37 mg/l/4h
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 6.5 - 7.5
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 6.5 - 7.5
Respiratory or skin sensitisation	: Not classified
Additional information	: May cause sensitisation of susceptible persons
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)

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Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

### SECTION 12: Ecological information

#### 12.1. Toxicity

Ecology - general	: Harmful to aquatic life with long lasting effects.
Acute aquatic toxicity	: Not classified (Based on available data, the classification criteria are not met)
Chronic aquatic toxicity	: Harmful to aquatic life with long lasting effects.

#### polyhexamethylene biguanide hydrochloride; PHMB (27083-27-8)

LC50 fish 1	0.026 mg/l (96 h; Oncorhynchus mykiss)
EC50 Daphnia 1	0.09 mg/l (48 h; Daphnia magna; (OECD 202 method))
ErC50 (algae)	0.0191 mg/l (72 h; Pseudokirchneriella subcapitata; (OECD 201 method))

#### 12.2. Persistence and degradability

##### AquaHy

Persistence and degradability	The product has not been tested.
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#### polyhexamethylene biguanide hydrochloride; PHMB (27083-27-8)

Persistence and degradability	Not readily biodegradable.
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#### 12.3. Bioaccumulative potential

##### AquaHy

Log Pow	Not applicable
Bioaccumulative potential	The product has not been tested.

#### polyhexamethylene biguanide hydrochloride; PHMB (27083-27-8)

Bioaccumulative potential	Bioaccumulation unlikely.
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#### 12.4. Mobility in soil

##### AquaHy

Ecology - soil	The product has not been tested.
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#### polyhexamethylene biguanide hydrochloride; PHMB (27083-27-8)

Ecology - soil	Adsorbs into the soil.
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#### 12.5. Results of PBT and vPvB assessment

##### Component

polyhexamethylene biguanide hydrochloride; PHMB (27083-27-8)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
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#### 12.6. Other adverse effects

No additional information available

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Waste treatment methods	: Disposal must be done according to official regulations. European waste catalogue. Do not dispose of with domestic waste. Do not discharge into drains or the environment.
European List of Waste (LoW) code	: 07 06 99 - wastes not otherwise specified

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## Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

HP Code

: HP14 - "Ecotoxic:" waste which presents or may present immediate or delayed risks for one or more sectors of the environment

### SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.4. Packing group</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

#### 14.6. Special precautions for user

##### Overland transport

Not applicable

##### Transport by sea

Not applicable

##### Air transport

Not applicable

##### Inland waterway transport

Not applicable

##### Rail transport

Not applicable

#### 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/legislation specific for the substance or mixture

##### 15.1.1. EU-Regulations

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:

3(c) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard class 4.1	AquaHy
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Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

##### 15.1.2. National regulations

No additional information available

#### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

### SECTION 16: Other information

#### Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
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
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative

Data sources : ECHA (European Chemicals Agency). MSDSs of the suppliers. Information provided by the manufacturer.

Department issuing data : KFT Chemieservice GmbH  
specification sheet: Im Leuschnerpark. 3 64347 Griesheim  
Postfach 1451 64345 Griesheim  
Germany

Phone: +49 6155-8981-400 Fax: +49 6155 8981-500  
Safety Data Sheet Service: +49 6155 8981-522

Contact person : Dr. Johann Klassen

#### Full text of H- and EUH-statements:

Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Aquatic Chronic 3	Hazardous to the aquatic environment — Chronic Hazard, Category 3
Carc. 2	Carcinogenicity, Category 2
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Skin Sens. 1B	Skin sensitisation, category 1B

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## Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

STOT RE 1	Specific target organ toxicity — Repeated exposure, Category 1
H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H351	Suspected of causing cancer.
H372	Causes damage to organs through prolonged or repeated exposure.
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.
EUH208	Contains polyhexamethylene biguanide hydrochloride; PHMB. May produce an allergic reaction.

### Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Aquatic Chronic 3	H412	Calculation method
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KFT SDS EU 00

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product*