

SAFETY DATA SHEET

In accordance with 1907/2006 annex II 2015/830 and 1272/2008
(All references to EU regulations and directives are abbreviated into only the numeric term)

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

1.1. Product identifier

Trade name HYDROCYN Aqua® (Gel)

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

Identified uses Moistening and debridement of wounds

1.3. Details of the supplier of the safety data sheet

Company Bactiguard (South East Asia) Sdn. Bhd. (formerly known as Vigilenz Medical Devices Sdn. Bhd.) 308 b, Jalan Perindustrian Bukit Minyak 18, Penang Science Park, 14100 Penang, Malaysia.
Telephone +60 4-5054241/9841
E-mail enquiry@vigilenzmd.com
Website www.vigilenzmd.com

1.4. Emergency telephone number

Acute cases: Call 112, request poison information.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Upon assessment, this mixture is not classified as hazardous according to 1272/2008

2.2. Label elements

Hazard pictogram Not applicable
Signal word Not applicable
Hazard statement Not applicable

2.3. Other hazards

This product does not contain any substances that are assessed to be a PBT or a vPvB

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Note that the table shows known hazards of the ingredients in pure form. These hazards are reduced or eliminated when mixed or diluted, see Section 16d.

Constituent	Classification	Concentration
SODIUM HYPOCHLORITE		
CAS No: 7681-52-9 EC No: 231-668-3		0.05%

Explanations to the classification and labelling of the ingredients are given in Section 16e. Official abbreviations are printed in normal font. Text in italics are specifications and/or complements used in the calculation of the classification of this mixture, see Section 16b.

SECTION 4: First aid measures

4.1. Description of first aid measures

Generally

In case of concern, or if symptoms occur, call a doctor/physician.

Upon breathing in

Fresh air and rest. If symptoms persist seek medical advice.

Upon eye contact

Immediately flush eyes with water and continue washing for several minutes with lukewarm water. If irritation persists, call a doctor.

Upon skin contact

Wash thoroughly with water if irritation occurs; If symptoms persist seek medical advice.

Upon ingestion

Rinse nose, mouth and throat with water. Get medical attention if you feel unwell.

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

No further relevant information available.

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

Symptomatic treatment.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

Extinguish with water mist, powder, carbon dioxide or alcohol resistant foam.

5.2. Special hazards arising from the substance or mixture

In case of fire, substances hazardous to health, or substances harmful in other respects, may be dispersed.

5.3. Advice for fire-fighters

Protective measures should be taken regarding other material at the site of the fire. In case of fire use proper breathing apparatus. Wear full protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

In case of spillage in protected water, call the emergency services immediately, tel. 112 (in Europe).

Avoid inhalation and exposure to skin and eyes. Use recommended safety equipment, see section 8.

Ensure good ventilation. Note that there is a risk of slipping if product is leaking/spilling.

6.2. Environmental precautions

Avoid emissions into soil, water or air.

6.3. Methods and material for containment and cleaning up

Small spills can be wiped up with a cloth or similar.

Then flush the spill site with water.

Larger spills should first be covered with sand or earth and then be collected.

Collected material should be disposed according to Section 13.

6.4. Reference to other sections

See section 8 and 13 for personal protection equipment and disposal considerations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Store this product separately from food items and keep it out of the reach of children and pets. Avoid spillage, inhalation and contact with eyes and skin.

Do not eat, drink or smoke in premises where this product is handled. Handle in premises which have modern ventilation standards.

Remove contaminated clothing.

Wash contaminated clothing before reuse. Avoid contact with other chemicals.

Keep away from incompatible products.

7.2. Conditions for safe storage, including any incompatibilities

This product should be stored well out of reach of young children and kept safely apart from products intended for consumption.

The product should be stored in a manner which prevents hazards to health and the environment. Avoid exposure to humans and animals and do not discharge the product in a sensitive environment.

Always use sealed and visibly labeled packages. Store in dry and cool area.

Keep away from light.

Do not store close to incompatible materials (see section 10.5).

7.3. Specific end uses

See identified uses in Section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. National limit values

All ingredients (cf. Section 3) lack occupational exposure limit values.

DNEL

No data available.

PNEC

No data available.

8.2. Exposure controls

The risks posed by the product or its constituents must be considered in the task specific risk assessment, in accordance with current working environment legislation. The risk assessment should be reviewed regularly and updated if necessary.

8.2.1. Appropriate engineering controls

The ventilation in the workplace must ensure an air quality that meets the requirements of the current working environment legislation. Local exhaust ventilation should be used to remove airborne contaminants at the source.

Eye/face protection

Eye protection should be worn if there is any danger of direct exposure or splashing.

Skin protection

Wear suitable protective clothing when necessary.

Protective gloves are normally not needed due to the properties of this product, but may be necessary for other reasons,

e.g. mechanical risks, temperature conditions or microbiological risks.

The most suitable protective glove should be chosen in consultation with the glove supplier, taking into account the risk assessment for the specific task and the properties of the chemicals involved. Note that the breakthrough time of the material is affected by the duration of the exposure, temperature conditions, abrasion, etcetera.

Respiratory protection

Respiratory protective equipment is not normally required when working with this product, given that adequate ventilation is provided.

The most appropriate respiratory protective equipment should be decided in consultation with the appointed safety representative, taking into account the risk assessment for the specific task.

8.2.3. Environmental exposure controls

For limiting environmental exposure, see section 12.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

a) Appearance	Form: viscous, thixotropic gel. Colour: Clear to slightly hazy .
b) Odour	Mild chlorine odour
c) Odour threshold	Not indicated
d) pH	9,00-10,50
e) Melting point/freezing point	Not indicated
f) Initial boiling point and boiling range	Not indicated
g) Flash point	Not indicated
h) Evaporation rate	Not indicated
i) Flammability (solid, gas)	Not applicable
j) Upper/lower flammability or explosive limits	Not indicated
k) Vapour pressure	Not indicated
l) Vapour density	Not indicated
m) Relative density	Not indicated
n) Solubility	Solubility in water: Soluble
o) Partition coefficient: n-octanol/water	Not applicable
p) Auto-ignition temperature	Not indicated
q) Decomposition temperature	Not indicated
r) Viscosity	Not indicated
s) Explosive properties	Not applicable
t) Oxidising properties	Not applicable

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product contains no substances which can lead to hazardous reactions at normal use.

10.2. Chemical stability

Stable for 18 months. Reacts with household chemicals such as toilet bowl cleaners, rust removers, vinegar, acids, or ammonia containing products to produce chlorine and other gases.

10.3. Possibility of hazardous reactions

Upon reaction with acids chlorine is released.

10.4. Conditions to avoid

Avoid heating.

Avoid contact with other chemicals.

The product is sensitive to light.

10.5. Incompatible materials

Strong oxidizing agents

10.6. Hazardous decomposition products

Oxygen.

Chlorine gas.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Information on possible health hazards are based on experience and / or toxicological properties of several components in the product.

Acute toxicity

The product is not classified as acutely toxic.

Skin corrosion/irritation

The product is not classified for skin corrosion/irritation.

Serious eye damage/irritation

The product is not classified for serious eye damage/eye irritation.

Respiratory or skin sensitisation

The product is not classified as sensitising.

Germ cell mutagenicity

The product is not classified as mutagen.

Carcinogenicity

The product is not classified as carcinogenic.

Reproductive toxicity

The product is not classified as a reproductive toxicant.

STOT-single exposure

The product is not classified for specific organ toxicity after single exposure.

STOT-repeated exposure

The product is not classified for specific organ toxicity after repeated exposure.

Aspiration hazard

The product is not classified as being toxic for aspiration.

SECTION 12: Ecological information**12.1.Toxicity**

Prevent release on land, in water and drains.

No ecological damage is known or expected in the event of normal use.

12.2.Persistence and degradability

The product degrades in the natural environment.

12.3.Bioaccumulative potential

This product or its constituents are not expected to accumulate in nature.

12.4.Mobility in soil

The product is miscible with water and is therefore variable in soil and water.

12.5.Results of PBT and vPvB assessment

This product does not contain any substances that are assessed to be a PBT or a vPvB.

12.6.Other adverse effects

No known effects or hazards.

SECTION 13: Disposal considerations**13.1. Waste treatment methods Waste handling of the product**

Avoid discharge into sewers.

The product is not classified as hazardous waste.

Empty, rinsed packaging is sent for recycling where practicable.

See directive 2008/98/EC on waste. Observe national or regional provisions on waste management.

SECTION 14: Transport information

Where not otherwise stated the information applies to all of the UN Model Regulations, i.e. ADR (road), RID (railway), ADN (inland waterways), IMDG (sea), and ICAO (IATA) (air).

14.1.UN number

Not classified as dangerous goods

14.2.UN proper shipping name

Not applicable

14.3.Transport hazard class(es)

Not applicable

14.4.Packing group

Not applicable

14.5.Environmental hazards

Not applicable

14.6.Special precautions for user

Not applicable

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

Not applicable

14.8 Other transport information

Not applicable

SECTION 15: Regulatory information**15.1.Safety, health and environmental regulations/legislation specific for the substance or mixture**

REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning the making available on the market and use of biocidal products.

15.2.Chemical safety assessment

Assessment and chemical safety report in accordance with 1907/2006 Annex I has not yet been performed.

SECTION 16: Other information**16a. Indication of where changes have been made to the previous version of the safety data sheet Revisions of this document**

This is the first version

16b. Legend to abbreviations and acronyms used in the safety data sheet Explanations of the abbreviations in Section 14

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

RID Regulations concerning the International Transport of Dangerous Goods by Rail

IMDG International Maritime Dangerous Goods Code

ICAO International Civil Aviation Organization (ICAO, 999 University Street, Montreal, Quebec H3C 5H7, Canada)

IATA The International Air Transport Association

16c. Key literature references and sources for data Sources for data

Primary data for the calculation of the hazards has preferentially been taken from the official European classification list, 1272/2008 Annex I, as updated to 2020-11-18.

Where such data was not available, alternative documentation used to establish the official classification was used, e.g. IUCLID (International Uniform Chemical Information Database). As a second alternative, information was used from reputable international chemical industries, and as a third alternative other available information was used, e.g. material safety data sheets from other suppliers or information from non-profit associations, where reliability of the source was assessed by expert opinion. If, in spite of this, reliable information could not be sourced, the hazards were assessed by expert opinions based on the known hazards of similar substances, and according to the principles in 1907/2006 and 1272/2008.

Full texts for Regulations mentioned in this Safety Data Sheet

- 1907/2006 REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation 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
- 2015/830 COMMISSION REGULATION (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- 1272/2008 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
- 2008/98 DIRECTIVE 2008/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 November 2008 on waste and repealing certain Directives

16d. Methods of evaluating information referred to in 1272/2008 Article 9 which was used for the purpose of classification

Hazard calculation for this mixture has been performed as a cumulative assessment with the aid of expert assessments in accordance with 1272/2008 Annex I , where all available information which may be significant to establishing the hazards of the mixture was assessed together, and in accordance with 1907/2006 Annex XI .

16e. List of relevant hazard statements and/or precautionary statements**16f. Advice on any training appropriate for workers to ensure protection of human health and the environment
Warning for misuse**

This product is not expected to cause severe harm to humans or the environment. The manufacturer, the distributor or the supplier are not responsible for adverse effects if the product is not handled in accordance with the directions for use.

Other relevant information

Not indicated