SAFETY DATA SHEET

Biocide BIOMEBA

Active substance: *Willaertia Magna C2c Maky*

PRESERVATIVES FOR LIQUID-COOLING AND PROCESSING SYSTEMS.
FOR WATERS TREATMENT OF INDUSTRIAL COOLING SYSTEMS.
R&D USE ONLY.

Version 4.2 – August 2017

SDS-TP11-BM-EN-Rev4.2

SECTION 1 - IDENTIFICATION OF SUBSTANCE/MIXTURE AND COMPANY

1.1. Product identifier:

Product name : BIOMEBA

Active substance : amoeba *Willaertia Magna C2c Maky*

Product Names, format and Catalog numbers	5 liters	10 liters	20 liters
BIOMEBA 3 % (3E+08 cells / l)	B35L	B310L	B320L
BIOMEBA 10% (1E+09 cells / l)	B105L	B1010L	B1020L
BIOMEBA 30 % (3E+09 cells / l)	B305L	B3010L	B3020L

1.2. Use of Substance / Mixture:

Preservative for liquid-cooling and processing systems.

1.3. Supplier of the safety data sheet:

European Union:

Manufacturer : Amoéba
38 avenue des Frères Montgolfier
69680 Chassieu
France

Emergency Phone # : +33 (0)4 26 69 16 00 (only during office hours)

E-mail : contact@amoeba-biocide.com

United States and Canada :

Manufacturer production site: Entreprise Amoeba Canada Inc.
SB5400-141 President-Kennedy
Montreal, QC
H2X 1Y4 CANADA

Manufacturer Administration: Entreprise Amoeba Canada Inc.
600-1800 McGill College Ave
Montreal, QC
H3A 3J6 CANADA

Emergency Phone # : 514 849-7600

E-mail : technicalsupport@amoeba-biocide.com

SECTION 2 - HAZARDS IDENTIFICATION

Classification and label elements according to Globally Harmonized System of Classification and Labelling of Chemicals (GHS)
[implemented in Europe through Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP)]
[implemented in the USA through : HCS/HazCom 2012 Final Rule & Appendices]
[implemented in Canada through : Workplace Hazardous Materials Information System (WHMIS 2015)]

2.1. Classification of the substance / mixture:

Physical Hazards : Substance / Preparation is not classified.

Health Hazards : Substance / Preparation is not classified.

Environmental Hazards : Substance / Preparation is not classified.

2.2. Label elements

Hazard pictograms (CLP) : None.

Signal word (CLP) : None.

Hazard statements (CLP) : None.

Precautionary statements (CLP) : None.

2.3 Other hazards

None.

SECTION 3 - INFORMATION ON INGREDIENTS

Components:
Active substance: amoeba *Willaertia Magna C2c Maky* [Less than 1% (w / v)].
Ionic components [Less than 2% (w / v)].
Purified water [More than 97% (v / v)].

SECTION 4 - FIRST AID MEASURES

General information:
Symptoms/injuries are not expected to present a significant hazard under anticipated conditions of normal use. In case of accident or feeling unwell, seek medical advice immediately. Show this Safety Data Sheet and label to the medical personnel.

Absorption through respiratory tract:
Rinse noise thoroughly with water. Get medical attention immediately. Show this Safety Data Sheet and label to the medical personnel.

Ingestion:
Do not induce vomiting. Rinse mouth thoroughly with water. Get medical attention immediately. Show this Safety Data Sheet and label to the medical personnel.

Skin contact:
Remove contaminated clothing immediately and wash skin thoroughly with soap and water. If drying occurs a topical lotion should be applied. Get medical attention if irritation persists after washing. Show this Safety Data Sheet and label to the medical personnel.

Eye contact:
Remove any contact lenses and open eyelids wide apart. Rinse immediately with plenty of water. Ensure water flushing of entire surface of eye and lid. Continue to rinse for at least 15 minutes and get medical attention. Show this Safety Data Sheet and label to the medical personnel.

SECTION 5 - EXPLOSION AND FIRE FIGHTING MEASURES

5.1. Extinguishing media:
CO_2, Dry Chemical, Water Fog

5.2 Special hazards arising from the substance or mixture:
Mixture is composed of more than 97% water (v/v) and is thus not inflammable.

5.3. Advice for firefighters:
Do not enter fire area without proper protective equipment, including respiratory protection. Use water spray to cool fire-exposed containers. Prevent fire-fighting water from entering environment.

SECTION 6 - ACCIDENTAL RELEASE / SPILL PROCEDURES

6.1. Personal precautions, protective equipment and emergency procedures:

6.1.1. For non-emergency personnel:
Evacuate the danger area. Refer to Section 4 for first aid measures.

6.1.2. For emergency responders:
Wear appropriate protection. Refer to Section 4 for first aid measures.

6.2. Environmental precautions:
Keep spills and cleaning run-off out of municipal sewers and open bodies of water.

6.3. Methods and material for containment and cleaning up:

6.3.1. For containment: Stop leak. Dike to contain spill. Cover with inert absorbent material.

6.3.2. For cleaning up: Sweep up absorbent material, and place in suitable container.

6.3.2. Other information: No additional information required.

6.4. Other information:
Refer to Section 4 for first aid measures. Refer to Section 8 for exposure control and personal protection.

SECTION 7 - HANDLING AND STORAGE

7.1. Precautions for safe handling:
Remove contaminated clothing and protective equipment before entering eating areas. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid spills into environment.
7.2. Storage conditions:
Keep only in the original closed container in a cool, dry and well ventilated place. Protect from heat and freezing by storage between 4°C and 45°C. Keep away from food, drink and animal feeding stuffs. Keep packaging away from corrosive substances.
7.3. Specific end-use:
Biocide used to control of Legionella and other microorganisms in cooling system fluids.

SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION

Occupational Exposure limit values:
No existing Union OEL.
Hand and skin protection:
None required based on mixture toxicological data.
Eye protection:
None required based on mixture toxicological data.
Respiratory protection:
None required based on mixture toxicological data.
Other information:
Do not eat, drink or smoke during use. Have eyewash facility close by. Wear appropriate clothes in accordance with local requirements when working close to the cooling system (i.e. but not limited to protective gloves, chemical goggles or safety glasses, mask).

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Colorless liquid.
Odor	:	Odorless.
Odor threshold	:	Not applicable.
pH	:	7,0 – 7,5.
Melting point	:	- 0.3°C at 1014.09 hPa (Solution 5 x 10^6 cells /L).
Boiling point	:	100°C.
Flash point	:	No data available.
Evaporation rate	:	No data available.
Flammability	:	Not applicable.
Explosive limits	:	No data available.
Vapor pressure	:	23,76 mmHg at 25°C.
Vapor density	:	No data available.
Relative density	:	~1,004 at 20°C
Solubility	:	No data available.
Partition coefficient	:	No data available.
Auto-ignition temperature	:	No data available.
Decomposition temperature	:	No data available.
Viscosity, dynamic	:	~1,2 mPa.s.
Explosive properties	:	No data available.
Oxidizing properties	:	No data available.
Explosive limits	:	No data available.

SECTION 10 - STABILITY AND REACTIVITY

10.1. Reactivity:
The product is stable at normal handling and storage conditions.
10.2. Chemical stability:
The product is stable at normal handling and storage conditions.
10.3. Possibility of hazardous reactions:
None at normal handling and storage conditions.
10.4. Conditions to avoid:
Avoid extremely low or high temperatures, i.e. below 4°C and above 45°C.

10.5. Incompatible materials:
Avoid contact with strong acids, strong bases, and chemical biocides. Avoid contact of packaging with corrosive substances.
10.6. Hazardous decomposition products:
None at normal handling and storage conditions.

SECTION 11 - TOXICOLOGICAL INFORMATION

Acute toxicity (Mixture):
No effects known. Based on available data, the classification criteria are not met.
Skin corrosion/irritation:
No effects known. Based on available data, the classification criteria are not met.
Serious eye damage/irritation:
No effects known. Based on available data, the classification criteria are not met.
Respiratory or skin sensitization:
No effects known. Based on available data, the classification criteria are not met.
Germ cell mutagenicity:
No effects known. Based on available data, the classification criteria are not met.
Carcinogenicity:
No effects known. Based on available data, the classification criteria are not met.
Reproductive toxicity:
No effects known. Based on available data, the classification criteria are not met.
Specific target organ toxicity (single exposure):
No effects known. Based on available data, the classification criteria are not met.
Specific target organ toxicity (repeated exposure):
No effects known. Based on available data, the classification criteria are not met.
Aspiration hazard:
No effects known. Based on available data, the classification criteria are not met.

Performed toxicological studies:

OECD Test No. 404: Acute Dermal Irritation/Corrosion
Study No. 20100231TLC
Results: Under the experimental conditions adopted, *Willaertia Magna* was found to be non-irritant for the skin of the rabbit.

OECD Test No. 405: Acute Eye Irritation/Corrosion
Study No. 20100232TLC
Results: Under the experimental conditions adopted, *Willaertia Magna* was found to be non-irritant for the eye of the rabbit.

OECD Test No. 406: Skin Sensitization
Study No. 20100233TCOC
Results: Under the experimental conditions adopted, the test item *Willaertia Magna* was found to be a non-sensitizer in the Guinea pig.

OECD Test No. 423: Acute Oral toxicity - Acute Toxic Class Method
Study No. 20100234TRC
Results: Under the experimental conditions adopted, the oral administration of *Willaertia Magna* caused no mortality and did not induce clinical signs at 2000 mg/kg during a 14-day period, in female Sprague-Dawley rats. Therefore, the maximum tolerated dose that did not induce mortality in female rats is higher than 2000 mg/kg.

Microbial Pesticide Test Guidelines OPPTS 885.3050 Acute Oral Toxicity/Pathogenicity Biodistribution
Study No. 20110134TRC
Results: Under the experimental conditions adopted, the oral administration of *Willaertia Magna* caused no mortality and did not induce any clinical signs in male and female Sprague-Dawley rats. The biodistribution assessment showed that the test item was not present in all the organ considered in the study and was present in feces in a very small proportion (less than 0.0001%) or in undetectable level. The presence of *Willaertia Magna* in feces could be attributed to a free-living amoeba of the microflora in digestive tract of the animals.

Microbial Pesticide Test Guidelines: OPPTS 885.3200 Acute Injection Toxicity/Pathogenicity
Study No. 20110135TRC
Results: Under the experimental conditions adopted, the intraperitoneal administration of *Willaertia Magna* caused no mortality and did not induce any clinical signs in male and female Sprague-Dawley rats.

Microbial Pesticide Test Guidelines: OPPTS 885.3150 Acute Pulmonary Toxicity/Pathogenicity
Study No. 20130134TRC

Results: Under the experimental conditions adopted, the single nasal administration of *Willaertia Magna* caused no mortality and no toxicological effect in male and female Sprague-Dawley rats. The biodistribution assessment showed that the test item was not present in all the organs considered in the study and was present on the treatment site (nasal cavity and turbinate) 1 and 4 days after treatment.

Microbial Pesticide Test Guidelines: OPPTS 885.3100 Acute Dermal Toxicity/Pathology

Study No. 20100135TLC

Results: Under the experimental conditions adopted, a single application of *Willaertia Magna* at 2 mL/kg of body weight had no effect on the skin of males or females New Zealand White rabbit.

SECTION 12 - ECOLOGICAL INFORMATION

Toxicity (Mixture):

No effects known. Based on available data, the classification criteria are not met.

Persistence and degradability:

Not established.

Bioaccumulative potential:

Not established.

Mobility in soil:

Not established.

Results of PBT and vPvB assessment:

Not established.

Performed ecotoxicological studies:

Daphnia magna, Acute Immobilization Test

Study No. 10-010-116210 based on *OECD Test No. 202: Daphnia sp. Acute Immobilization Test.*

Results: The absence of inhibitory effect during the limit test demonstrates the EC50 of *Willaertia Magna C2c Maky* on Daphnia magna is greater than 100.10^6 amoeba/L and so greater than the maximum recommended concentration of use (10^6 amoeba/L) after 48hours.

Fish, Acute Toxicity Test

Study No. 10-011-116210 based on *OECD Test No. 203: Fish, Acute Toxicity Test.*

Results: The absence of mortality during this limit test demonstrates that the LC50 of the test *Willaertia Magna C2c Maky* on Danio rerio is greater than 71.8 10^6 amoeba/L and also the maximum recommended concentration of use (10^6 amoeba/L) after 96 hours of exposure.

Alga, Growth Inhibition Test

Study No. 10-009-116210 based on *OECD Test No. 201: Freshwater Alga and Cyanobacteria, Growth Inhibition Test.*

Results: The absence of inhibitory effect during this limit test demonstrates that the EC_{50} of *Willaertia Magna C2c Maky* on the growth of the unicellular green alga species: *Pseudokirchneriella subcapitata* is greater than 60.10^6 amoeba/l and also the maximum recommended concentration of use (10^6 amoeba/L) after 72 hours of exposure.

Activated Sludge, Respiration Inhibition Test

Study No. 11-003-116210 based on *OECD Test No. 209: Activated Sludge, Respiration Inhibition Test (Carbon and Ammonium Oxidation).*

Results: The absence of inhibitory effect during this limit test demonstrates that the EC50 of the test item, on respiration of activated sludge, is greater than 100.10^6 amoebae/L (initial concentration), after a contact time of 3 hours.

Earthworm acute toxicity study

Study No. 15-004-155072 based on *OECD Test No. 209: Earthworm, Acute Toxicity Test.*

Results: No effect of the test item on the survival of the earthworms *Eisenia fetida* was measured at the test concentration of $2,71.10^9$ amoeba/kg of soil (dry weight). It should be noticed a significant increase of biomass of the earthworms exposed to amoeba, during 14 days, compared to unfed control (36.1% versus 7.9% for control conditions).

Acute contact toxicity on honey bees (Apis mellifera)

Study No. 15/201-216MT based on *OECD Test No. 214: Honeybees, Acute Contact Toxicity Test.*

The acute contact toxicity of the living test item (*Willaertia magna C2c Maky*) was tested on honey bees (*Apis mellifera L.*) under laboratory conditions. Based on the results the test item is not toxic to honey bees at the maximal commercial concentration of Amoéba biocide (~ 3 x 10^9 cells/L/bee). No adverse effects were noticed on behaviour.

Chronic oral toxicity study on honey bees (Apis mellifera)

Study No. 15/201-216MT based on *OECD Test No. 213: Honeybees - Acute Oral Toxicity Test, EFSA Guidance on risk assessment on Bees (4 July 2013)* and *US EPA Microbial Pesticide Test Guidelines - OPPTS 885.4380 Honey Bee Testing,Tier I.*

Results: The toxicity of the living test item (*Willaertia magna C2c Maky*) was tested on honey bees (*Apis mellifera*) in a chronic oral toxicity study under laboratory conditions. Based on the results the test item is not toxic to honey bees at

the maximal commercial concentration of Amoéba biocide (3 x 10^9 cells/L). No adverse effects were noticed on behaviour.

Soil Microorganisms: Carbon Transformation Test

Study No. 402/15/1153F/d-e based on *OECD Test No. 217: Soil Microorganisms: Carbon Transformation Test*.

Results: test item had no long-term adverse effect on carbon transformation because no impact of *Willaertia magna C2c Maky* was recorded on respiration rate.

Soil Microorganisms: Nitrogen Transformation Test

Study No. 402/15/1153F/c-e based on *OECD Test No. 216: Soil Microorganisms: Nitrogen Transformation Test*.

Results: A growth of nitrate content was observed in MEM Control and test item containers relative to the control. So, no inhibition of nitrate production was observed, but an increase of the nitrate content has been found into the test item and the MEM Control compared to the Control. The presence of *Willaertia magna C2c Maky* showed no inhibition on the nitrate production.

Effects on seedling emergence and early growth of higher terrestrial plants

Study No. 402/15/1153F/b-e based on *OECD Test No. 208: Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test*.

Results: the test item *Willaertia magna C2c Maky* has no effect on germination and on results of biomass.

Toxicity to freshwater aquatic plants

Study No. 15-006-155072 based on *OECD Test No. 221: Lemna sp. Growth Inhibition Test*.

Results: The study results showed that under the test conditions the test item: Willaertia magna C2c Maky has no significant toxic effect on vegetative growth of Lemna minor to the initial concentration of 3.0E+09 amoeba/L (Time-weighted mean over 7 days: 1.74E+09 amoeba/L).

Acute oral toxicity of substances to birds

Study No. ST042 based on *OECD Test No. 223: Avian Acute Oral Toxicity Test.*

Results: As no mortality in the birds was observed in the limit dose test like in the control birds, the DL50 value for the oral administration of *Willaertia magna C2c Maky* in the Japanes quail (Coturnix coturnix japonica) is higher than 2000 mg/kg of body weight.

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste treatment methods / Waste disposal recommendations:

Do not discharge into drains / surface waters / groundwater. Triple- or pressure-rinse the empty container. Add the rinsings to the spray mixture in the tank. Make the empty container unsuitable for further use. For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency.

Container disposal:

Packaging should be emptied as far as possible; then it can be passed on for recycling.

SECTION 14 - TRANSPORTATION INFORMATION

UN number	:	Substance / mixture is not subject to UN transportation of dangerous goods classification.
ADR	:	Substance / mixture is not subject to ADR classification.
RID	:	Substance / mixture is not subject to RID classification.
ADN	:	Substance / mixture is not subject to ADN classification.
IMDG	:	Substance / mixture is not subject to IMDG classification.
ICAO	:	Substance / mixture is not subject to ICAO classification.

SECTION 15 - REGULATORY INFORMATION

European Union:

Amoéba biocidal product has not yet been granted a European marketing authorization in compliance with Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning biocidal products. Application to get marketing authorization is in process. Amoéba biocidal product will not be commercially available before marketing authorization will have been granted. Amoéba biocidal product is however authorized to be used for PT11 applications (Product Type 11 - Preservatives for liquid-cooling and processing systems) in some EU member states for Research and Development use in accordance with Article 56.2 of Regulation (EU) No 528/2012.

United States of America: Amoéba biocidal product has not yet completed the registration process under the Federal Insecticide, Fungicide, and Rodenticide Act and cannot be distributed, sold or used in the United States of America except for experimental use purpose.

Canada:
Amoéba biocidal product has not completed the registration process under the Pest Control Products Act. Amoéba biocidal product has however been granted a Research authorization (073-RA-16 / 074-RA-16 / 075-RA-16) in Canada and can be manufactured, imported, distributed, or used in Canada for research and development purpose only.

SECTION 16 - OTHER INFORMATION

Data 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.

Training advice:
Use biocides safely. Always read the label and product information before use. Ensure adequate training and/or instructions has been received before use.

Notice:
The information contained herein is offered in good faith and is believed to be accurate based on the data available to us as of the date of MSDS preparation. The information in this document applies to this specific product as supplied. It may not be appropriate for this product if the product is used in combination with other materials. The information in this document is not intended to constitute product performance information. Some of the information presented and conclusions drawn herein are from sources other than direct test data on the product. No statement shall be construed as an endorsement of any product or process. The recommended industrial hygiene and safe handling procedures are believed to be valid in the context of the intended use as described in product labeling. However, each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate. You are urged to obtain material safety data sheets for all products you buy, process, use or distribute, and are encouraged to advise those who may come in contact with such products of the information contained therein. Regulatory requirements are subject to change and may differ between locations. It is the buyer's/user's responsibility to ensure that his activities comply with all federal, state, provincial or local laws. No warranty or guarantee is expressed or implied with respect to this product, the accuracy and sufficiency of the data or recommendations herein, or the results to be obtained from the use of this product. In no event shall the company Amoéba be liable for any loss, claim, damage or liability of any kind, which may arise from or in connection with the information contained in this document or from the use, handling or storage of the product by the buyer/user, whether direct, indirect, or consequential, or for any claim by any third party, beyond the purchase price or replacement of the product in connection with which such loss, claim, damage or liability arose. The foregoing limitations apply regardless of the causes or circumstances giving rise to such loss, claim, damage or liability, even if such loss, claim, damage, or liability is based on negligence or other torts or breach of contract.

Indication of changes:

Version	Changes	Date
Version 3.0	Addition of new 10% and 5-liter references (Section 1). Addition of ecotoxicological study results (Section 12). Update of regulatory status in Canada (Section 15).	January 2016
Version 4.0	Change in R&D marketing authorization Canada	November 2016
Version 4.1	Addition of Canadian facility + GHS mention + Product codes	August 2017
Version 4.2	Formatting for letter paper + title change + US status update	August 2017