

# Summary of product characteristics for a biocidal product

**Product name:** Aquabac XT

**Product type(s):** PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)

**Authorisation number:**

**R4BP 3 asset reference number:** IT-0017252-0000

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## Administrative information

### 1.1. Trade names of the product

Aquabac XT
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### 1.2. Authorisation holder

<b>Name and address of the authorisation holder</b>	Name	CERA
	Address	16, rue de Saint-Pétersbourg 75008 PARIS France
<b>Authorisation number</b>		
<b>R4BP 3 asset reference number</b>	IT-0017252-0000	
<b>Date of the authorisation</b>	01/08/2016	
<b>Expiry date of the authorisation</b>	30/06/2026	

### 1.3. Manufacturer(s) of the biocidal products

<b>Name of the manufacturer</b>	Becker Microbial Products Inc
<b>Address of the manufacturer</b>	11146 N.W. 69TH Place FL 33076 Parkland United States
<b>Location of manufacturing sites</b>	11146 N.W. 69TH Place FL 33076 Parkland United States

### 1.4. Manufacturer(s) of the active substance(s)

<b>Active substance</b>	5 - Bacillus thuringiensis subsp. israelensis Serotype H14, Strain AM65-52
<b>Name of the manufacturer</b>	Becker Microbial Products Inc
<b>Address of the manufacturer</b>	11146 N.W. 69TH Place FL 33076 Parkland United States
<b>Location of manufacturing sites</b>	11146 N.W. 69TH Place FL 33076 Parkland United States

## 2. Product composition and formulation

### 2.1. Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Bacillus thuringiensis subsp. israelensis Serotype H14, Strain AM65-52	Bacillus thuringiensis subsp. israelensis Serotype H14, Strain AM65-52	Active Substance			8

### 2.2. Type of formulation

SC - Suspension concentrate (= flowable concentrate)
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## 3. Hazard and precautionary statements

<b>Hazard statements</b>	Contains 1,2 benzisothiasole-3(2H)-one. May produce an allergic reaction.
<b>Precautionary statements</b>	

## 4. Authorised use(s)

## 4.1 Use description

### Use 1 - TRAINED PROFESSIONALS

<b>Product type</b>	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
<b>Where relevant, an exact description of the authorised use</b>	AQUABAC XT is used for the control of mosquito larvae in water where mosquito breeding occurs
<b>Target organism(s) (including development stage)</b>	Scientific name: Culicidae: Common name: Aedes mosquitoes Development stage: Larvae  Scientific name: Culicidae: Common name: ochlerotatus Development stage: Larvae  Scientific name: Culicidae: Common name: culex Development stage: Larvae
<b>Field(s) of use</b>	Outdoor
<b>Application method(s)</b>	Spraying - Ground application (manual application)
<b>Application rate(s) and frequencies</b>	2.5 L/ha (waters containing moderate levels of organic matter) The product can be diluted or not in water prior to application. Time delay : 24H after application - 100 - -
<b>Category(ies) of users</b>	Trained professional
<b>Pack sizes and packaging material</b>	Bottle, Plastic: HDPE , 1L Drum, Plastic: HDPE , 10L IBC (intermediate bulk container), Plastic: HDPE , 1000L

#### 4.1.1 Use-specific instructions for use

-Always read the label or leaflet before use and respect follow all the instructions provided.-Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc).-Equipment used for treatments must be appropriate, properly maintained and calibrated.-Take into account the life cycle and characteristics of target insects to adapt treatments. In particular, target the most susceptible stage of the pest, timing of applications and areas to be treated.-Inform the authorisation holder if the treatment is ineffective.-Before treatment, determine precisely [the areas to be treated/routes to be followed] (on a map or a plan) .- Spraying must not be carried out where there is upward air movement or where a temperature inversion prevents the spray cloud settling within the treated area.-To optimise the treatment efficacy, do not apply in case of rain (forecasted for the next 24 hours) or wind (above 15 km/h).-The product is not intended to be used in polluted water.  
-AQUABAC XT should not be used by professional workers affected by immunodeficiency, primary or secondary, or in treatment with

immunosuppressive agents, which can significantly reduce the effectiveness of the immune system response.-Non users are not permitted in area being treated.  
-The labeling of the product should provide information to the user about the responsibility to follow any local requirements regarding consultation with relevant authority, before the use of AQUABAC XT in a natural water habitat. -When applying AQUABAC XT to ecosystems of great value for biodiversity, i.e. Natura 2000 or nature reserve, specific permission is required. -The user shall keep records of all uses, including treated areas and concentrations used, for at least 10 years and upon request provide the information to authorities or research.

#### **4.1.2 Use-specific risk mitigation measures**

-Professionals must wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), working coverall, goggles and respiratory mask (with P3 filter)-In case of re-entry after treatment, it is recommended to workers to wear a working coverall and gloves.-AQUABAC XT should not be applied in water surrounding crops, except in water surrounding rice for which a pre harvest interval of 1 month is required.-Do not apply in standing water in fields growing crops when edible parts of plants are present.  
-For ground uses, do not exceed a dose of 2.5 kg/ha with an interval of at least 5 days between two applications.

#### **4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

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#### **4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging**

-Dispose of unused product, its packaging and all other waste in accordance with local regulations.-Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.

#### **4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage**

-Do not store more than one year at a temperature superior to 25 °C-Store away from light.

### **5. General directions for use**

#### **5.1. Instructions for use**

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#### **5.2. Risk mitigation measures**

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### 5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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### 5.4. Instructions for safe disposal of the product and its packaging

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### 5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

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## 6. Other information

-Minimum certified values of the micro-organism "BMP144" in term of CFU/g in the biocidal product AQUABAC XT, and the maximum certified value of the bioactivity for AQUABAC XT in term of ITU/g and according to batches analysis are required in post registration, within 6 months.-A study of pertinence foaming at the maximum use concentration (40 % v/v) is required in post registration, within 6 months.-The in progress new stability study of the biocidal product AQUABAC XT at ambient temperature and in its commercial packaging (PA) should be provided in post registration, within 2 years. This study should include before and after storage data on biopotency (with variation lower than 10 % and with biopotency higher the minimum certified value in the biocidal product AQUABAC XT) and the determination of microbial contaminants according to OECD 65 using validated methods or international standard methods.

-The authorization holder has to submit field or semi-field studies (in experimental conditions closed to the real conditions) performed on Culex genus at claimed application rates and larval stages, for ground application within 6 months.-The authorization holder has to submit field or semi-field studies (in experimental conditions closed to the real conditions) performed on Aedes genus at the minimum application rate claimed of 2.5 L/ha within 2 years.

-In the case of more than two ground applications with an interval of at least 5 days between two applications, effects arising from long term and large scale uses of the product on natural biological diversity including aquatic food webs should be reported by the authorization holder to Competent Authorities (CA).-In the case of repeated ground applications with an interval of at least 5 days between two applications on large scale, effect of these applications on natural biological diversity including terrestrial food webs should be reported by the authorization holder to Competent Authorities (CA), Data dealing with the assessment of effect on biodiversity should be provided every 24 months.

-Within 12 months a composition change of AQUABAC XT is required in order to replace the preservative propylparaben by a preservative which is registered in the european review program as a PT6 active biocidalsubstance.