

Board for the Authorisation of Plant Protection Products and Biocides

Registered

Ateca Production B.V.
Oude Boomgaardstraat 1
2513 TN 's-GRAVENHAGE

Letter number 10/0840 CKO/SEG
Dealt with by Mrs. dr. ing. C.M.D. Komen
Direct line +31 (0)3714-471844
Your reference
Date 26th February 2010
Subject

Dear Sir or Madam,

please see the attached decision on approval of the biocide

ICA-systeem, 13293 N

Your attention is hereby drawn to the following:

Regarding the composition, form and manufacture of the product

As you can see from § 11 of this decision, its composition, form and manufacture may not be changed without further approval. If you are intending to make any changes to it, then an application to do so must be submitted to the Board for the Approval of Plant Protection Products and Biocides.

Classification and labelling

With regard to labelling, you must follow the instructions in § 4 of the enclosed decision carefully. For the other statements on or with the packaging and regarding the requirements that the packaging must fulfil, I refer you to the Wet Milieugevaarlijke Stoffen (Substances Hazardous to the Environment Act) and the More Detailed Rules on the Packing and Marking of Substances and Products Hazardous to the Environment.

Regarding the recent coming into force of the Wet gewasbeschermingsmiddelen en biociden (Plant Protection Products and Biocides Act), the Act has not yet been published. You can consult the text of the Act on our website (www.ctgb.nl).

For the text of the Substances Hazardous to the Environment Act, you can consult the internet on wetten.overheid.nl.

yours faithfully,

The Board for the Approval of Plant Protection Products and Biocides (CTGB).

On behalf of the above:

The Secretary/Director

Dr. A.T.C. Bosveld



The Board for the Approval of Plant Protection Products and Biocides

1 APPROVAL

With regard to the application dated 20th August 2007 (20070779 TB) by

Ateca Production B.V.
Oude Boomgaardstraat 1
2513 TN 's-GRAVENHAGE

on obtaining approval on the basis of the active materials copper and silver,

ICA-systeem

regarding Article 121, Paragraph 1 together with Article 44, Paragraph 1, Plant Protection Products and Biocides Act,

THE BOARD DECIDES as follows:

1.1 Approval

1. The ICA-systeem product is approved under number 13293 N for the applications mentioned in Annex 1 with effect from the date of this letter. For the reasons for this decision, you are referred to Annex II to this decision.
2. The approval is valid until 1st February 2020. (the approval is extended to February 1st 2021, after which the new approval is expected)

1.2 Composition, form and packaging

The approval applies exclusively to the product in the composition, form and packing for which the approval was granted.

1.2b Other conditions

The ICA electrodes and associated equipment must meet all the conditions and requirements set out in BRL K14010-2/01 (Guideline on assessment for Kiwa certification with product certificate for legionella prevention with alternative techniques, Part 2: Electrochemical techniques: copper/silver ionisation and anodic oxidation).

1.3 Use

The product may only be used in accordance with the provisions of A in Annex I to this decision.

1.4 Classification and labelling

Regarding Article 50, Paragraph 1, Sub. d, Plant Protection Products and Biocides Act,

- 1 The statements that must be made on the packaging according to Articles 9.2.3.1 and 9.2.3.2 of the Wet milieubeheer (Environmental Management Act) and Articles 14, 15a, 15b, 15c and 15d of the More Detailed Rules on the Packing and Marking of Substances and Products Hazardous to the Environment are specified as follows:

Nature of the product: one copper electrode and one silver electrode

<i>Active material:</i>	<i>Content:</i>
<i>Copper</i>	<i>Metal in solid form (99.9%)</i>
<i>Silver</i>	<i>Metal in solid form (99.99%)</i>

word for word and without any addition:

other very toxic, toxic, corrosive or hazardous substance(s):-

hazard symbol:-

marking:-

Specific statements:

DPD14 - Information sheet regarding safety is available to the professional user upon request.

- 1) In addition to the markings and statements specified under 1. and the others specified in the Substances Hazardous to the Environment Act and More Detailed Rules on the Packing and Marking of Substances and Products Hazardous to the Environment, the packaging must show:

- word for word and without any addition:

the statutory regulation on use

The text of the statutory regulation on use is shown under A in Annex I.

- either word for word or with the same factual content:

the instructions for use

The text of the instructions for use is shown under B in Annex I.

The text may be supplemented by technical information for proper control provided that this does not conflict with that text.

2 DETAILS OF THE APPLICATION

2.1 Application

This concerns an application to obtain approval for the ICA-systeem product (13293 N), a product based on the active materials copper and silver. The application is made regarding this product for combating *Legionella* bacteria and biofilms in water pipe systems for drinking water in priority installations (in accordance with Article 17i of the Waterleidingbesluit (Water Pipe Order)).

Given that ICA-systeem contains an active material that is new to the Netherlands (see below), the procedure for giving an opinion as specified in Article 2.3 Besluit bestuursreglement regeling toelating gewasbeschermingsmiddelen en biociden (Order regarding administrative regulations on the approval of plant protection products and biocides) Ctgb 2007 apply. No opinions were received within the period specified for this.

2.2 Information concerning the substance

The copper and silver active material is a new substance. To date, no other products have been approved in the Netherlands on the basis of this active material.

The copper active material is referred to in the context of Biocide Directive 98/8/EC for Product Type 5 and has been assessed by France (FR). There is no draft of the European assessment available.

The silver active material is referred to in the context of Biocide Directive 98/8/EC for Product Type 5 and has been assessed by Sweden (SE). There is no draft of the European assessment available.

No decision has been taken to date on the categorisation of the active materials in Annex 1, 1A or 1B of Biocide Directive 98/8/EC.

2.3 Character of the product

The ICA-systeem product consists of copper/silver electrodes which are used in copper/silver ionisation equipment of the ICA brand.

The copper/silver electrodes are precursors. The copper and silver ions formed by ionisation of copper and silver are the real active materials.

The copper and silver ions attach themselves by electrostatic bonds to the charged areas of the bacterial cell wall. This weakens the cell wall and the silver ions penetrate the cell interior where they attack the DNA, RNA, enzymes and protein chains present. This prevents the bacteria from reproducing.

2.4 History

The application was received on 17th August 2007. On 27th August 2007, the application charges due were received. Processing of the application commenced with the letter dated 11th January 2010.

2.5 Conclusion

With its use in accordance with the Wettelijk Gebruiksvoorschrift/Gebruiksaanwijzing (Statutory Regulation on Use/Statutory Instructions on Use), the ICA-systeem product is satisfactorily effective on the basis of the active materials copper and silver and it has no harmful effect on human health or the environment (Article 28, Plant Protection Products and Biocides Act).

Anyone whose interests are directly affected by this decision may, in accordance with Article 119, Paragraph 1 Plant Protection Products and Biocides Act and Article 7.1 Paragraph 1 of the Algemene wet bestuursrecht (General Administrative Law Act) submit a letter of objection within six weeks following the day on which this decision was announced to: the Board for the Approval of Plant Protection Products and Biocides (Ctgb), Postbus 217, 6700 AE WAGENINGEN. The Ctgb has not set up the option of electronic submission of a letter of objection.

Wageningen, 26th February 2010

THE BOARD FOR THE APPROVAL OF
PLANT PROTECTION PRODUCTS AND
BIOCIDES

dr. D. K. J. Tommel
Chairman