

Ecas Quattro Srl
Via P. Miliani, 7
40132 Bologna, Italia

Your ref:
Our ref: 2019/224256
Date: 19.12.2019
Org.no: 985 399 077

Att. Alessandra Quadrelli

Norwegian Food Safety Authority



APPROVAL OF ECAS4 ANOLYTE AS A DISINFECTANT FOR DRINKING WATER TREATMENT

We refer to your application of October 10th 2019, for approval of Ecas4 Anolyte as a disinfectant for drinking water locally in buildings.

The Norwegian Food Safety Authority is handling the formal approval of these products, based on a toxicological evaluation by the Norwegian Institute of Public Health (NIPH). The approval is issued pursuant to Regulations Concerning Water Supply and Water intended for Human Consumption, (FOR-2016-12-22-1868, ofrom01.01.2017, §14), and is based on the information in the application provided by Ecas Quattro Srl.

The applicant has provide documentation on efficacy. However, a specific guidance for efficacy testing in water works is currently not developed. Thus, this aspect could not be fully evaluated. Until such guidance is developed, we therefore presume that the aspect of efficacy is fulfilled as long as the requirements in the Norwegian Biocidal Regulation (FOR-2017-04-18-480), are met.

Evaluation

NIPH has undertaken the evaluation of Ecas4 Anolyte for use as disinfectant for drinking water locally in buildings, on behalf of the Norwegian Food Safety Authority. We received their evaluation December 17th 2019.

They conclude that the product does not represent any health hazard when used in drinking water locally in buildings according to the following premises:

- the product is used according to the information given in the application
- the producer's instructions for use and maximum dosage of 2 ppm are followed, leading to maximum concentrations in the drinking water of 0.7 ppm of free active chlorine
- the concentrations of chlorate and chlorite in the drinking water shall not exceed 0.7 mg/l of either substance
- the pH of the drinking water shall be between 6.5 and 9.5 as is required in the Norwegian Drinking Water regulations
- the product does not negatively affect the quality of the drinking water

Decision

Norwegian food Safety authority approves Ecas4 Anolyte as a drinking water treatment product. The approval is valid for 10 years. The approval cease to apply if the product, including its ingredients, the way of use or the status according to the Norwegian Biocidal Regulation is changed. After these 10 years, the approval automatically becomes invalid. It is possible to apply for re-approval of the product. This should be done in due time before the approval ceases.

The approval assumes that the product is in accordance with the Norwegian Chemicals Regulations managed by the Norwegian Environment Agency; <http://www.miljodirektoratet.no/en/>

The manufacturer/importer is responsible for the product, including ensuring that the product is produced in accordance with good manufacturing practice (GMP). Content of impurities in the product should be as low as technically possible. The chemical components of the product should not cause any health hazard when consuming the drinking water.

The Norwegian Food Safety Authority consider it unlikely that this product will pose a health risk when used in drinking water, as long as the instructions and premises are followed. The approval implies no guarantee of the water treating effect claimed, and must therefore not be used in marketing purposes with this regard (Norwegian Marketing Regulation (LOV-2009-01-09-2, from 01.06.2009, §7 and 26).

The product "Ecas4 Anolyte" will be listed under the category "Disinfectants" on the list of "Approved Chemical products for drinking water treatment" at Norwegian Food Safety's web; www.mattilsynet.no

Charge of Payment

Charge of payment is claimed according to "Regulation of payment of fees for special tasks from the Norwegian food Safety authority" (FOR-2004-02-13-406, §5, Appendix 1, Chapter II, payment class d). Invoice will be sent by the National Institute of Public Health, which has undertaken the toxicological risk assessment.

Appeal

The applicant can appeal the decision, in accordance with the Public Administration Act (LOV-2017-06-16-63 from 01.01.2018, §28). Appeals must be sent to the Norwegian Food Safety Authority within three weeks of the receipt of this letter (§29).

Yours Sincerely

Abdelkarim Abdellaue
Head of Department

Anna Mehl
Senior Scientific Officer

Copy:

Norwegian Environmental Agency, Section for Biocides and
Declaration of Chemicals
Cleancoat AS, Jan Ivar Sylte