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8402 SORTLAND

Your ref:
Our ref: 2023/239322
Date: 12.07.2024
Org.no: 985 399 077

Norwegian Food Safety Authority



APPROVAL OF KLAROLAKS FOR USE IN DISINFECTION OF DRINKING WATER TREATMENT

We refer to your application of 07.11.2023, for approval of Klarolaks for use in disinfection of drinking water centrally in waterworks and locally in buildings/internal distribution networks. 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, 01.01.2017, §14), and is based on the information in the application provided by Roam Technology NV. The documentation necessary for evaluation was complete 21.06.2024 and was then sent to NIPH for a toxicological evaluation.

Evaluation

NIPH has undertaken the evaluation of Klarolaks on behalf of the Norwegian Food Safety Authority based on the product information provided by Last Viking Norway AS and SWS Distribution Ltd. and concludes that the product does not represent a health hazard when used in drinking water treatment.

Premises for the evaluation are that:

- the product is produced according to good manufacturing practice
- the product is used according to the information given in the application, including information on maximum dosage (0.2-0.5 ppm) of active components of the product
- the dosing of the product will not lead to values of chlorite and chlorate above WHO's guideline values of 0.7 mg/l for both substances in the drinking provided to the consumers
- the necessary control system is in place to ensure correct dosing and production of active disinfectant or that this is adequately controlled in other ways
- the product does not negatively affect the quality of the drinking water.

The evaluation concerns potential health effects from use of the product based on the information on content and dose of active components. The product's ability as disinfectant has not been evaluated.

Decision

Norwegian food Safety authority approves Klarolaks as a drinking water treatment product. The approval is valid for 10 years. The approval ceases to apply if the product, including its ingredients

or 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 other relevant regulations. It is further assumed that the product and the active ingredient meet the requirements of regulation 18 April 2017 no. 480 on biocides (the biocides regulation).

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-2021-06-18-122, of 01.07.2022, §7 and 26).

The products "Klarolaks" will be listed under the category "Disinfectants" on the list of "Approved Chemical products for drinking water treatment" at Norwegian Food Safety's home page.

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-2022-12-19-2338, 01.01.2022, § 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) on e-mail to postmottak@mattilsynet.no

Yours Sincerely

Anna Mehl

*This document has been electronically approved, and sent without signature.
Documents that require a signature will also be sent as a paper copy.*

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