

**Final Screening Assessment for *Nitrococcus* sp.
16972-7 and *Nitrosococcus* sp. 16971-6**

Environment Canada

Health Canada

February 2015

Cat. No.: En84-127/2015E-PDF
ISBN 978-0-660-23122-8

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Synopsis

Pursuant to paragraph 74(b) of the *Canadian Environmental Protection Act, 1999* (CEPA 1999), the Ministers of the Environment and of Health have conducted a screening assessment on two lower-hazard (Priority C) micro-organism strains.

Living organisms on the DSL were prioritized into three groups (Priority A, B, C) based on known hazard characteristics. The 22 micro-organisms in the Priority C (lower-hazard) group were further sub-divided into four “Lots” for assessment based on their taxonomic classification (genus or species) and their known and potential uses related to their biological properties and on whether they remain in commerce in Canada. This screening assessment pertains to Lot 2 of the Priority C group (see Table 1 below). For more information, please refer to [Prioritization of Micro-organisms on the Domestic Substances List prior to the Screening Assessment under paragraph 74\(b\) of CEPA 1999](#).

Table 1. List of micro-organisms in Lot 2 of the Priority C group

Organism	Strain/Accession Number
<i>Nitrococcus</i> species	16972-7
<i>Nitrosococcus</i> species	16971-6

Where strain-specific data were not available, surrogate information from literature searches was used. Surrogate organisms are identified in each case to the taxonomic level provided by the source. Information identified up to May 2013 was considered for inclusion in the screening assessment.

While this screening assessment was prepared by staff at Health Canada and Environment Canada, information related to *Nitrosococcus* spp. also underwent written peer review by Martin G. Klotz (University of North Carolina, Charlotte), a scientist external to the government who has expertise in this micro-organism.

Nitrococcus sp.16972-7 and *Nitrosococcus* spp. 16971-6 were nominated to the DSL under the Masked Name Regulations pursuant to section 113 of CEPA 1999. More detailed assessments of these micro-organisms were prepared, but in order not to disclose the precise identity of these micro-organisms, specific information used in the assessments and the corresponding scientific references are not published in this screening assessment.

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1. Hazard Assessment

The two micro-organisms in Lot 2, *Nitrococcus* species strain 16972-7 and *Nitrosococcus* species strain 16971-6, are naturally occurring bacteria which thrive mainly in marine, coastal and brackish waters. Neither is recognized as a human pathogen by the Public Health Agency of Canada and no adverse human health effects have been associated with these strains, their genetic material, secondary metabolites or structural components. Similarly, neither of these strains is recognized as an animal or plant pathogen by the Canadian Food Inspection Agency. Furthermore, an in-depth scientific literature search yielded no reports of the presence of virulence factors or evidence of toxicity or pathogenicity towards humans, plants, vertebrates, or invertebrates. These observations are supported by our understanding of the roles played by these micro-organisms in nature, which do not suggest a potential for pathogenic effects and by genomic sequencing and analysis (Gillespie et al., 2011) which did not identify attributes associated with pathogenicity.

The hazard potential associated with *Nitrococcus* species strain 16972-7 and *Nitrosococcus* species strain 16971-6, was estimated to be low for both the environment and human health.

2. Exposure Assessment

The exposure associated with the two micro-organism strains in Lot 2 was gathered from publicly available sources and through a mandatory information-gathering survey (Notice) under section 71 of CEPA 1999, as published in the Canada Gazette on October 3rd, 2009. Based on responses to this survey, neither strain was in commerce in 2008.

While there are no known current uses for the two micro-organism strains in Lot 2 in Canada, their ability to degrade nitrogenous compounds makes them of potential use as ingredients in microbial-based products used for the maintenance of aquaria and ornamental ponds, wastewater treatment, soil biodegradation; in pharmaceuticals or personal care products; and for production of enzymes (Alleman et al. 1991).

If potential uses were realized, human exposure would occur primarily through direct contact with consumer, household and commercial products containing these micro-organisms and is expected to be moderate. Indirect exposure through treated aquarium and pond water, wastewater and industrial effluents, or biodegraded soil is not expected to be significant. If *Nitrosococcus* sp. 16971-6, specifically, is used in pharmaceuticals or personal care products, direct human exposure could be high, but would depend on the product formulation, frequency of use, and mode of application.

Nitrosococcus sp. and *Nitrococcus* sp. have very specific growth requirements, including saltwater, nitrogen availability, temperature, oxygen and light (Koops and Pommerening-Roser, 2005; Spieck and Bock, 2005). Outside of their specialized niche, these two micro-organisms are anticipated to have limited growth and persistence. Environmental flora and fauna may come into contact with these micro-organisms when they are released directly into aquatic ecosystems and wastewater from household, commercial, industrial or manufacturing activities. Nonetheless, based on available information and data, these Lot 2 strains are not expected to persist in the environment, except where their specific growth requirements are met.

Given the range of potential applications of these two micro-organism strains, and market trends towards microbial-based products to replace chemical products in certain sectors, the scale and frequency of use of these strains is expected to increase (Chatzipavlidis et al, 2013), so conservative assumptions were applied to the exposure characterization. Therefore, the exposure associated with these micro-organisms in Lot 2 is estimated to be moderate for both the environment and human health.

3. Risk Characterisation

The two strains in Lot 2 are not recognized to cause disease, and the routes of exposure are not expected to lead to adverse environmental or human health effects.

Given that these are naturally occurring micro-organisms, given that they play a key role in the ecosystem, and given the lack of documented evidence for adverse effects in the published literature, it is considered that these microorganisms present a low hazard towards the environment and human health. Therefore, taking into account the exposures resulting from all their numerous potential uses, the estimated risk is expected to be low for both the environment and human health.

4. Conclusion

Based the available information, it is concluded that these micro-organisms are not entering the environment in a quantity or concentration or under conditions that:

- have or may have an immediate or long-term harmful effect in the environment or its biological diversity;
- constitute or may constitute a danger to the environment on which life depends;
- or
- constitute or may constitute a danger in Canada to human life or health.

Therefore, it is concluded that these micro-organisms do not meet the criteria as set out in section 64 of the CEPA 1999.

6. References

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