



Government
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Final Screening Assessment Report of:

***Nitrobacter winogradskyi* (ATCC 25391)**

***Nitrobacter* species (18132-6)**

***Nitrobacter* species (16969-4)**

***Nitrosomonas europaea* (ATCC 25978)**

***Nitrosomonas* species (16968-3)**

***Nitrosomonas* species (18133-7)**

***Rhodopseudomonas palustris* (ATCC 17001)**

***Rhodopseudomonas* species (18136-1)**

Canada 

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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 of eight lower-hazard (Priority C) micro-organism strains. These strains were nominated and added to the DSL because they were manufactured in or imported into Canada between January 1, 1984 and December 31, 1986, and they entered or were released into the environment without being subject to CEPA 1999 or any other federal or provincial legislation.

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 are being assessed using an expedited approach in parallel with the more complex assessment of 16 micro-organisms in the Priority A (higher hazard) group with the objective of assessing the entire number of DSL micro-organisms more efficiently and to provide greater certainty to industries that use these microorganisms. The Priority C group was 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 assessment pertains to Lot 1 of the Priority C group. 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 the Priority C Lot 1

Organism	Strain/Accession Number
<i>Nitrobacter winogradskyi</i>	ATCC 25391
<i>Nitrobacter</i> species	18132-6
<i>Nitrobacter</i> species	16969-4
<i>Nitrosomonas europaea</i>	ATCC 25978
<i>Nitrosomonas</i> species	16968-3
<i>Nitrosomonas</i> species	18133-7
<i>Rhodopseudomonas palustris</i>	ATCC 17001
<i>Rhodopseudomonas</i> species	18136-1

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 January 2012 was considered for inclusion in the screening assessment report.

This screening assessment was prepared by staff in Health Canada and Environment Canada. Both the human health and ecological portions of the *Nitrobacter* species assessment underwent written peer review by Peter Bottomley (Oregon State University), a scientist external to the government who has expertise in that organism.

Nitrobacter sp. 18132-6, *Nitrobacter* sp. 16969-4, *Nitrosomonas* sp. 16968-3, *Nitrosomonas* sp. 18133-7 and *Rhodopseudomonas* sp. 18136-1 were nominated into 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 identity of the micro-organisms, specific information used in the assessments and the corresponding scientific references are not published in this report.

Hazard assessment

The eight micro-organisms in Lot 1 are naturally occurring bacteria. None 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, none of these strains is recognized as an animal or plant pathogen by the Canadian Food Inspection Agency or by any member country of the International Plant Protection Convention. 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 which did not identify attributes associated with pathogenicity (Starkenbourg et al., 2006; Chain et al., 2003; Larimer et al., 2004). In the highly unlikely event of infection, all Lot 1 strains are susceptible to clinically relevant antibiotics.

The hazard potential associated with the micro-organisms in Lot 1 was estimated to be low for both the environment and human health.

Exposure assessment

The purpose of the exposure assessment is to characterize human and environmental exposure to these eight strains from their deliberate use in consumer or industrial products used in Canada.

The exposure associated with the eight micro-organism strains in Lot 1 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, strains in Lot 1 are used in quantities ranging from 50-200 kg per year as ingredients within commercial and consumer products. No information on *Nitrobacter* sp. 18132-6, *Nitrosomonas* sp. 18133-7, or *Rhodopseudomonas* sp. 18136-1 was collected through the Notice as they were nominated to the DSL after the survey took place.

Current and potential uses of Lot 1 micro-organisms are as ingredients in microbial-based products used for bioremediation, biological waste treatment, and municipal waste water treatment; to clean drains and grease traps in restaurants; and to improve water quality in commercial and hobby fish production facilities, and more. Their mode of action is based on their ability to degrade nitrogenous wastes, grease and oils, and man-made

chemicals in industrial effluents (halogenated and aromatic compounds, and active pharmaceutical ingredients).

Human exposure is expected primarily through direct contact with consumer and commercial products containing these micro-organisms. For example, during the application of household products containing these strains, dermal exposure and inhalation of aerosolized droplets or particles containing micro-organisms is likely. Contact with the eyes and incidental ingestion secondary to the contamination of hands and food preparation surfaces may also occur. Intended and potential uses are likely to introduce these micro-organisms to soil and water. Human exposure through treated water, wastewater effluent or bioremediation sites is not expected to be significant, but environmental flora and fauna may come into contact with these micro-organisms when they are released from commercial, industrial or manufacturing activities.

There is little information on background concentrations of Lot 1 micro-organisms or their persistence in the environment. *Nitrobacter winogradskyi* has been reported to be present in soil at concentrations of 10^4 - 10^5 cells per gram (Rennie and Schmidt, 1977), which is consistent with the nature of *Nitrobacter winogradskyi* as a slow-growing, difficult to culture micro-organism that declines quickly when introduced into environments that do not provide ideal growth conditions. No measurement of *Nitrosomonas europaea* concentrations in natural soil was found; however, ammonium oxidizing organisms are estimated to be present at concentrations between 10^5 to 10^6 organisms/cm³ (Lang and Elliott, 1997). Ammonia oxidizing organisms are able to survive periods of desiccation (up to 10 weeks) through polysaccharide encapsulation (Allison and Prosser, 1991). There is no information or data on survival or persistence of *Rhodopseudomonas palustris* populations. Based on available information and data, Lot 1 strains are not expected to persist in the environment at concentrations above background levels.

Given the range and potential applications of these micro-organisms, and market trends towards increased use of microbial-based products instead of chemical products in certain sectors, the scale and frequency of use of these strains is expected to increase with consequently higher releases to the environment (Chatzipavlidis et al, 2013). Conservative assumptions have therefore been applied to the exposure characterization.

Therefore, the exposure associated with the micro-organism in Lot 1 is estimated to be moderate for both the environment and human health.

Risk assessment

The eight strains are not recognized to cause disease and the routes of exposure are not expected to lead to adverse environmental or human health effects.

Given the ubiquity of these organisms in nature, 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 known and potential uses, the estimated risk is expected to be low for both the environment and human health.

Based on the available information, it is concluded that the micro-organisms listed in this Notice do not meet the criteria under paragraph 64(a) or (b) of CEPA 1999 as they 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 on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends. It is also concluded that the micro-organisms listed in this Notice do not meet the criteria under paragraph 64(c) of CEPA 1999 as they are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

Conclusion

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

More information on the assessment approach for lower hazard micro-organisms on the Domestic Substances List is available on the Government of Canada's [Chemical Substances Web site](#).

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