New substances: risk assessment summary, new substances notification 21835

Official title: New substances: risk assessment summary, New Substances Notification 21835 – Schedule 1 of the *New Substances Notification Regulations (Organisms)*

Notified organism: *Bacillus paralicheniformis* CH00005

Schedule of the NSNR(O): Schedule 1 - Information Required in Respect of Micro-organisms

Organism type: Bacterium

Use: Manufacture of *B. paralicheniformis* CH00005 as a component of microbial based cleaning products (MBCPs) used for degradation of organic waste, prevention of clogging in drains, and controlling foul odours.

Anticipated quantity: confidential and not for disclosure.

Assessment level of concern:

- Human health hazard: Low
- Human exposure: Medium
- Environmental hazard: Low
- Environmental exposure: Medium

Assessment conclusion under section 64 of the *Canadian Environmental Protection Act, 1999* (CEPA): Low risk, not suspected to be toxic

Recommended action: None

Waiver: None

Synopsis

B. paralicheniformis CH00005 was notified for its use as an ingredient in MBCPs for degradation of organic waste, prevention of clogging in drains receiving wastewater rich in fat, oil, and grease, and controlling foul odours. Other potential uses include bioremediation applications. There is no evidence to suggest a potential risk of adverse environmental effects at the exposure levels predicted for the Canadian environment from its intended and potential uses. There is medium potential for exposure, but owing to the low potential for hazard, *B. paralicheniformis* CH00005 is not suspected to meet the criteria in paragraphs 64(a) or (b) of CEPA. Similarly, there is no evidence to suggest a risk of adverse human health effects at the exposure levels predicted for the general Canadian population from its intended and potential uses. There is medium potential for exposure, but owing to the low potential for hazard, *B. paralicheniformis* CH00005 is not suspected to meet the criteria in paragraph 64(c) of CEPA.

Background information

B. paralicheniformis CH00005 (hereafter called CH00005) is a naturally occurring bacterium isolated from the notifier's facility as part of screening for micro-organisms with high lipolytic activity. No genetic modifications were made to the strain.

Specifically, CH00005 was notified to be used as a component of several commercial preparations of MBCPs that will be manufactured under the brand name 'Kersia', intended to degrade organic waste (ex. septic tanks, grease traps, wastewater of agri-food industries to prevent clogging of drains receiving wastewater rich in fat, oil, and grease (ex. drains in restaurants and collective kitchens, drains in food courts) and control foul odours (ex. trash compactors, garbage trucks, bathrooms). CH00005 can potentially be used in other applications, like bioremediation.

Hazard

The environmental hazard potential of CH00005 is determined to be low because:

1. *B. paralicheniformis* is naturally occurring and can inhabit diverse environments (i.e., soil, water, air, plant rhizosphere, human, animal, fermented food). It is expected that CH00005 could inhabit these same environments. CH00005 was isolated from the environment and has not been genetically modified. It will not have any competitive advantage at the site of introduction compared to other indigenous strains with respect to survival, persistence or dispersal.
2. Emetic toxin and enterotoxin genes generally found in *Bacillus cereus* and *Bacillus thuringiensis* were not found in the notified strain.
3. The pathogenicity and toxicity test data from a relevant surrogate species provided by the notifier, *B. licheniformis*, along with a comprehensive review of the literature, did not identify any adverse effects related to *B. paralicheniformis* on aquatic and terrestrial species.
4. CH00005 has been classified as Risk group 1 terrestrial animal pathogen (organisms that pose a low risk to the health of individuals or animals, and a low risk to public health or animal population. RG1 pathogens can be opportunistic and may pose a threat to immunocompromised individuals) by the Public Health Agency of Canada (PHAC).

The human hazard potential of CH00005 is determined to be low because:

1. CH00005 is a naturally occurring microorganism isolated in Canada based on its lytic enzyme activity and identified as a strain of *B. paralicheniformis*. It has not been genetically modified; thus no changes have been introduced to confer a selective advantage or that would alter the host range, pathogenicity, or toxicity to humans.
2. CH00005 is classified as Risk Group 1 organism for human health by PHAC. There are no reports in the published literature suggesting infections in humans related to *B. paralicheniformis* or the notified strain CH00005. In addition, reports of human infections

caused by a closely related surrogate organism, *B. licheniformis*, are also rare. When they do occur, they are typically reported in individuals with immunocompromised or underlying medical conditions.

3. *B. paralicheniformis* strains have been approved for use as biopesticides, feed additives and for food grade enzymes production organism with no reported cases of adverse effects.
4. In the absence of pathogenicity and toxicity testing data on the CH00005, surrogate information for *B. licheniformis* provided by the notifier and based on the program's literature review was determined to be acceptable. The surrogate data and information did not identify any pathogenicity or toxicity or adverse effects on any animal models tested. It is reasonable to expect that CH00005 would behave similarly to the surrogate strain. Furthermore, genome sequence analysis of CH00005 did not reveal any presence of genes associated with virulence and toxicity.
5. While the CH00005 genome analysis conducted by the notifier and Health Canada did identify genes that may confer resistance to several antibiotics; an antibiotic susceptibility profile of CH00005 was also provided by the notifier. This profile clearly demonstrated that the notified organism would be susceptible to several clinically relevant antibiotics. Thus, based on this evidence it is expected that there would be effective antibiotic treatments available in the unlikely (i.e., rare) event of infection.
6. Amino acid sequence analyses of all proteins predicted from CH00005 genome using the AllergenOnline Database did not identify any potential for allergenicity.

Hazards related to micro-organisms used in the workplace should be classified accordingly under the Workplace Hazardous Materials Information System (WHMIS)[1].

Exposure

The environmental exposure potential of CH00005 is determined to be medium because:

1. The notified organism will be manufactured in Canada in a Containment Level 2 facility that is certified by PHAC.
2. The packaging of the commercial formulation of MBCPs with CH00005 will occur in a Biosafety Level 1 facility in accordance with PHAC's Canadian Biosafety standards, 3rd edition and associated guidelines.
3. Intended uses of products that contain diluted CH00005 will result in release to the environment. There is the potential for accidental release of high concentrations of the notified strain from the manufacturing site.
4. CH00005 does not have a competitive advantage over other naturally occurring microorganisms to persist and proliferate in the environment. Based on inoculation test

[1] A determination of whether one or more of the criteria of section 64 of CEPA are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposure in the general environment. For humans, this includes, but is not limited to, exposure from air, water and the use of products containing the substances. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the criteria in the *Hazardous Products Regulations,* which is part of the regulatory framework for the Workplace Hazardous Materials Information System (WHMIS) for products intended for workplace use.

data from relevant surrogate species *B. licheniformis*, high concentrations of B. *paralicheniformis* would normalize to a background level in the environment over time.

5. Test data from a relevant, acceptable surrogate species (*Bacillus licheniformis*), with an ecological niche overlap and shared physiological traits with the notified organism demonstrated no toxicity or infectivity to non-human species. CH00005 is expected to show a similar safety profile.
6. CH00005 is a ubiquitous species commonly and naturally found in all types of habitats of the biosphere. In addition, it can form spores which can spread through water, snow, aerosols, and other means.
7. CH00005 has not been genetically modified. In the case of an accidental release, it is expected that CH00005 will be introduced at higher concentrations at the point of introduction. However, its concentration should decrease over time to background levels due to various factors, including competition with other naturally occurring strains.
8. The notified strain belongs to the *Bacillus subtilis* complex. A comprehensive search of the scientific literature did not suggest any reports indicating the production or persistence of toxins by strains of the *B. subtilis* complex in the environment.

The human exposure potential of CH00005 is determined to be medium because:

1. CH00005 is notified as a component of different MBCP's intended for commercial and industrial applications such as degradation of organic waste, prevention of clogging in drains receiving wastewater rich in fat, oil, and grease, and controlling foul odours. CH00005 may potentially be used in other MBCPs for consumer applications.
2. Product labels will be provided to customers with comprehensive information for safe handling, including precautionary measures and first aid instructions to minimise direct exposure to the users.
3. CH00005 will be manufactured at the notifier's manufacturing facility, which is a PHAC-certified containment level 2 (CL 2) facility. All activities related to the manufacture will be undertaken under CL2 in accordance with the PHAC Canadian Biosafety Standard 3rd Edition.
4. The packaging of the commercial formulation of MBCPs with CH00005 will occur at Corporate Headquarters. Although the notified organism is not known to be an infectious agent, the notifier has indicated they will adhere to procedures described in Guide 158 of the Emergency Response Guidebook published by Transport Canada for managing accidental release during transportation of CH00005 from the manufacturing facility to the packaging facility.
5. Both the manufacturing and the packaging facilities are designed to limit the releases of CH00005 into the environment. All liquid, solid, and gaseous wastes containing the notified organism from the manufacturing facility will be inactivated prior to disposal or release into the environment. Methods have been adequately described to handle accidental spills at both the manufacturing and the packaging facilities.
6. CH00005 is a naturally occurring organism without any selective advantage over wild type strains, thus its environmental concentration would not change as a result of its intended

uses (i.e., degradation of organic waste, prevention of clogging in drains receiving wastewater rich in fat, oil, and grease and control of foul odours). Additionally, computational modelling by the program indicates that exposure of the general population to CH00005, including vulnerable subpopulations, via environmental releases arising from manufacture and intended uses would be significantly lower than exposure at the points of introduction.

7. CH00005 could also be potentially used in other activities like bioremediation. However, exposure to the general population from such use is not expected to be higher than the exposure as a result of primary points of introduction to the environment, i.e., resulting from the intended end user of these MBCP.
8. CH00005 may sporulate, survive extreme conditions and persist in the environment. However, its concentration should decrease over time due to competition with other naturally occurring strains. Therefore, exposure of the general population to CH00005 via the environment will be lower than that resulting from its introduction.
9. Once added to the Domestic Substances List, exposure to the general population may increase depending on any expanded uses of CH0005 by the notifier or those which may be permitted by the notifier to use the proprietary strain. Notwithstanding this and for the aforementioned reasons, adverse effects to human health are not expected as CH00005.

Risks from workplace exposure to the notified strain are not considered in this assessment[2].

Risk Characterization

There is medium potential for environmental and human exposure to the environment, but owing to the low potential for hazard, the environmental and human health risk associated with the use of CH00005 in MBCPs used for the degradation of organic waste, prevention of clogging in drains receiving wastewater rich in fat, oil, and grease and control of foul odours and other potential uses such as bioremediation is assessed to be low.

Risk Assessment Conclusion

There is no evidence to suggest a potential risk of adverse environmental or human health effects at the exposure levels predicted for the Canadian environment and the general Canadian population from the use of CH00005 in MBCPs used for the degradation of organic waste, prevention of clogging in drains receiving wastewater rich in fat, oil, and grease, and control of foul odours or for other potential uses such as bioremediation. The risk to the environment and human health associated with CH00005 is not suspected to meet criteria in paragraphs 64(a), (b), or (c) of CEPA. No further action is recommended.

[2] A determination of whether one or more criteria of section 64 of CEPA are met is based on an assessment of potential risks to the environment and/or to human health associated with exposure in the general environment. For humans, this includes, but is not limited to, exposure from air, water and the use of products containing the substances. A conclusion under CEPA may not be relevant to, nor does it preclude, an assessment against the criteria specified in the *Hazardous Products Regulations*, which is part of the regulatory framework for the Workplace Hazardous Materials Information System (WHMIS) for products intended for workplace use.