**Example Microbial Safety Statement**

**Example statement of the rationale for human health and environmental safety of microorganisms as plant biostimulant guaranteed substances**

**DESCRIPTION OF THE MICROBIAL PRODUCT**

The microbial product to be registered has the trademark name of Product X. The microbial label for Product X states “*Bacillus licheniformis* at 1 x 10^3 CFU/mL”. This *B. licheniformis* is delivered in a water-based culture medium.

The “water-based culture medium” in Product X is a proprietary, low-nutrient solution. The water-based culture medium for the Product X *Bacillus licheniformis* growth is very low nutrient, particularly after the culture fermentation is complete. Analyses of key nutrients in the spent water-based culture medium includes: Nitrate-N less than 50 ppm, Ammonia-N less than 2 ppm, Phosphate-P less than 50 ppm, and Potassium less than 250 ppm. Micronutrients are all below 100 ppm (water-soluble magnesium, zinc, iron, and sulfur). Chemical oxygen demand (COD) indicative of remaining carbon in the spent medium, is low at less than 100 ppm.

Please see the Appendix attached to this report for evidence from an independent identification by MIDI Labs (Newark, DE) for the microbe listed in the microbial label of Product X as *B. licheniformis.* The MIDI Labs report serves as a confirmation of the identity of the *B. licheniformis* in Product X.

**BACILLUS LICHENIFORMIS SAFETY INFORMATION**

Risk group confirmation for *B. licheniformis*

The Federal Institute for occupational Safety and Health (BAUA) in the “TRBA-466.pdf” December 2010 publication lists *Bacillus licheniformis* as a Biosafety Risk Group 1 organism, a biological agent unlikely to cause disease in an individual. Similarly, the DSMZ-German Collection of Microorganisms and Cell Cultures lists *Bacillus licheniformis* as a Biosafety Risk Group 1 organism.

Biosafety recognition of *B. licheniformis* species in registered products

The Canadian government has listed a strain of *B. licheniformis* on the domestic substances list (<https://www.canada.ca/en/health-canada/services/chemical-substances/fact-sheets/chemicals-glance/domestic-substances-list-bacillus-licheniformis-subtilis-group.html> accessed 10-31-22) indicating that the *B. licheniformis* is a safe species that may be released into the environment for use in consumer or commercial products or industrial processes in Canada. Similarly, the US environmental protection agency through the Federal Register of the National Archives (<https://www.federalregister.gov/documents/2018/04/20/2018-08309/bacillus-licheniformis> accessed 10-31-22) lists a strain of *B. licheniformis* as safe for use and eliminates the need to establish a maximum permissible level for residues of *B. licheniformis* because the strain is considered safe.

**CONCLUSIONS**

The microbial label for the product Product X products lists *Bacillus licheniformis* at 1 x 10^3 CFU/mL. A report from an independent service laboratory confirmed the identity of the labeled bacteria in Product X as *B. licheniformis*. Multiple sources list the species of *B. licheniformis* as being in Risk Group 1, unlikely to cause disease in an individual. *B. licheniformis* is registered for sale in Canada and the United States. These findings support the presumption of safety for the *B. licheniformis* species in Product X and demonstrates that no additional safety information is required to support a registration application.

See Appendix on following page

**Appendix: Report from MIDI Labs (Newark, DE) for the dominant spore-forming isolate in a Dec 3, 2020 batch of Product X**

Table

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