STERILEX®
Innovative Solutions for Microbial Control

January 1, 2024

Statement of Continuing Guaranty, Food Safety, and HACCP
Sterilex® Ultra CIP EPA# 63761-8

FDA Continuing Guaranty

Sterilex's products, including Sterilex® Ultra CIP, may be used in USDA and FDA inspected facilities, food processing plants, and animal premise environments. This product is not intended for direct or indirect addition to food and, when following labeled instructions, will not result in contact with food. Sterilex hereby guarantees that each shipment of final product is manufactured to the specifications of the submitted US EPA registrations. Given the applications are not intended for food contact, Sterilex products would not fall within the scope of the requirements under the US Federal Food, Drug, and Cosmetic Act.

Food Safety and Bioterrorism

Sterilex products, including Sterilex® Ultra CIP, are not foods, food ingredients, or intended for direct contact to foods. Therefore, the production sites for these products are not subject to the requirements of FDA or USDA inspected or registered facilities. All sanitizers, disinfectants, activators, or other products you receive from Sterilex are regulated by the US EPA. Our manufacturing facilities are EPA registered establishments where required by regulation and subject to EPA inspection programs.

HACCP (Hazard Analysis Critical Control Point programs for food processing facilities)

This statement serves to certify that Sterilex is exempted from operating under the Federal mandated HACCP regulations. Sterilex is a registrant under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) and falls outside the scope of compliance under 21 CFR parts 120 and 123. All Sterilex products are manufactured in accordance with procedures and specifications under EPA FIFRA regulations. While Sterilex is not subject to regulations under HACCP, our products may be used in support of quality programs in USDA and FDA inspected facilities, food processing plants, and animal premise environments in accordance with product labeling.

Certified By,

Kendra Reising
Regulatory Affairs Specialist

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