VIA E-MAIL (Co. No. 1677)

Ms. Oleta Melnicoe
Agent for Ecolab Inc.
Technology Sciences Group, Inc.
712 Fifth Street, Suite A
Davis, California 95616

Dear Ms. Melnicoe:

Re: Registration of the New Active Ingredient n,n-bis(3-aminopropyl)laurylamine Contained in Sanitizing Wash N Walk (EPA Reg. No. 1677-239)
Chemical Code: 067300.

The New York State Department of Environmental Conservation (Department) has reviewed the application and additional data submitted for the above-referenced product. The initial application was received on June 11, 2013 and determined to be technically complete on November 20, 2013 which established a registration decision due date of April 18, 2014. The Department issued a technical issues letter dated March 4, 2014 regarding concerns raised by the New York State Department of Health for impacts to product users. A response to these concerns was received on April 1, 2014. The registrant’s representative waived the registration decision date of April 18, 2014 in order that the Department would have adequate time to evaluate the new information.

Sanitizing Wash N Walk (EPA Reg. No. 1677-239) is for use as a cleaner/sanitizer for non-food contact surfaces that are hard/non-porous such as floors, sink drains, and floor drains. The formulated product contains 2.06% of the active ingredient n,n-bis(3-aminopropyl)laurylamine and is diluted at two fluid ounces per gallon of water. Treated surfaces must remain wet for five minutes. The above-referenced product contains the active ingredient n,n-bis(3-aminopropyl)laurylamine, which is a new active ingredient for registration in New York State.

The Department will register Sanitizing Wash N Walk (EPA Reg. No. 1677-239) as labeled with no additional New York State requirement to wear gloves. The initial human health assessment determined potential dermal sensitivity to repeated use of the product but was lacking information specific to worker exposure from use of this product. The registrant was able to submit occupational exposure studies for the labeled use pattern which have provided the necessary data to mitigate these concerns. The product is labeled for indoor use only and therefore only a human health assessment was conducted for the technical review and registration of this product. The New York State Department of Health Human Health Assessment can be located as Attachment A.
Enclosed for your record are copies of the Certificate of Pesticide Registration and stamped “Accepted for Registration” label. Please note that a proposal by Ecolab Inc. or any other registrant to register a product that contains n,n-bis(3-aminopropyl)-laurylamine, and whose labeled uses are likely to increase the potential for significant impact on humans, nontarget organisms, or the environment, would constitute a major change in labeling. Such an application must be accompanied by a new application fee and meet the requirements listed in Appendix 1.B. of “New York State Pesticide Product Registration Procedures” (April 2009). Such information, as well as forms, can be accessed at our website as listed in our letterhead.

Please be aware that any unregistered product may not be sold, offered for sale, distributed, or used in New York State. If there are questions or concerns regarding this letter, please contact Paula McBath, of the Pesticide Product Registration Section at 518-402-8768.

Sincerely,

Scott Menrath, P.E.
Director
Bureau of Pest Management

Enclosures
ATTACHMENT A

Human Health Assessment:

The New York State Department of Health (DOH) reviewed the additional data submitted on April 1, 2014, by Ecolab Inc. to register the pesticide product Sanitizing Wash N Walk (EPA Reg. No. 1677-239) in New York State. This product contains the new active ingredient n,n-bis(3-aminopropyl)laurylamine (aka: bis(3-aminopropyl)dodecylamine; BAPDA) and is labeled as a cleaner/sanitizer for hard/non-porous/non-food contact surfaces (i.e., floors, sink drains, floor drains) for the reduction of Staphylococcus aureus, Enterobacter aerogenes, Escherichia coli, Escherichia coli O157:H7, Listeria monocytogenes and Salmonella typhimurium.

In a previous review of Sanitizing Wash N Walk and its active ingredient BAPDA dated February 26, 2014, DOH expressed concern over the local and systemic toxicity observed at relatively low doses in the 90-day dermal toxicity study on the active ingredient, and the formulated product’s potential to cause dermal sensitization. The product label stated that “prolonged or frequently repeated skin contact may cause allergic reactions in some individuals,” but lacked a requirement for the use of gloves. In addition, the U.S. EPA identified incidental oral and dermal toxicity endpoints for the active ingredient, but an occupational risk assessment for workers exposed to this active ingredient was not submitted by the registrant. Consequently, there was not adequate information to fully evaluate the potential risks to workers who would routinely handle and apply this product.

In response to DOH concerns, the registrant submitted a U.S. EPA occupational risk assessment for dermal and inhalation exposure to BAPDA from the use of Sanitizing Wash N Walk via mopping in industrial and institutional sites. For determining margins of exposure (MOEs), the U.S. EPA compared estimated dermal exposures to a LOEL of 5 mg/kg/day from a 90-day dermal toxicity study in rats (dermal erythema and edema in both sexes and sternal bone marrow hyperplasia in females) and inhalation exposures to a NOEL of 7.6 mg/kg/day from a developmental toxicity study in rats (clinical signs, decreased mean body weight gain and mean food consumption) for all exposure durations combined (short-(1-30 days), intermediate-(1-6 months), and long-term (>6 months)). The MOEs for dermal and inhalation exposures from mopping applications were 820 and 130,000, respectively. The U.S. EPA considered dermal MOEs of 300-fold or greater and inhalation MOEs of 100-fold or greater to provide adequate worker protection.

The U.S. EPA review additionally reported the results of a post-application risk assessment for dermal and incidental oral exposures to children crawling or playing on treated floors in institutional settings (e.g., daycare facilities). For determining dermal MOEs, estimated short-, intermediate-, and long-term dermal exposures were compared to a LOEL of 5 mg/kg/day from the previously mentioned 90-day dermal toxicity study in rats. Incidental oral MOEs were calculated by comparing estimated short- and intermediate-term incidental oral exposures to a NOEL of 7.6 mg/kg/day from the previously mentioned developmental toxicity study in rats.

1 U.S. EPA Memorandum Revised Application and Post-application Exposure Assessment for Bis-3-aminopropyl dodecylamine, March 24, 2006.
The short-, intermediate-, and long-term dermal MOE for children was 312 while the short- and intermediate-term incidental oral MOE was 8085. The U.S. EPA considered MOEs of 300-fold or greater for dermal exposure and 100-fold or greater for incidental oral exposure to provide adequate protection for children from exposure to BAPDA on treated floors.

The additional information submitted by the registrant has addressed our concerns for registration of this product in New York State. The available information indicates that BAPDA exposure from the labeled use of Sanitizing Wash N Walk (mopping of floors, sink drains and floor drains) should not pose a significant risk to workers. In addition, post-application dermal and incidental oral exposures are not expected to pose a significant risk to children from crawling or playing on the treated floor. Given the above, we do not object to the registration of Sanitizing Wash N Walk in New York State.