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MEMORANDUM

TO: Danny Wong, Chief
Bureau of Stationary Sources

DW

FROM: Joel Leon, Section Chief, Operating Permit Section
Bureau of Stationary Sources

SUBJECT: Applicability of Sanitizing Operations to N.J.A.C. 7:27-16.24, Industrial Cleaning

DATE: April 9, 2024

This memorandum concerns an applicability determination for Industrial Cleaning at N.J.A.C. 7:27-16.24. A facility uses a solution consisting of 70% isopropyl alcohol/30% water (Solution) to sanitize cosmetic manufacturing equipment after the equipment has been cleaned with a detergent. The sanitizing is consistent with Good Manufacturing Practices guidelines, available from the U.S. Food and Drug Administration (www.fda.gov). A request was made for the Department to determine whether the application of the Solution was subject to N.J.A.C. 7:27-16.24 since its volatile organic compound (VOC) content does not comply with the limits set forth at N.J.A.C. 7:27-16.24.

The provisions of N.J.A.C. 7:27-16.24 are based on the USEPA Control Techniques Guidelines (CTG) for Industrial Cleaning Solvent (ICS). Neither the ICS CTG nor N.J.A.C. 7:27-16.24 addresses the difference between sanitizing versus cleaning. Therefore, the Department, in consultation with USEPA, has identified “Medical device and pharmaceutical manufacturing operations" as an appropriate surrogate to consider if the sanitizing is a distinctly separate operation than cleaning (i.e., the surface is cleaned first with another cleaner and then sanitized with the Solution). Since the “Medical device and pharmaceutical manufacturing operations" category is exempted from the provisions of N.J.A.C. 7:27-16.24, it can be concluded that the use of the Solution, for the purpose of sanitizing equipment, is not subject to the provisions of N.J.A.C. 7:27-16.24.

Sufficient documentation should be provided before the sanitization exemption is granted. This may include, but may not be limited to, the following:

1. Any equipment is cleaned with detergent or other compliant cleaning agent prior to sanitization.

2. The equipment is operated to meet Good Manufacturing/Laboratory Practice, available from the U.S. Food and Drug Administration (www.fda.gov).

3. Products manufactured in the equipment are used for direct human use or consumption.

The volatile organic compound (VOC) emissions from sanitizing process are subject to all other applicable rule provisions.