

US EPA ARCHIVE DOCUMENT

(12-15-00)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Product Chemistry Review of **VigorOx SP-15 Antimicrobial Agent**

DP Barcode: **D268939**

Reg. No. or File Symbol: **65402-3**

Manufacturing-use []

End-use Product [X]

Active Ingredient Composition:

Peroxyacetic acid.....15%

TO: Marshall Swindell PM 33

FROM: Alex Traska, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510C)

RT 12.115/00

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510C)

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510 C)

BACKGROUND:

This application for amended registration, covering the subject sanitizer and disinfectant, was submitted by the registrant, FMC Corporation.

The registrant, in this submission, has requested approval to add new uses to the product label and to replace the stabilizer [REDACTED] a

INERT INGREDIENT INFORMATION IS NOT INCLUDED

alternate [REDACTED] which is permitted in food-contact sanitizers. The proposed new uses involve food contact surfaces and for this reason, the CSF with [REDACTED] was requested to be deleted and replaced with a new CSF based on the use of [REDACTED].

The following documents were submitted and examined in the chemistry review of this submission: registrant's cover letter and transmittal document dated July 26, 2000, proposed new product label dated July 2000, revised Basic Formulation CSF dated July 26, 2000, obsolete Basic Formulation CSF dated 12/21/99.

FINDINGS:

1. The revised Basic Formulation CSF for **VigorOx SP-15 Antimicrobial Agent** which is now utilizes [REDACTED] as a stabilizer, meets the requirements of a food-contact sanitizer under 21 CFR 178.1010 (b) (30) (c)(25).
2. PR Notice requirements have been met.
3. Upper and lower certified limits for both the active and inert ingredients are acceptable.
4. The Basic Formulation CSF dated 12/21/99 which utilized the stabilizer, [REDACTED] has marked obsolete and dated 12/15/00.
5. Since the active ingredient, peroxyacetic acid, is formed via reaction, both the Basic and Alternate Formula CSF's, should be marked "pre-reaction CSF" and "post-reaction CSF" for clarity.
6. The EPA Reg. No. [REDACTED] for hydrogen peroxide should not appear on the the post- reaction CSF only on the pre-reaction CSF for the Basic and Alternate Formulations.
7. All other elements of the CSF and label are acceptable.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

RECOMMENDATIONS:

This amendment, requesting the addition of new food-contact surface uses for this product along with the use of the stabilizer [REDACTED] is accepted with comment.

The comments noted in item 5 and 6 under Findings should be addressed at the next convenient time by the registrant.

12/15/00 AT

INGREDIENT INFORMATION IS NOT INCLUDED