

(11-28-01)



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: **D278323**

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

Manufacturing-use []

End-use Product [X]

Active Ingredient Composition:

Peroxyacetic acid.....15%

Hydrogen peroxide.....10%

TO: Marshall Swindell PM 33

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

AT 11/19/01

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

KPH
11/28/01

THRU: Michele E. Wingfield, Chief
Product Science Branch
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BACKGROUND:

This re-submission, covering the subject sanitizer and disinfectant, was made by the Keller and Heckman LLP on behalf of the registrant, FMC Corporation.

The registrant, in this re- submission, is responding to the May 9, 2001 Agency letter which requested changes to the CSF and product label.

The following documents were submitted and examined in the chemistry review of this submission: agent's cover letter dated October 2, 2001, revised pre and post-reaction CSF dated September 27, 2001, revised product label dated October 2, 2001, existing Basic and Alternate CSF dated July 26, 2000 and the May 9, 2001 Agency letter.

FINDINGS:

1. The revised Basic Formulation CSF, for **VigorOx SP-15 Antimicrobial Agent**, now meets the requirements of a food-contact sanitizer under 21 CFR 178.1010 (b) (30) (c)(25).
2. PR Notice 91-2 requirements have been met.
3. The upper and lower certified limits for both the active and inert ingredients are acceptable.
4. The ingredient declaration, on the product label, has been revised to show hydrogen peroxide as an active ingredient with a nominal concentration of 10%.
5. The [REDACTED] has been reduced to [REDACTED] to comply with 40 CFR 180.1001 (c) requirements.
6. The following revisions to the draft October 2, 2001 product label are required:
 - a. under Directions for Use covering Biofouling in Pulp and Paper Mill Systems item #4; the ppm for peroxyacetic acid should be 15 to 90 and not 15 to 100 as given- the ppm for hydrogen peroxide should be 10 to 60 and not 15 to 225 as given
 - b. under Directions for Use covering Control of Bacteria and Fungi in Dispersed Pigments the gram quantity should be 545 and not 554 as given- the ppm for peroxyacetic acid should be 30 to 180 and not 35 to 205 as given- the ppm for hydrogen peroxide should be 20 to 120 and not 30 to 150 as given
 - c. all use directions are based on a fluid measure therefore all dosage units must be shown as fluid ounces or fl oz - the use of ounces or oz as units of measure is not acceptable
 - d. at the bottom of page 4, peroxyacetic acid was written as peroxyacetic acid
7. All other elements of the revised pre and post-reaction CSF were acceptable.

ALL INFORMATION CONTAINED HEREIN IS UNCLASSIFIED

RECOMMENDATIONS:

This re-submission, in support of the amended registration for **VigorOx SP-15 Antimicrobial Agent**, is accepted with comment.

Registrant must address changes requested in item 6 of the Findings.

11/19/01 AT