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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

June, 27, 2006

MEMORANDUM

SUBJECT: Proposed FMC for Ethaneperoxoic Acid and Hydrogen Peroxide
Aseptic Packaging Use

FROM: Robert Quick, Chemist *Robert Quick*
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ID#: 65402-3-VigorOx SP-15 Antimicrobial Agent

DP BARCODE: D320032

DECISION NO.: 358772

PC CODE: 063201, 000595

CHEMICAL NAME: Ethaneperoxoic Acid, Hydrogen Peroxide

CAS#: 7722-84-1, 64-19-7

MRID#: 465930-00, 465930-05, 465930-03, 465930-04, 465930-06

~~THIS INFORMATION IS NOT INCLUDED~~

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Introduction:

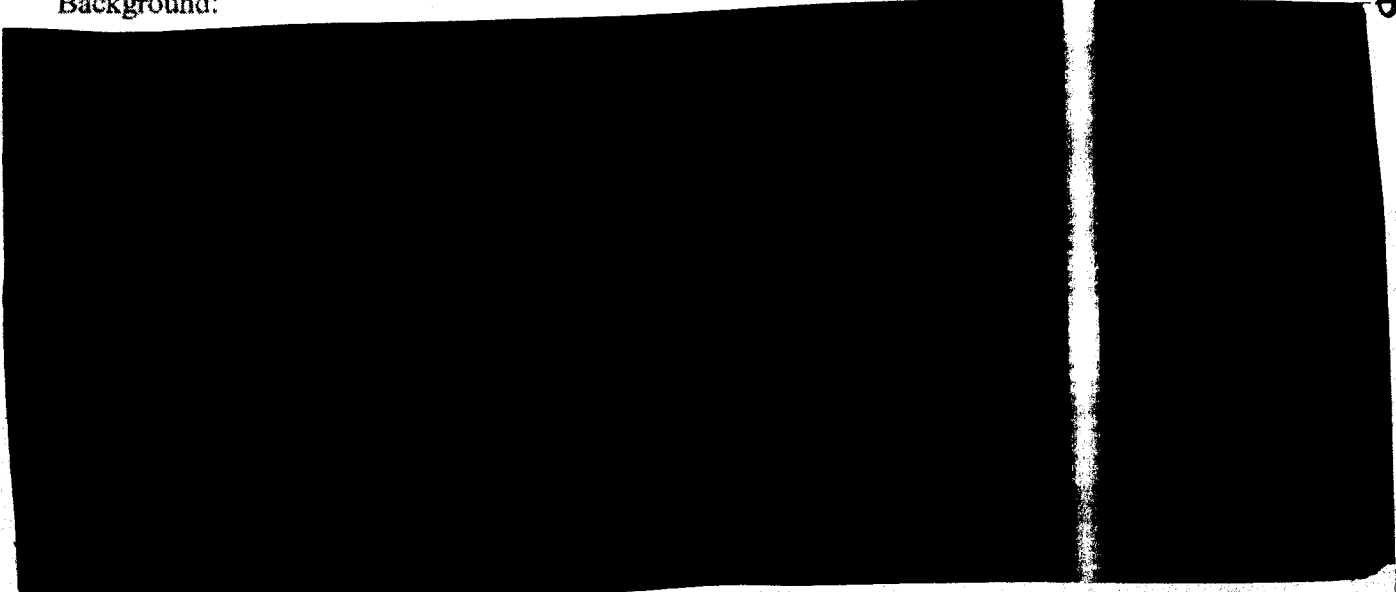
Keller and Heckman, on behalf of FMC Corporation, has submitted an application to amend the registration of VigorOx™ SP-15 Antimicrobial Agent to add new uses.

The first use is to add the use of peroxyacetic acid on polymeric containers immediately prior to fill in food processing facilities.

The registrant also proposes to add sporicidal claims to the label for sterilization of non-medical device surfaces and equipment.

This memo is a residue chemistry review of the proposed amended registration and addresses only the aseptic use in food processing facilities.

Background:



There is an existing Regulation in 40 CFR Part 180.1196 (b) for "Peroxyacetic Acid; Exemption From the Requirement of a Tolerance" dated December 1, 2000. This Regulation permits use of sanitizing solutions containing a diluted end-use concentration of peroxyacetic acid up to 500 ppm on food processing equipment including aseptic equipment.

Detailed Considerations

Proposed Use:

The proposed use is for application to food packaging as an aseptic packaging antimicrobial rinse prior to fill in food processing operations complying with "applicable regulations at 21 C. F.R. Parts 108, 110, 113, and/or 114".

INERT INGREDIENTS LISTED IN THE LABEL ARE NOT INCLUDED

The product is to be applied on the exterior and interior of food containers and closure systems (caps, seals, etc.). The application rate is for 2000 to 6000 ppm peroxyacetic acid at temperatures ranging from 40 to 60EC. The solution is to remain in contact with the packaging surface for a minimum of 5 seconds. Longer contact times may be needed on certain aseptic food processing lines. **Containers must be rinsed with sterile water prior to filling with processed food.**

Neither the proposed use section of the label for VigorOx SP-15 Antimicrobial Agent nor the proposed use section of Volume 6, page 5 of 29 provide dilution directions for the dilution of the product with water. The label should be revised to provide use directions for the number of ounces of product to be mixed per gallon of water.

Residue Discussion:

The letter from FDA dated September 22, 2005, to Mr. Douglas J. Behr, Keller & Heckman states in part,

“Based on previous reviews, we conclude that peroxyacetic acid would decompose to acetic acid and oxygen before the food in the treated package is consumed. Acetic acid is generally recognized as safe for direct addition to food (21 CFR 184.1005), and is therefore permitted to be used as a component of a food-contact article by 21 CFR 174.5(d)(1).

MEAD 465930, w; 465930-05; 0470x

Page 4 is not included in this copy.

Pages _____ through _____ are not included in this copy.

The material not included contains the following type of information:

- Identity of product inert ingredients.
- Identity of product impurities.
- Description of the product manufacturing process.
- Description of quality control procedures.
- Information concerning unregistered product.
- Identity of the source of product ingredients.
- Sales or other commercial/financial information.
- A draft product label.
- The product confidential statement of formula.
- Information about a pending registration action.
- FIFRA registration data.
- The document is a duplicate of page(s) _____.
- The document is not responsive to the request.
- Internal deliberative information.
- Attorney-Client work product.
- Claimed Confidential by submitter upon submission to the Agency.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

[REDACTED]

Conclusions:

[REDACTED]

3. The FDA has concluded that residues of hydrogen peroxide and peroxyacetic acid would decompose before food in the packaged material is consumed.

Based on [REDACTED] and on the information submitted by the registrant on the aseptic treatment and on [REDACTED] RASSB has no residue chemistry questions regarding the proposed use. No additional residue chemistry data are required to support the proposed use.

NEED TO REPORT ALL INFORMATION TO AGENCY EXCLUDED