MEMORANDUM:

Subject: Product Efficacy Review for EPA Reg. No.: 65402-1 / VigorOx Liquid Sanitizer  
        DP Barcode: D266967  
        Case No: 031420

To: Marshall Swindell, PM 33  
    Regulatory Management Branch  
    Antimicrobials Division (7510C)

From: Emily Mitchell, Team Leader  
       Efficacy Evaluation Team  
       Product Science Branch  
       Antimicrobials Division (7510C)

Applicant: FMC Corporation

FORMULATION FROM LABEL:

<table>
<thead>
<tr>
<th>Active Ingredient(s)</th>
<th>% by wt.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peroxyacetic Acid</td>
<td>5.1</td>
</tr>
<tr>
<td>Hydrogen Peroxide</td>
<td>21.7</td>
</tr>
<tr>
<td>Other Ingredient(s)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>73.2</td>
</tr>
<tr>
<td></td>
<td>100.0%</td>
</tr>
</tbody>
</table>

The supplemental data/information hand delivered by Keller and Heckman is acceptable to support the claims for *Escherichia coli, Salmonella typhimurium*, using 75 ppm solution of Vigorox 5% when exposed for 30 seconds. The product was also effective against *Listeria monocytogenes* using 100 ppm solution of Vigorox 5% when exposed for 30 seconds.

PM: Make sure the label claims are the same as the accepted supplemental efficacy data.
MEMORANDUM:

Subject: Product Efficacy Review for EPA Reg. No.: 65402-1 / VigorOx Liquid Sanitizer
DP Barcode: D266967
Case No: 031420

To: Marshall Swindell, PM 33
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, PM 34
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Emily Mitchell, Team Leader
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

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

Applicant: FMC Corporation

FORMULATION FROM LABEL:

Active Ingredient(s):
- Peroxyacetic Acid
  5.1 % by wt.
- Hydrogen Peroxide
  21.7 %
- Other Ingredient(s):
  73.2 %
Total: 100.0 %
BACKGROUND: FMC Corporation has submitted two product efficacy studies in support of their product “Vigorox Liquid Sanitizer”. The purpose of these studies is:

1. To reduce the concentration (lower limit) of peroxyacetic acid needed for institutional industrial sanitizing of previously cleaned, non-porous surfaces.
2. To add to the label that this product is an effective sanitizer against *Salmonella typhimurium* and *Listeria monocytogenes*.

RECOMMENDATIONS: PSB findings are:

1. MRID Number 451300-1: “Food Contact Sanitizer Test on VigorOx Liquid Sanitizer and Disinfectant, 5% Peroxyacetic acid.” By Daniel L. Prince, Ph.D. Gibraltar Laboratories, Inc. GBL Study # GR 1573. Study Completion Date 4/7/2000.

VigorOx 5%, when diluted to a concentration of 85 ppm in 400 ppm AOAC Hard Water, killed 99.999% of *Escherichia coli* (ATCC #11229) and *Staphylococcus aureus* (ATCC #6538) when exposed for 30 and 60 seconds at 25 °C. This supports FMC Corporations desire for labeling stating that sanitization of surfaces contaminated with *Escherichia coli* (ATCC #11229) and *Staphylococcus aureus* (ATCC #6538) may be carried out using a 85 ppm solution of Vigorox 5%.

The report lists a reported “log reduction” for the two species tested, but does not give the bacterial count for the control (non-test material-treated) or treated bacteria. This is a major flaw in this study/report. This study is currently unacceptable. This study cannot be accepted until this raw data giving the treated and untreated bacterial counts is reported.

2. MRID Number 451300-02: “Food Contact Sanitizer Test On Vigor Ox Liquid Sanitizer 5%” GR 1532. by Daniel L. Prince, Ph.D. Gibraltar Laboratories, Inc. GBL Study # 1532. Study Completion Date 12/16/99.

VigorOx Liquid Sanitizer 5% killed 99.999% of *E. coli* (ATCC #35150) and *Salmonella typhimurium* (ATCC #14028) within 30 seconds at concentrations of 50 ppm and 100 ppm when diluted into 400 ppm AOAC hard water with a 5% organic soil load. VigorOx Liquid Sanitizer 5% killed 99.999% of *Listeria monocytogenes* (ATCC #984) in 30 seconds at a concentration of 100 ppm when diluted into 400 ppm AOAC hard water with a 5% organic soil load. VigorOx Liquid Sanitizer 5% did not kill 99.999% of *Listeria monocytogenes* within 30 seconds at 50 ppm.

This study had a report in that the report claimed that *E. coli, Salmonella typhimurium* and *Listeria monocytogenes* (against a 50 ppm concentration of test material) were conducted against VigorOx Liquid Sanitizer 15%, not 5%. An E-Mail from the Daniel L. Prince of Gibraltar Labs (see attached) clarified this matter and informed us that this study only tested VigorOx Liquid Sanitizer 5%, and that there is no VigorOx Liquid Sanitizer 15%.

After the problems with the test material identification were resolved, it then became apparent that this report does not give any information on a positive control. The report lists a reported “log reduction” for the three species tested, but does not give the bacterial count for the control (non-test material-treated) or treated bacteria. This is a major flaw in this study/report. This study is currently unacceptable. This study cannot be accepted until this raw data giving the treated and untreated bacterial counts is reported.
LABELING:

1. Under the section titled “Sanitizing Non-Porous Food Contact Surfaces, #6: *Listeria monocytogenes* should be italicized.