May 14, 2009

DP BARCODE: # 363805

MRID: none

SUBJECT: Brace

REG. NO. OR FILE SYMBOL: 777-99

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [ ] OR End-use Product [X]

INGREDIENTS (PC Codes) Ethanol (001501)
                          Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium saccharinate (069171)

CAS Number: 64-17-5, 68989-01-5

TEST LAB: not applicable

SUBMITTER: Reckitt Benckiser, Inc.

GUIDELINE: none

REVIEWER: Alex Traska

ORGANIZATION: AD

APPROVER: Karen P. Hicks

APPROVED DATE: 5/14/09

COMMENT: Amendment
MEMORANDUM

Subject: Review of EPA Reg. No. 777-99
From: Alexander W. Traska, Chemist
       Chemistry and Toxicology Team
       Product Science Branch
       Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
       Chemistry and Toxicology Team
       Product Science Branch
       Antimicrobials Division (7510P)

Thru: Michele E. Wingfield, Chief
       Product Science Branch
       Antimicrobials Division (7510P)

To: Adam Heyward PM #34
    Regulatory Management Branch
    Antimicrobials Division (7510P)

Applicant: Reckitt Benckiser, Inc.
Action Code: (362) Formula Change, Technical
Due out date: 29 June 2009

Formulations from Label

<table>
<thead>
<tr>
<th>Active Ingredient(s)</th>
<th>% by wt.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alkyl (50% C14, 40% C12, 10% C16)</td>
<td></td>
</tr>
<tr>
<td>dimethyl benzyl ammonium saccharinate</td>
<td>0.10</td>
</tr>
<tr>
<td>Ethanol</td>
<td>58.00</td>
</tr>
<tr>
<td>Other Ingredients</td>
<td>41.90</td>
</tr>
<tr>
<td>Total</td>
<td>100.00</td>
</tr>
</tbody>
</table>
I    BACKGROUND

This amendment application, for the subject antibacterial spray, was submitted by the registrant, Reckitt Benckiser, Inc.

The registrant, in this amendment, has requested approval to add additional suppliers of alternate grades of ethanol to the end-use antibacterial spray product, Brac. Also, requested was the addition of the new Alternate Formula #1325-133 (Original Scent). A total of seventeen (17) alternate formulations were provided in this submission which proposed the use additional alternate grades of ethanol and the addition of a new alternate formulation.

The following documents were submitted and examined in the chemistry review of this amendment application: registrant’s cover letter dated March 26, 2009, pesticide application covering this amendment dated March 26, 2009, updated CSFs for Alternate Formula #1178-172 (Crisp Linen Scent), Alternate Formula #1314-032 (Citrus Meadows Fragrance), Alternate Formula #1314-033 (Vanilla & Blossoms Fragrance), Alternate Formu-la #1314-038 (Lavender 2 Fragrance), Alternate Formula #1338-015 (Spring Waterfall Scent), Alternate Formula #1338-016 (Summer Breeze Scent), Alternate Formula #1338-017 (Kitchen Citrus Scent), Alternate Formula #1338-018 (Green Apple Breeze Scent), Alternate Formula #1338-019 (Country Scent), Alternate Formula #1338-020 (Garden Mist Scent), Formula #1338-021 (Crisp Berry Scent), Alternate Formula #1338-022 (Original Scent), Alternate Formula #1338-023 (Fresh Scent), Alternate Formula #1338-024 (Energy Scent), Alternate Formula #1338-026 (Early Morning Breeze Scent), Alternate Formula #1338-027 (Unfragranced) and the new Alternate Formula #1325-133 (Original Scent) all dated March 26, 2009.

Also submitted were the following documents: Agency letter dated November 18, 2008, meeting minutes covering the use of additional ethanol grades dated July 8, 2008, cover letter for the proposed new end-use product Brac dated August 19, 2005, Product Chemistry Review dated September 16, 2008 covering label allowance and addition of new alternate formulations with copies of subject alternate formulations dated July 10, 2008 and April 6, 2007 provided, MSDS for new alternate ingredient suppliers with mixed dates (identified in red text on CSFs) and revised product label dated November 18, 2008.

II    FINDINGS

1. The requirements of PR Notice 91-2 were satisfied. The nominal concentrations of the active ingredients given in the following updated and new alternate formulations agreed with the percentages declared on the product label: Alternate Formula #1178-172 (Crisp Linen Scent), Alternate Formula #1314-032 (Citrus Meadows Fragrance), Alternate Formula #1314-033 (Vanilla & Blossoms Fragrance), Alternate Formula #1314-038 (Lavender 2 Fragrance), Alternate Formula #1338-015 (Spring Waterfall
Product ingredient source information may be entitled to confidential treatment

Scent), Alternate Formula #1338-016 (Summer Breeze Scent), Alternate Formula #1338-
017 (Kitchen Citrus Scent), Alternate Formula #1338-018 (Green Apple Breeze Scent),
Alternate Formula #1338-019 (Country Scent), Alternate Formula #1338-020 (Garden
Mist Scent), Formula #1338-021 (Crisp Berry Scent), Alternate Formula #1338-022
(Original Scent), Alternate Formula #1338-023 (Fresh Scent), Alternate Formula #1338-
024 (Energy Scent), Alternate Formula #1338-026 (Early Morning Breeze Scent),
Alternate Formula #1338-027 (Unfragranced) and new Alternate Formula #1325-133
(Original Scent). All of the proposed updated and new alternate formulations were dated
March 26, 2009.

2. The upper and lower certified limits for the active and other ingredients given
in the proposed new alternate formulations, were acceptable.

3. The registered product, [redacted] is the source of the active ingredient, alkyl (50% C_{14}, 40% C_{12},
10% C_{16}) dimethyl benzyl ammonium saccharinate. Ethanol, which is not EPA
registered, is the other active ingredient utilized in the proposed formulations. The
additional alternate grades of ethanol were found to be acceptable.

4. All other ingredients utilized in the proposed new formulations are acceptable
for use in this and other pesticide formulations.

5. All other elements of this amendment were acceptable. All of the proposed
seventeen (17) updated and new alternate formulations, all dated March 26, 2009, are
accepted.

III CONCLUSIONS

This amendment, which requested approval to add additional suppliers of
alternate grades of ethanol and to add a new Alternate Formula #1325-133 (Original
Scent) under the BrAce registration, is accepted.