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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

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**

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



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May 14, 2009

MEMORANDUM

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

AWT 5/14/2009

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

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Alkyl (50% C14, 40% C12, 10% C16)	
dimethyl benzyl ammonium saccharinate.....	0.10
Ethanol.....	58.00
Other Ingredients.....	<u>41.90</u>
Total	100.00

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, **Brace**. 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 Formula #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 Brace dated August 19, 2005, Product Chemistry Review dated September 16, 2008 covering label amendment 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 concentration 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% C₁₄, 40% C₁₂, 10% C₁₆) 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.