

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-043**

**CHEMISTRY REVIEW(S)**

**DIVISION OF OTC DRUG PRODUCTS**  
Review of Chemistry, Manufacturing, and Controls

**NDA #:** 21-043

**DATE REVIEWED:** 4/20/99

**REVIEW #:** 1

**REVIEWER:** C. Yaciw

**SUBMISSION TYPE    DOCUMENT DATE    CDER DATE    ASSIGNED DATE**

|          |         |         |         |
|----------|---------|---------|---------|
| ORIGINAL | 8/31/98 | 9/2/98  | 9/30/98 |
| AR       | 9/9/98  | 9/9/98  |         |
| BC       | 11/4/98 |         |         |
| BZ       | 2/19/99 | 2/26/99 | 3/18/99 |

**NAME & ADDRESS OF APPLICANT:** Soltec Research  
8 Macro Court  
Rowville, Victoria 3178  
Australia

**DRUG PRODUCT NAME**

Proprietary: Rid  
Established: Pyrethrum extract and piperonyl butoxide  
Code Name/#:  
Chem. Type/Ther. Class: 3S

**PHARMACOL. CATEGORY/INDICATION:** pediculicide

**DOSAGE FORM:** aerosolized foam

**STRENGTHS:** 0.33% and 4.0%

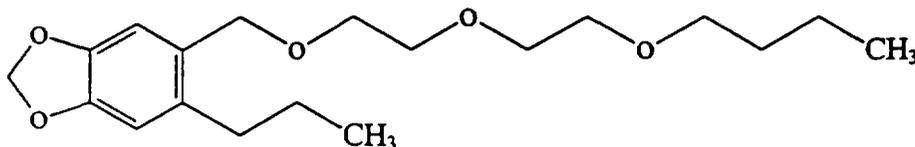
**ROUTE OF ADMINISTRATION:** topical

**Rx/OTC:**  Rx  OTC

**SPECIAL PRODUCTS:**  Yes  No

**CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA,  
MOLECULAR WEIGHT:**

Pyrethrum extract is a mixture of six related esters (see comments under Drug Substance).  
Piperonyl butoxide (not USP) 5-[2-(2-butoxyethoxy)ethoxymethyl]-6-propyl-1,3-benzodioxole,  
C<sub>14</sub>H<sub>30</sub>O<sub>5</sub>, 338.45, CAS-51-03-6



12-12-99  
Merritt

OCT 19 1999

**DIVISION OF OTC DRUG PRODUCTS**  
Review of Chemistry, Manufacturing, and Controls

**NDA #:** 21-043

**DATE REVIEWED:** 10/19/99

**REVIEW #:** 2

**REVIEWER:** C. Yaciw

**SUBMISSION TYPE DOCUMENT DATE CDER DATE ASSIGNED DATE**

|              |         |         |         |
|--------------|---------|---------|---------|
| ORIGINAL     | 8/31/98 | 9/2/98  | 9/30/98 |
| AR           | 9/9/98  | 9/9/98  |         |
| BC           | 11/4/98 |         |         |
| BZ           | 2/19/99 | 2/26/99 | 3/18/99 |
| AZ* (was BZ) | 9/2/99  | 9/7/99  | 9/17/99 |
| NC*          | 9/8/99  | 9/9/99  | 9/17/99 |

\*covered by this review

**NAME & ADDRESS OF APPLICANT:**

Soltec Research  
8 Macro Court  
Rowville, Victoria 3178  
Australia

**DRUG PRODUCT NAME**

Proprietary: Rid  
Established: Pyrethrum extract and piperonyl butoxide  
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Chem. Type/Ther. Class: 3S

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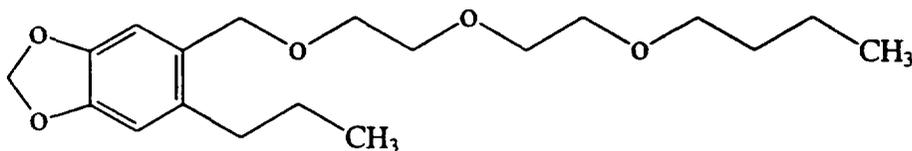
**SPECIAL PRODUCTS:** \_\_\_ Yes  No

**CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA,**

**MOLECULAR WEIGHT:**

Pyrethrum extract is a mixture of six related esters (see comments in Review #1).

Piperonyl butoxide 5-[2-(2-butoxyethoxy)ethoxymethyl]-6-propyl-1,3-benzodioxole, C<sub>14</sub>H<sub>30</sub>O<sub>5</sub>, 338.45, CAS-51-03-6



**SUPPORTING DOCUMENTS:** See review #1.

**RELATED DOCUMENTS (if applicable):** None

**CONSULTS:** None initiated by chemistry.

**REMARKS:**

The 9/2/99 amendment was judged to be a complete response which triggered the review clock. After a quick review of the information provided, it was decided by the OTC Team that there were still CMC and labeling issues so this should be a Class 2 Resubmission – 6 month review period – action due 3/7/2000. This will allow additional time to settle the outstanding issues and increase the chances that a full Approval letter can be issued.

A report was provided (pages 069 and 070) showing that Rid Mousse meets the CPSC definition for “flammable”.

**CONCLUSIONS & RECOMMENDATIONS:**

APPROVABLE. This NDA may not be approved until Items 1 (improper use of USP designation) and 10 (compatibility of container with contents) have adequate responses. These responses are currently incomplete.

**/S/**

Charlotte Yaciw, Review Chemist, HFD-830/550

**/S/**

Amit K. Mitra, Acting Team Leader, HFD-550

cc:

Org. NDA 21-043  
HFD-560/Division File  
HFD-550/Chem/CYaciw  
HFD-560/PM/BMerritt  
HFD-830/CWChen

HFD-550/AMitra  
HFD-560/LKatz

**APPEARS THIS WAY  
ON ORIGINAL**

copy

**DIVISION OF OTC DRUG PRODUCTS**  
Review of Chemistry, Manufacturing, and Controls

**NDA #:** 21-043

**DATE REVIEWED:** 1/3/2000

**REVIEW #:** 3

**REVIEWER:** C. Yaciw

**SUBMISSION TYPE DOCUMENT DATE CDER DATE ASSIGNED DATE**

|     |          |          |          |
|-----|----------|----------|----------|
| BC* | 11/1/99  | 11/4/99  | 11/12/99 |
| BC* | 11/10/99 | 11/12/99 | 11/30/99 |

\*covered by this review

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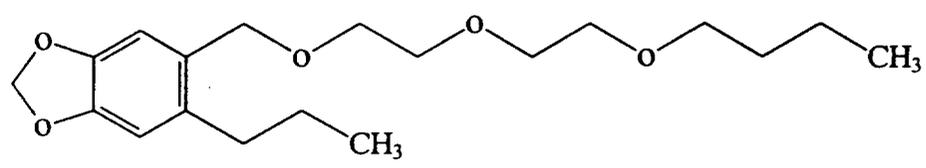
**ROUTE OF ADMINISTRATION:** topical

**Rx/OTC:** \_\_\_ Rx  OTC

**SPECIAL PRODUCTS:** \_\_\_ Yes  No

**CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA,**

**MOLECULAR WEIGHT:** Pyrethrum extract is a mixture of six related naturally occurring esters (see comments in Reviews #1 & 2). Piperonyl butoxide 5-[2-(2-butoxyethoxy)-ethoxymethyl]-6-propyl-1,3-benzodioxole, C<sub>14</sub>H<sub>30</sub>O<sub>5</sub>, 338.45, CAS-51-03-6



**SUPPORTING DOCUMENTS:** See review #1.

**RELATED DOCUMENTS (if applicable):** None

**CONSULTS:** None initiated by chemistry.

**REMARKS:**

Review #2 found that the responses to Items 1 (improper use of USP designation) and 10 (compatibility of container with contents) of the 9/2/99 amendment were inadequate. This was relayed to Soltec by FAX on November 2, 1999. The November 10, 1999 amendment is the response. The November 1, 1999 amendment is notification that the USP is considering revising the pyrethrum extract monograph to include the 50% strength. The company is deleting the USP designation until the 50% Pyrethrum Extract becomes official.

**CONCLUSIONS & RECOMMENDATIONS:**

APPROVE

**/S/**

\_\_\_\_\_  
Charlotte Yaciw, Review Chemist, HFD-830/550

**/S/**

\_\_\_\_\_  
Mona Zarifa, Acting Team Leader, HFD-550

cc:

Org. NDA 21-043  
HFD-560/Division File  
HFD-550/Chem/CYaciw  
HFD-560/PM/BMerritt  
HFD-830/CWChen

HFD-550/ChemTL  
HFD-560/LKatz

APPEARS THIS WAY  
ON ORIGINAL

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