8-4-95

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

ANTIMICROBIAL PROGRAM BRANCH

EFFICACY REVIEW - FORM 1

Date RD Received: 20 December 94 Review Start Date: 4 August 1995

Date EPA Received: 13 December 94 Project Return Date: 13 March 95

Review Completion Date: 4 August 1995

Reviewed By: Michele E. Wingfield, Microbiologist

EPA Reg. No. or File Symbol: 10492-4

Product Manager & Team No.: Marion Johnson - 31

Product Name: Isotex -70 Disinfecting Towelettes

Company Name: Palmero Health Care

Submission Purpose: MOU Compliance per PR Notice 94-4

Labeling:

Proposed tamper resistant seal with MOU restrictive label language is acceptable.

On the front panel, remove the paragraph starting with, "Isotex 70 is tuberculocidal against Mycobacterium bovis BCG... fungicidal against Trichophyton mentagrophytes ... in 4 minutes at 20°C." The prominence of these statements on the front panel imply actual contact times however, they are contradictory to the contact time listed in the use directions: 6 minutes for disinfection of pre-cleaned, hard, non-porous inanimate surfaces. Therefore, it is a violation of 40 CFR 156.10.

> (5) False or misleading statements.
> (vii) A true statement used in such a way as to give a false or misleading impression to the purchaser.

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6-9-4

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

REVIEW -I

ANTIMICROBIAL PROGRAM BRANCH

IN: 7-24-96 OUT: 8-5-96

Reviewed by Z.Vaituzis Date 7-30-96

LAN Code 10492-4.608

EPA Reg. No. or File Symbol 10492-4

EPA Petition or EUP No. None

Date Division Received 12-6-95

Type Product Pre-Saturated Towelettes

MRID No(s) None

Product Manager PM 31 - Johnson/Terry

Product Name Isotex-70 Disinfecting Towelettes

Company Name Palmero Health Care

Submission Purpose: Comment on rebuttal letter in response to Agency's letter dated 11-7-95

Type Formulation Single-Use Pre-Saturated Towelettes

Active Ingredients(s)

Isopropanol	**63.0 %**
068104 (quat.)	**0.12%**
069111.(quat.)	**0.12%**

COMMENT:

In a letter dated December 6, 1995, SRA International, on behalf of Palmero Health Care (PHC), responded to the Agency's letter of November 7, 1995. The Agency requested that PHC cease marketing Isotex-70 Disinfecting Towelettes (DisCide) as being effective against M.tuberculosis in one minute on hard, environmental surfaces. The PHC response effectively is a refusal to comply with the Registration Division (RD) request.

PHC does not recognize the Agency's minimum 5 minute tuberculocidal contact time published in the "Data Call-In Notice for Tuberculocidal Effectiveness Data for All Antimicrobial Pesticides with Tuberculocidal Claims", dated June 13, 1986, as

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valid. They cite Dr. Norman Miner of MicroChem Laboratories as a more authoritative source on this subject than the Agency's published guidance.

In addition, PHC repeats their contention that the Agency accepted a one minute TB contact time for Isotex-70 Disinfecting Towelettes. This is not consistent with the requirements given to PHC at the time of product registration when PHC was instructed to adhere to the contact time in the Directions for Use. This was clearly communicated to Marci Aderiye of SRA International by Z. Vaituzis via facsimile on 8-13-93. PHC had originally requested a 2 minute tuberculocidal contact time. It was not accepted. Instead, on another part of the label, not in the Directions for Use, PHC was permitted to list by what laboratory tests the tuberculocidal, fungicidal and bacteriocidal properties were determined. PHC was instructed that these contact times cannot appear in the Directions for Use.

The 8-13-93 communication to Marci Aderiye contained the following quotes:

> **"Isotex-70 is tuberculocidal against Mycobacterium bovis BCG by the Log Reduction Suspension test within 1 minute at 20° C; ...fungicidal against Trichophyton mentagrophytes by the AOAC Fungicidal Activity test in 4 minutes at 20° C.**
>
> **The above cannot be listed as use-contact times.**
>
> **The implication that these are actual use contact times is misleading since the tuberculocidal and the fungicidal tests were liquid suspension tests.**
>
> **Efficacy data developed by suspension culture tests, while highly quantitative and controllable in the laboratory, have the dual disadvantage of irrelevancy to real-use situations as well as a degree of sensitivity that can mislead users into a false sense of efficacy (safety). "**

In light of the labeling claim instructions given to PHC at the time of registration, marketing of DisCide with one minute tuberculocidal use claims remains misleading because the one minute tuberculocidal claims do not appear in the Directions for Use as required by FIFRA (Section 136 (q)(1)(F), 1990)*. The DisCide label Directions for Use, which the users must follow, list a 6 minute contact time.

Adherence to the contact times in the label Use Directions is required for the protection of public health regardless of what laboratory data contact times are developed for the product by liquid suspension testing methods. Liquid suspension methods

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demonstrate presumptive efficacy which, in the case of tuberculocidal claims, must be confirmed by carrier tests. Carrier tests simulate the actual product use conditions.

The Agency does not invoke the confirmative tuberculocidal testing requirement on data developed by the Log Reduction Suspension test because this method lists a minimum permissible contact time of 5 minutes which is deemed sufficient to achieve efficacy in actual use situations. However, because PHC desires to have a tuberculocidal claim of less than 5 minutes, the Agency has accepted PHC's request that PHC submit data at less than a five minute contact time developed using a carrier-based test which will simulate the actual use conditions (where tubercle bacilli in sputum droplets and dried on environmental surfaces).

On 7-26-96 PHC submitted a protocol for evaluating pre-saturated towelettes for tuberculocidal activity on hard surfaces. This protocol was reviewed, accepted with comments and returned via facsimile to PHC (Frederick T. Smith of SRA International) on 8-2-96. A copy of the protocol with comments is attached.

However, until the tuberculocidal hard surface carrier test data are submitted and accepted by the Agency, the 6 minute contact time required by the Agency at the time of registration for the use of this product remains in effect.

PHC also requested a copy of EPA's formal statement requiring all registrants to use a 5 or 10 minute (tuberculocidal) label claim. Attached is a copy of the "Data Call-In Notice for Tuberculocidal Effectiveness Data for All Antimicrobial Pesticides with Tuberculocidal Claims", dated June 13, 1986, wherein the requirement is listed. (NOTE: PHC had to be in possession of this document in order to develop the submitted tuberculocidal data. The 5 minute incremental contact times are in the **Log Reduction Suspension test** method used by PHC from the "Data Call-In Notice for Tuberculocidal Effectiveness Data for All Antimicrobial Pesticides with Tuberculocidal Claims").

*(A pesticide is misbranded if:)

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment;

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