

JUL 26 1980

Mr. Rod J. de King
President
Mela Balm Corporation of Australia, Inc.
c/o Mr. Harold B. Igdaloff
Sungro Chemicals, Inc.
P.O. Box 24632
Los Angeles, CA 90024

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Dear Mr. de King:

Subject: Request for Formulation and Label Amendments
EPA Registration No. 55253-1
Your Confidential Statement of Formula Dated October 18, 1989

The amendments referred to above, submitted in connection with registration under section 251.7(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, are acceptable subject to the following comments.

1. The terms ACTIVE INGREDIENTS and INERT INGREDIENTS should be in the same type size, be aligned to the same margin, and be equally prominent.
2. The following statement should be added to PIPERONYL BUTOXIDE as a footnote to the ingredient statement:

Equivalent to 0.40% (butylcarbityl)
(6-propylpiperonyl)ether and 0.10% related
compounds.

3. Submit data confirming that the sodium lauryl sulfate in your product does not contain formaldehyde. Your supplier may contact us directly referencing your EPA Registration Number in their response.

51221:I:WP5.0:Mendelsohn:C.Disk:KENCO:07/03/90:DD:vo:jh:de

CONCURRENCES

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

In the May 17, 1988 Formaldehyde Registration Standard, the Agency "determined that formaldehyde and paraformaldehyde are pesticidally active when used as a preservative in pesticide formulations." Further, "products that contain formaldehyde or paraformaldehyde as a preservative must include the statement: 'Formaldehyde (or paraformaldehyde) is present solely to preserve the pesticide formulation and does not otherwise contribute to the product's pesticidal activity'." This statement must appear on your product's label if your product contains formaldehyde.

4. Change the company name and address on the labels to reflect your letter of May 1, 1990.
5. Per your letter of May 1, 1990, change "For Dogs" to "For Dogs and Cats." Change "Wet the dog's coat," to "Wet the animal's coat."
6. Add the statement "Do not use on puppies or kittens less than 6 weeks old" to the Hazards to Humans and Domestic Animals section.

Sincerely yours,



Phil Hutton
 Product Manager (17)
 Insecticide-Rodenticide Branch
 Registration Division (H7505C)

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Australian

MELA BALM

FLEA • TICK • LICE
SKIN CARE • GROOMING
SHAMPOO



1 GAL.

GIVES A GLOSSY BEAUTIFUL COAT
CLEANS, CONDITIONS • DISENTANGLES
CONTAINS OIL OF MELALEUCA ALTERNIFOLIA
KEEP OUT OF REACH OF CHILDREN

CAUTION:

See back panel for additional warnings

Australian **MELA BALM**

A flea, tick and lice shampoo that contains Melaleuca oil Alternifolia which penetrates the skin.

CLEANS • CONDITIONS
Detangles And Deodorizes • All At The Same Time

DIRECTIONS

It is a violation of Federal law to use this product in a manner inconsistent with its label.

Wet the dogs coat. Remove surface dirt. Apply desired amount of shampoo to coat and massage thoroughly for three to five minutes before rinsing.

KEEP OUT OF REACH OF CHILDREN

CAUTION

Hazardous to Humans & Domestic Animals
Harmful if swallowed. Avoid contact with eyes. In case of eye contact, rinse immediately with water.

DISPOSAL

Do not reuse empty container. Wrap container and put in trash.

ACTIVE INGREDIENTS

Pyrethrins	0
Piperonyl Butoxide	0
INERT INGREDIENTS	99

Contains oil of Melaleuca Alternifolia

Est. No. 11474CA01
E.P.A. Reg. No. 55253-1

Made in U.S.A.
Manufactured By

AUSTRALIS PHARMACEUTICALS, INC.
GLENDALE, CA 90039

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUL 25 1990

Under the Federal Insecticide,
Fungicide and Rodenticide Act and
approved for the pesticide
label under EPA Reg. No.

55253-1