

US EPA ARCHIVE DOCUMENT

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Safer, Inc.  
60 William Street, Suite G-20  
Wellesley, MA 02181

Gentlemen:

Subject: Your Insecticidal Soap Products  
EPA Registration Nos. 42697-1,  
42697-2, 42697-6 and 42697-11  
Your Application Dated January 14, 1986

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is not acceptable, for the reasons given below.

Comments on EPA Registration No. 42697-1:

1. This product was registered under the Cite-All provisions of FIFRA. Some acute toxicity data were previously submitted by you. According to that data, product falls under the following toxicity categories:

<u>Exposure Route</u>	<u>Toxicity Category</u>
Acute dermal	IV
Primary dermal irritation	III
Primary eye irritation	III

2. No additional acute toxicity data were submitted with this application. Although you claim to have made no changes in the precautionary labeling, several differences from the last accepted label were noted. You should justify making those changes. Otherwise, statements given below should be modified as specified before the updated label can be accepted.
  - a. The statement "In case of eye contact . . ." should be placed under a proper subheading like Statement of Practical Treatment or First Aid.

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CONCURRENCES

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- b. Environmental Hazards statement should read, "Keep out of lakes, streams, and ponds" instead of "Do not apply to lakes, streams, and ponds"; the former includes disposal of unused pesticide also.
  - c. Why was the Physical or Chemical Hazards statement deleted? It should be reinstated.
  - d. Storage and Disposal Statement should be revised per PR Notice 83-3.
3. Data on the dermal sensitization potential of this product is required.
  4. The statement "Help without harm" is an implied safety claim and must be deleted.

Comments on EPA Registration No. 42697-2:

1. This product is a [REDACTED]
2. No acute toxicity data were submitted for EPA review. Although your claim to have made no changes in the precautionary labeling, several differences from the last accepted label were noted. You should justify making those changes. Otherwise, statements given below should be modified as follows before the updated label can be accepted.
  - a. "And Domestic Animals" should be added to "Hazards to Humans."
  - b. Environmental Hazards statement should read, "Keep out of lakes, streams, and ponds" instead of "Do not apply to lakes, streams, and ponds"; the former includes disposal of unused pesticide also.
  - c. Why was "Avoid contamination of feed and foodstuffs" deleted?
  - d. Storage and Disposal statement should be revised per PR Notice 83-3.
3. You must submit data on the dermal sensitization potential of this product. A study on the concentrate will adequately support this product.
4. The statement "Help without harm" is an implied safety claim and must be deleted.

Manufacturing Process Information is not Included

- 5. You must submit a label which includes both the use on ornamentals and fruits and vegetables on the same label. We must have a label on file which includes all the uses.

Comments on EPA Registration No. 42697-6:

Inert Ingredient Information is not included  
 Manufacturing Process Information is not included

- 1. This product is a [REDACTED]
- 2. No acute toxicity data were submitted for EPA review. Although you claim to have made no changes in the precautionary labeling, several differences from the last accepted label were noted. You should justify making those changes. Otherwise, statements given below should be modified as follows before the updated label can be accepted.
  - a. "And Domestic Animals" should be added to "Hazards to Humans."
  - b. Environmental Hazards statement should read, "Keep out of lakes, streams and ponds" instead of "Do not apply to lakes, streams, and ponds"; the former includes disposal of unused pesticide also.
  - c. Why was "Avoid contamination of feed and foodstuffs" deleted?
  - d. Storage and Disposal statement should be revised per PR Notice 83-3.
- 3. You must submit data on the dermal sensitization potential of this product. A study on the concentrate will adequately support this product.
- 4. The statement "Help without harm" is an implied safety claim.
- 5. With [REDACTED] some eye and skin effects can be expected. Product should be labeled for eye irritation toxicity category III. Alternatively, you should submit eye irritation data to demonstrate that product falls in toxicity category IV for eye irritation.
- 6. In use directions, add "eyes" to "Avoid getting shampoo into sores or open wounds."

Comments on EPA Registration No. 42697-11:

- 1. This product is a dilution [REDACTED]

2. No acute toxicity data were submitted for EPA review. Although you claim to have made no changes in the precautionary labeling several differences from the last accepted label were noted. You should justify making those changes. Otherwise, statements given below should be modified as follows before the updated label can be accepted.
  - a. "And Domestic Animals" should be added to "Hazards to Humans"
  - b. Environmental Hazards statement should read, "Keep out of lakes, streams, and ponds" instead of "Do not apply to lakes, streams, and ponds"; the former includes disposal of unused pesticide also.
  - c. Why was "Avoid contamination of feed and foodstuffs" deleted?
  - d. Storage and Disposal Statements should be revised per PR Notice 83-3.
3. You must submit data on the dermal sensitization potential of this product. A study on the concentrate will adequately support this product.
4. The statement "Help without harm" is an implied safety claim.

Sincerely yours,



William H. Miller  
Product Manager (16)  
Insecticide-Rodenticide Branch  
Registration Division (TS-767C)