

DATE: September 6, 1978

003052

SUBJECT: Aquat EPA Registration#11133-R  
Caswell#16

FROM: William Dykstra, Ph.D  
Toxicology Branch/HED

WLD 9/7/78

TO: Joseph Tavano  
Product Manager #31

Registrant: Peroxide & Specialties Co.  
Div. of Jones-Hamilton Co.  
Newark, Ca. 94560

Action Type: New Registration

Recommendations:

1. There is a discrepancy between the percent active ingredient listed on the label and the percent active ingredient listed in the confidential statement of formulation of the product.
2. No additional toxicology studies are required for registration of this product.
3. The label signal word, precautionary statements, statement of practical treatment and note to physician are correct for the product and adequate to protect the user of the product.

\*No RPAR criteria have been exceeded in these studies.

Product Name: Aquat

<u>Ingredient</u>	<u>Percent Weight</u>
Alkyl (C <sub>14</sub> , 50%; C <sub>12</sub> , 40%; C <sub>16</sub> , 10%) Dimethyl Benzyl Ammonium chloride	10
<u>Inerts</u>	<u>90</u> 100

Most ingredient information

Uses: Disinfection of Barber Tools

Barber tools (such as combs, brushes, razors and scissors) can be disinfected by immersing in a 1/2 ounce/gal solution of Aquat.

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Review:

- I. Method of support (2.b) from Lonza Barquat MB-50 + MB-80.
- a. Toxic Studies on Barquat MB-80 (6/30/75; Bio-Tox Labs., Inc.)  
Memo of 5/24/76 from W. Greear.
1. Eye Irritation: Core Minimum Data at 72 hours.

TOX Category I: DANGER (Maximum Score)

2. Acute Oral LD<sub>50</sub>: Core Minimum Data  
LD<sub>50</sub> = .43 ml/kg (both sexes in rats)

TOX Category II: WARNING

3. Primary Skin Irritation: Core Minimum Data  
P.I. = 6.29

TOX Category II: WARNING

4. 20 Day Subacute Dermal Toxicity Study

- a. 0.25% Active/kg-mild erythema
- b. 0.1% Active/kg-moderate erythema, slight edema, slight desquamation, weight loss
- c. 0.2% Active/kg-moderate erythema, slight edema, moderate erythema, weight loss: Supplementary Data

5. Dermal LD<sub>50</sub> of Barquat MB-80 dated 10/14/77 (Leberco Laboratories).

Memo of 12/12/77, W. Greear. LD<sub>50</sub> > 5 gm/kg (female rabbits)  
Supplementary Data: TOX Category III: CAUTION

6. Teratologic Evaluation of Four Quaternary Compounds (FDR Labs. 2/11/77, Lab.#5154)

Memo of 8/8/77 from R. Gessert, D.V.M.

Conclusion: Daily oral administration of Barquat MB-50, Barquat MX-50, Barquat 4250 or Barquat 4250-2 to rats at doses of 10, 25, or 50 mg/kg during days 6-15 of pregnancy did not produce any indication of significant fetotoxicity or teratogenicity in these studies.

Classification: Core Minimum Data

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Conclusion on Toxicology Data:

The eye irritation study, although evaluated up to 72 hours only (rather than also at 7 days), demonstrated a maximum score of 110/110 for each of 6 rabbits. This study on M3-89 (Technical) can be suitably extrapolated to the formulated product and can be used to establish the toxicity category of the formulated product. (Fox I, PANLER). Although the acute dermal LD<sub>50</sub> + 20 day subacute dermal toxicity study are considered supplementary data, it can be concluded that routine dermal exposure to the formulated product, in accordance with label precautions, and the use dilution of the formulated product will not produce a risk of systemic toxicity. The teratological study shows that female human exposure will not result in fetotoxic or teratogenic risks. Other data on file indicate that the technical material is not a skin sensitizer. Therefore, it can be concluded that no additional toxicology studies are required to evaluate the human hazards from exposure to the product from the proposed use patterns.

TOX/HED:th:Reto Engler:8/30/78

*FE 9/8/78*

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