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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM JUL 16 1982 8 JUL 1982

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: A. E. Castillo
Product Manager, No. 32
Registration Division (TS-767)

THRU: Christine F. Chaisson, Ph.D. C.F. Chaisson
Toxicology Branch
Hazard Evaluation Division (TS-769)

SUBJECT: Evaluation of Skin Sensitization Study in Human Volunteers (EPA. Reg. No. ~~10182-19~~, Acc. No. 247255, Caswell No. 676).

Registrant:

ICI Americas, Inc.
Wilmington, Delaware 19897

Action Requested:

Review and evaluation of skin sensitization study with Baquacil in human volunteers.

Conclusion and Recommendations:

Tox. Branch considers this chemical a human skin sensitizer under the test conditions.

Review

Test Chemical:

Vantocil IB, Code Y 00156/001/005. A clear odorless, colorless liquid (20% active).

Testing Laboratory:

IAN Smith Consultancy, Longniddry, Edinburgh, Scotland.
Project No. 0018, November 1981.

Procedure:

A total of 209 volunteers commenced the study, a total of 191 subjects completed the human repeat insult patch test according to the study protocol which involved induction applications of Vantocil IB at 2% v/v with challege applications at both this and lower concentrations.

DANGER:

KEEP OUT OF REACH OF CHILDREN

EPA-PR

See side panel for additional precautionary statements and statement of First Aid treatment

EPA Reg No 10182-19
EPA Est No 10182-DE-01

Active Ingredient: Poly(iminoimido-carbonyliminoimidocarbonyliminohexamethylene hydrochloride) 20%
Inert Ingredients: 80%

BAQUACIL® is a registered trademark of Imperial Chemical Industries PLC.
Not recommended for spa baths or pools equipped with air jet streams

Net Contents:
2½ Gallons

At Last!
A Substitute for
Chlorinating Chemicals for Pools

BAQUACIL®

Swimming Pool Sanitizer and Algicide

PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER:

CORROSIVE, CAUSES EYE DAMAGE. HARMFUL IF SWALLOWED

Do not get concentrate in eyes. Avoid contact with skin and clothing. Avoid breathing spray or mist. Wash thoroughly after handling. Wear goggles or face shield when handling concentrate.

Keep container closed.

First Aid:

In case of contact with concentrate, immediately flush eyes with plenty of water for at least 15 minutes and call a physician. If redness, itching or a burning sensation develops following skin contact, get medical attention.

If swallowed, drink plenty of water or milk. Do not induce vomiting. Call physician. Wash clothing and decontaminate shoes before reuse.

Note to Physician:

The potential hazard from ingestion of concentrate is corrosive action to mucous membranes. Acute systemic toxicity is slight.

Environmental Hazards:

This product is toxic to fish. Do not comtaminate water by cleaning of equipment or disposal of wastes. Do not discharge concentrated products or treated pool water directly into lakes, streams, or public waters unless in accordance with an NPDES permit. For guidance, consult the regional office of the EPA.

The test material was applied throughout the induction stages of the study in 0.5 ml aliquots to a 2x2 cm Webril pad, located centrally in a piece of Blenderm adhesiv tape which was then applied to the dorsal surface of the upper arm of each subject. Induction patches were applied 3 times per week for 24 hours in the first three weeks and for one time in the fourth week.

On the six week of the test schedule, challenge patches of four different concentraions (in distilled water) were applied. These patches were removed after 24 hours.

The study consisted of 3 subgroups as follows:

1. Preliminary Panel:

   Fifty four volunteers commenced the study, exposed initially to a concentration of 2% for six induction patches, then to 3 patches at 4%, then the concentration was reduced to the original for the rest of the period. Fourty nine subjects completed the study up to the challenge phase.

2. Main Panel:

   One hundred and twenty six volunteers exposed to the concentration of 4% v/v, then to a reduced concentration of 2% v/v.

3. Additional Panel:

   Twenty nine volunteers were recruited and treated with induction patches with a concentration of 2% v/v for 4/5 times.

Results :

SUMMARY OF SENSITISATION INDICES

1. Preliminary Panel

54 volunteers commenced the study; 49 completed

Challenge Concentration(% v/v)	Incidence of Positive Reactions
2.0	8/49
1.0	7/49
0.5	7/49
0.1	2/49

2. Main Panel

126 volunteers commenced the study; 114 completed

Challenge Concentration(% v/v)	Incidence of Positive Reactions
0.5	18/114
0.2	7/114
0.1	0/114
0.05	0/114

3. Additional Panel

29 volunteers commenced the study; 28 completed

Challenge Concentration(% v/v)	Incidence of Positive Reactions
0.5	1/28
0.2	0/28
0.1	0/28
0.05	0/28

Discussion and Conclusions:

Vantocil IB when applied under patch test conditions on human volunteers at a level of 2% v/v resulted in skin sensitization when challenged by concentrations from 2% to as low as 0.1% v/v. This concentraiton is considered to be 20 fold greater than the recommened use in swimming pools (50 ppm).

It is not possible also to predict whether a threshold level for induction may exist under the conditions of this test since the lowest concentration used in the induction phase was 2% v/v.

However, since users may vary in their sensitivity or response to a skin sensitizing agent and they may not also adhere to the concentration recommended by the registrant, therefore, the true safety factor may be a lot lower than this study may indicate.

G. Ghali 7/16/82

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