

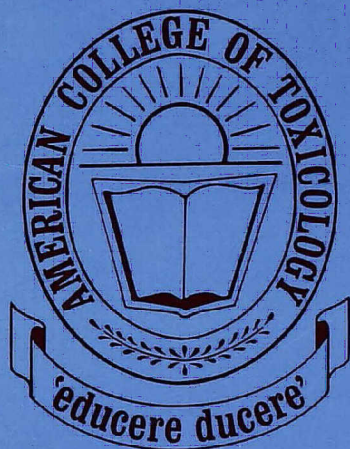
HEALTH SCIENCES LIBRARY

VOLUME 7 NUMBER 3 1988

ISSN 0730-0913

**FOURTEENTH REPORT OF THE COSMETIC
INGREDIENTS REVIEW EXPERT PANEL**


**JOURNAL OF THE
AMERICAN COLLEGE OF TOXICOLOGY**



**SPECIAL
ISSUE**

editor

MILDRED S. CHRISTIAN

Maru Ann Liebert, Inc.  *publishers*

**DOCKET
ALARM**

Find authenticated court documents without watermarks at docketalarm.com.

Journal of the American College of Toxicology

Editor-in-Chief: Mildred S. Christian

Assistant to the Editor: Carolyn P. Nettles

Argus Research Laboratories, Inc.
935 Horsham Road
Horsham, PA 19044
(215) 443-8710

Associate Editors

Arthur Furst
Institute of Chemical Biology
University of San Francisco
San Francisco, CA 94117
(415) 666-6415

Robert M. Diener
Ciba-Geigy Pharmaceuticals Division
Summit, NJ 07901
(201) 277-5430

Editorial Board

GENERAL TOXICOLOGY

Section Editor

Bruce K. Bernard
Washington, DC

Section Associate Editors

Joseph F. Borzelleca
Wayne M. Galbraith
Donald Hughes
Rudolph J. Jaeger
Carol A. Mapes
Ian C. Munro

ACUTE AND SUBCHRONIC TOXICITY

Section Editor

Richard A. Parent
Baton Rouge, LA

SAFETY EVALUATION AND RISK ASSESSMENT

Section Editor

Robert G. Tardiff
Springfield, VA

CARCINOGENESIS

Section Editor

Yin-tak Woo
Washington, DC

Section Associate Editors

F. Peter Guengerich
Charles C. Irving
David Y. Lai
John H. Weisburger
Hanspeter R. Witschi

IMMUNOTOXICOLOGY

Section Editor

Stewart Wong
Waverly, PA

Section Associate Editors

Thomas H. Shepard
Robert E. Staples
Peter Voytek
Ernest F. Zimmerman

GENETIC TOXICOLOGY

Section Editor

W. Gary Flamm
Rockville, MD

Section Associate Editors

Virginia Dunkel
George Hoffmann
Verne A. Ray

EPIDEMIOLOGY AND CLINICAL TOXICOLOGY

Section Editor

Edward J. Calabrese
Amherst, MA

MECHANISMS OF TOXICITY

Section Editor

Ronald W. Hart
Jefferson, AR

Section Associate Editor

Gerald N. Wogan

DEVELOPMENT OF NON-ANIMAL TESTING TECHNIQUES

Section Editor

Alan M. Goldberg
Baltimore, MD

Section Associate Editors

Thomas E. Hickey
Dennis Stark

QUALITY ASSURANCE

Section Editor

Jane E. Goeke
Horsham, PA

VETERINARY TOXICOLOGY

Section Editor

E. Murl Bailey, Jr.

GENERAL INFORMATION

The *Journal of the American College of Toxicology* publishes fully refereed papers covering the entire field of toxicology. These include research in risk assessment, general toxicology, carcinogenicity, safety evaluation, reproductive and genetic toxicology, epidemiology and clinical toxicology, mechanisms of toxicity, new approaches to toxicological testing, and alternatives to animal testing. Reviews and major symposia in the field are included.

Journal of the American College of Toxicology (ISSN:0730-0913) is published bimonthly for \$130 per year by Mary Ann Liebert, Inc., 1651 Third Avenue, New York NY 10128. (212) 289-2300. Second-class postage paid at New York, NY and at additional mailing offices.

Postmaster: Send address changes to *Journal of the American College of Toxicology* c/o Subscription Department, Mary Ann Liebert, Inc., Publishers, 1651 Third Avenue, New York, NY 10128.

Subscriptions should be addressed to the Publisher and are payable in advance. Rates are \$130 per volume of 6 issues in the United States and Possessions, \$163 air mail, elsewhere.

Reprints, except special orders of 100 or more, are available from the authors.

Business communications should be addressed to the Publisher.

Advertising inquiries should be addressed to Mary Ann Liebert, Inc., 1651 Third Avenue, New York, NY 10128. (212) 289-2300.

Manuscripts should be directed to the Editor: Mildred Christian, Argus Research, 935 Horsham Rd., Horsham, PA 19044.

All authored papers and editorial news and comments, opinions, findings, conclusions, or recommendations in the *Journal of the American College of Toxicology* are those of the author(s), and do not necessarily reflect the views of the journal and its publisher, nor does their publication in the *Journal of the American College of Toxicology* infer any endorsement.

Copyright © 1988 by The American College of Toxicology. Printed in the United States of America.

This Journal is indexed in *Current Contents* and *Science Citation Index*.

U.S. Postal Service STATEMENT OF OWNERSHIP, MANAGEMENT AND CIRCULATION Required by 39 U.S.C. 3685			
1. TITLE OF PUBLICATION JOURNAL OF THE AMERICAN COLLEGE OF TOXICOLOGY		2. ISSUE DATE 10/01/87	3. DATE OF FILING 10/01/87
4. FREQUENCY OF ISSUE Bimonthly		5. YEAR OF ESTABLISHMENT 6	6. ANNUAL SUBSCRIPTION PRICE \$130.00
7. COMPLETE MAILING ADDRESS OF OWNER/PUBLISHER (Street, City, County, State and ZIP Code (see instructions)) 1651 Third Avenue, New York, N.Y. 10128			
8. COMPLETE MAILING ADDRESS OF THE HEADQUARTERS OF GENERAL BUSINESS OFFICE OF THE PUBLISHER (Other priority) 1651 Third Avenue, New York, N.Y. 10128			
9. FULL NAMES AND COMPLETE MAILING ADDRESSES OF PUBLISHER, EDITOR AND MANAGING EDITOR (Print name with ZIP code) Publisher: Mary Ann Liebert, Inc., 1651 Third Avenue, New York, N.Y. 10128 Editor: Mildred A. Christian, Argus Research Labs, Inc., 935 Horsham Rd., Horsham, PA 19044 Managing Editor: (Street and Complete Mailing Address) Same as above			
10. OWNER (If owned by a corporation, its name and address, together with the names and addresses of all stockholders owning or holding 1 percent or more of total amount of stock; if not owned by a corporation, the names and addresses of all individual owners; if owned by a partnership or other unincorporated firm, its name and address, together with the names and addresses of all individual owners; if the publication is published by a sole proprietor, his or her name and address.)			
11. FULL NAME AND COMPLETE MAILING ADDRESS Mary Ann Liebert, Inc. 1651 Third Avenue New York, N.Y. 10128			
12. FULL NAME AND COMPLETE MAILING ADDRESS Mildred A. Christian 935 Horsham Rd. Horsham, PA 19044			
13. FULL NAME AND COMPLETE MAILING ADDRESS Mildred A. Christian 935 Horsham Rd. Horsham, PA 19044			
14. FOR COMPLETION BY SUBPUBLISHERS PUBLISHED SEPARATELY: SPECIAL ADVERTISING SECTION (SEE INSTRUCTIONS) The name, title, and complete address of the publisher and the mailing address (Print name with ZIP code) None			
15. EXTENT AND NATURE OF CIRCULATION A. TOTAL NO. COPIES (Net press run) B. PAID AND UNPAID CIRCULATION C. PAID AND UNPAID CIRCULATION (Net of A and B) D. PAID AND UNPAID CIRCULATION (Net of A and B)			

Final Report on the Safety Assessment of Polyquaternium-10

Polyquaternium-10 is a polymeric quaternary ammonium derivative of hydroxyethyl cellulose that is used in cosmetics as a conditioner, thickener, and emollient at concentrations of $\leq 0.1\%$ – 5% . Polyquaternium-10 has, at most, only a low potential to penetrate the stratum corneum but is adsorbed by keratinous surfaces. The oral LD_{50} of Polyquaternium-10 was not obtained at 16 g/kg in rats. Inhalation, dermal, and ocular animal test data indicated, at most, only a low degree of toxicity at test concentrations of Polyquaternium-10 greater than that used in cosmetic products. Polyquaternium-10 with and without metabolic activation was not a mutagen in three separate assay systems. Polyquaternium-10 was neither an irritant nor a human sensitizer when tested at 2.0%. Cosmetic products containing up to 1% Polyquaternium-10 were not human irritants, sensitizers, or photosensitizers. On the basis of the information presented, it is concluded that Polyquaternium-10 is safe as a cosmetic ingredient in the present practices of use.

INTRODUCTION

Polyquaternium-10 is a cationic form of hydroxyethyl cellulose that adsorbs and sorbs well to proteinaceous surfaces. It is used in cosmetics as a conditioner, thickener, and emollient in hair care products, lotions, and makeup.

CHEMISTRY

Definition

Polyquaternium-10, also known as Quaternium-19, is a polymeric quaternary ammonium salt of hydroxyethyl cellulose reacted with a trimethyl ammonium substituted epoxide. There are various grades of Polyquaternium-10 with different average molecular weights generally ranging from 250,000 to 600,000. Polyquaternium-10 has three CAS numbers: 53568-66-4, 54351-50-7, and 55353-19-0.⁽¹⁻³⁾

Chemical and Physical Properties

Polyquaternium-10 is a white granular powder with a characteristic amine odor. It is soluble in water and insoluble in alcohol and nonpolar organic sol-

vents. Polyquaternium-10 used in cosmetics has 0.5% maximum water insolubles, 1.7 to 2.2% nitrogen-containing components, 2% maximum ash (NaCl), and 6% maximum volatile material. The particle size specifications are 95% minimum through a 20 mesh filter and 85% minimum through a 40 mesh filter. The viscosity of a 2% aqueous solution (25°C) is between 60 and 150 centipoises.⁽⁴⁾

Polyquaternium-10 alters the surface tension of aqueous solutions of anionic surfactants. Addition of 1% and 2% Polyquaternium-10 lowered the surface tension of aqueous solutions of sodium lauryl sulfate, sodium tridecylbenzenesulfonate, and potassium laurate.⁽⁵⁾

Reactivity

Polyquaternium-10 is a cationic, surface-active polymer that is adsorbed by keratinous surfaces, such as hair and skin (stratum corneum). The adsorption of the polymer was not readily affected by pH in the range of 4 to 10. It undergoes slow hydrolytic cleavage outside this pH range. Sorption of Polyquaternium-10 to keratinous surfaces was decreased by the addition of electrolytes (salts), such as aluminum, iron, calcium, or sodium. Polyquaternium-10 is biologically degradable. The presence of ethyl alcohol or propylene glycol adds to the stability of Polyquaternium-10.⁽⁶⁻⁹⁾

Analytical Methods

The most common analytical method for quaternary ammonium compounds is colorimetric testing following separation by acid extraction.⁽¹⁰⁾

Method of Manufacture

Polyquaternium-10 is generally produced by reacting hydroxyethylcellulose with epichlorhydrin, followed by quaternization using trimethylamine. It is stable within a pH range of 4 to 8.

Impurities

Inorganic impurities of Polyquaternium-10 used in cosmetics include water (up to 0.5%), nitrogen (1.7 to 2.2%), and ash (NaCl up to 2%). Information was not available on organic impurities of Polyquaternium-10.⁽⁴⁾ Epichlorhydrin was not detected in any of six different Polyquaternium polymers analyzed with an average detection limit of about 0.5 ppm.⁽¹¹⁾ A maximum of 10.8 ppm Trimethylamine was detected in lots of Polyquaternium-10 that were produced and sold during 1985.⁽¹²⁾

USE

Purpose in Cosmetics

Polyquaternium-10 is used as a conditioner, emollient and viscosity controlling agent in cosmetics.^(3,13,14)

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.