

K974485

510(k) SUMMARY

SAUFLON MULTIPURPOSE SOFT
(HYDROPHILIC) CONTACT LENS SOLUTION

FEB 24 1998

- 1. Submitted by: Sauflon Pharmaceuticals, Ltd
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(312) 553-0828
- 2. Date prepared: February 9, 1998
- 3. Device:
Common Name Multipurpose Contact Lens Solution
Trade Name Sauflon Multipurpose Soft (hydrophilic)
Contact Lens Solution
- 4. Classification Class II (Performance Standards)
21 CFR 886.5928
Soft (hydrophilic) contact lens solution
- 5. Substantial equivalence This product is substantially equivalent to the currently marketed Bausch and Lomb ReNu Multipurpose Solution.
- 6. Device description A sterile, isotonic solution that contains Poloxamer, sodium phosphate buffer, sodium chloride, and disodium edetate; preserved with polyhexanide 0.0001%. Contains no chlorhexidine or thimerosal. Cleans, loosens and removes accumulations of films, deposits and debris from soft contact lenses. Destroys harmful microorganisms on the surface of the lens. Rinses, stores and rewets lenses before the lenses are placed on the eye.
- 7. Intended use The Sauflon Multipurpose Soft (hydrophilic) Contact Lens Solution is indicated for use in chemical (not heat) disinfection, daily cleaning, rinsing and storage of daily and extended wear soft contact lenses as recommended by the eye care practitioner.
- 8. Comparison to predicate devices: see following table

K974485 Summary

SUBSTANTIAL EQUIVALENCE COMPARISON

	SAUFLON MULTIPURPOSE SOFT (HYDROPHILIC) CONTACT LENS SOLUTION	BAUSCH & LOMB ReNu ALL-IN-ONE
SALT	NaCl	NaCl
CHELATOR	Edetate disodium	Edetate disodium
BUFFER	Phosphate	Borate
SURFACTANT	Poloxamer	Poloxamine
ANTIMICROBIAL	Polyhexanide (0.0001% w/v)	Polyhexanide (0.00005% w/v)
WATER	qs	qs
OTHER	Sterile Isotonic	Sterile Isotonic

Introduction

The Sauflon Multipurpose Soft (hydrophilic) Contact Lens Solution is a solution intended to be used as a daily cleaner, rinsing agent, disinfecting and storage solution, and wetting/rewetting solution prior to lenses being placed on the eye, in the care of soft (hydrophilic) lenses. It is comparable to currently marketed multipurpose solutions such as ReNu, Complete and Solocare.

Contained in this submission are comparisons of the product to the predicate device, information on the chemistry and manufacturing, results of toxicological and microbiological tests, and the report of a clinical trial of 246 subjects, who have used the product over a period of at least three months. Details are included in the appropriate sections.

I. Chemistry

The Sauflon Multipurpose Soft (hydrophilic) Contact Lens Solution is a sterile, isotonic solution that contains poloxamer, sodium phosphate buffer, sodium chloride, and disodium edetate; preserved with polyhexanide 0.0001%. It contains no chlorhexidine or thimerosal.

K974485 Summary

A. Solution compatibility

The compatibility of the Sauflon Multipurpose Soft (hydrophilic) Contact Lens Solution was demonstrated by cycling lenses through 30 cycles of simulated use, using the Sauflon Multipurpose Soft (hydrophilic) Contact Lens Solution for cleaning, rinsing, disinfecting and storing. Parameters of lenses were measured before and after the 30 cycles, and no differences were found.

B. Cleaning effectiveness

The efficacy of the Sauflon Multipurpose Soft (hydrophilic) Contact Lens Solution as a daily cleaner was shown by determining the critical micelle concentration.

II. Toxicology

The toxicological testing is summarized below, and reports are attached. The solution was shown to be non-toxic in all tests. Additional toxicity testing (cytotoxicity, systemic toxicity and ocular irritation) was done to verify the safety of the solution in the contract manufacturer's bottle.

A. Agar Overlay Cytotoxicity:

Representative lenses from all four groups of soft (hydrophilic) lens types were exposed to the Sauflon Multipurpose Soft (hydrophilic) Contact Lens Solution for 24 hours, then tested in a direct contact cytotoxicity assay. All test lens types were noncytotoxic.

B. Systemic toxicity:

The Sauflon Multipurpose Soft (hydrophilic) Contact Lens Solution was evaluated for systemic toxicity by intraperitoneal (ip) injection in healthy mice, 50ml/kg body weight. The animals were observed over a 72 hour period, and showed no difference from control animals injected with saline. The solution passed the test requirements, that there be no difference between the response of test and control animals.

K974485 Summary

C. Acute Oral toxicity

The Sauflon Multipurpose Soft (hydrophilic) Contact Lens Solution was evaluated for acute oral toxicity by intubation in healthy rats, 5ml/kg body weight. The animals were observed immediately after intubation, after 2 and 4 hours, then daily for fourteen days. The animals were weighed prior to intubation, at 7 days, and at 14 days. All animals showed no clinical signs of toxicity from test initiation to Day 14, therefore the Sauflon Multipurpose Soft (hydrophilic) Contact Lens Solution passed the test requirements of no acute oral toxicity.

D. Acute Ocular irritation:

The Sauflon Multipurpose Soft (hydrophilic) Contact Lens Solution was instilled directly into one eye of each of three rabbits, the other eye receiving sterile water as a control. Examinations over 72 hours showed no differences between test and control eyes, with no evidence of ocular irritation with either the test or control solutions. The Sauflon Multipurpose solution therefore meets the requirements of the acute ocular irritation test.

E. Full USP Class VI Testing of Sauflon Multipurpose Soft (hydrophilic) Contact Lens Solution in bottles manufactured of high density polyethylene.

1. Cytotoxicity test:

Under the conditions of this study, the saline test extract showed no evidence of causing cell lysis or toxicity. The negative controls, reagent controls, and the positive controls performed as anticipated. The saline test extract was not cytotoxic and passed this test.

2. Systemic Toxicity Test:

Under the conditions of this study, there was no mortality or evidence of significant systemic toxicity from the extracts. Each test article extract met the requirements of this test.

3. Ocular Irritation Study:

Under the conditions of this study, there was no evidence of significant irritation in the test or control eye of any rabbit. The saline and cottonseed oil test article extracts would not be considered irritants to the ocular tissue of the rabbits.

K974485 Summary

III. Microbiology

A. Sterility

The Sauflon Multipurpose Soft (hydrophilic) Contact Lens Solution passed the requirements of sterility testing.

B. Preservative efficacy

The Sauflon Multipurpose Soft (hydrophilic) Contact Lens Solution passed the requirements of the modified preservative efficacy test with rechallenge at 14 days.

C. Disinfection Efficacy

The Sauflon Multipurpose Soft (hydrophilic) Contact Lens Solution passed the requirements of the stand-alone disinfection test, obviating the requirements for the multi-item testing.

D. Stability

Stability testing is in progress; the solution has currently passed stability testing corresponding to a shelf-life of 11 months.

IV. Clinical Studies

A clinical trial of 6 months usage of the Sauflon Multipurpose Soft (hydrophilic) Contact Lens Solution by 246 subjects, wearing representative lenses from all groups of soft (hydrophilic) contact lenses, compared to 117 control subjects using currently marketed care products, showed that the product is substantially equivalent to those current solutions.

Twelve (12) investigators enrolled a total of 246 test subjects. The control group included 59 subjects using a commercially available multipurpose solution and 58 using a commercially available two-step peroxide system. The age range was from 12 to 73, 70.4% female and 29.6% male. Analysis of the discontinuations among the various groups, test vs control, female vs male, showed that the differences in the incidence of discontinuations for cause (stain, discomfort, etc) were not statistically significant.

(1) Adverse Reactions

The only adverse events in the test population were one case of mild conjunctivitis and one case of marginal keratitis; both cases resolved with no permanent sequelae.

K974485 Summary

(2) Slit Lamp Findings:

Table A compares the incidence of slit lamp findings in the investigational group and the two control groups.

TABLE A

SLIT LAMP FINDINGS

FINDING	TEST	CONTROLS	
		MULTIPURPOSE	PEROXIDE
NO FINDINGS ^a	79.1	57.5	67.0
EDEMA ^b	0.2	0.8	0.6
NEOVASCULAR	3.4	6.4	9.3
STAINING	2.9	15.9	8.9
HYPEREMIA	10.8	12.5	6.0
PALPEBRAL	11.1	26.4	18.3
OTHER	0.6	0.9	0.4

^a Percent of eyes examined with no findings, regularly scheduled visits only

^b Percent of eyes with finding, regularly scheduled visits only

(3) Symptoms, Problems and Complaints:

Symptoms, problems and complaints were reported by the investigators at each visit. Discomfort, burning, lens awareness, variable vision and need for cleaning were the most frequently reported symptoms among all subjects. Table B compares the incidence of selected symptoms in the three groups (test, multipurpose and peroxide controls).

TABLE B

SELECTED SYMPTOMS, PROBLEMS AND COMPLAINTS

SYMPTOM	TEST	CONTROLS	
		MULTIPURPOSE	PEROXIDE
NONE ^a	83.7	79.6	85.3
DISCOMFORT ^b	2.9	3.5	3.6
PAIN, BURNING	2.0	2.9	2.7
VARIABLE VISION	1.5	4.5	1.6
LENS AWARENESS	4.0	3.3	3.9
NEED FOR CLEANING	1.8	5.2	1.8

^a Percent of eyes examined with no findings, regularly scheduled visits only

^b Percent of eyes with finding, regularly scheduled visits only

K974485 Summary

(4) Visual Acuity:

The appropriate acuity was achieved by 97.1% of the test eyes, 98.4% of the multipurpose control, and 100% of the peroxide control eyes.

(5) Wear Time:

Wear time remained essentially unchanged over the six months of the study.

(6) Lens Cleanliness:

Overall, the reports of the lens cleanliness evaluation showed that 97.6% of test lenses, 92.7% of the multipurpose and 93.8% of the peroxide were clinically clean at scheduled visits.

(7) Gender Analysis:

The overall test population was 68.7% female, 31.3% male, and the visit distribution over the study was 67.7% female, 32.3% male. Overall, there were no slit lamp findings at 79% of the visits; among females, at 76.9%, among males at 83.9% of the visits. For symptoms, there were no symptoms reported at 84% of the visits; among females, no symptoms were reported at 83%, among males, at 86%. There is no significant difference in the findings, and no further analysis was warranted.

OVERALL CONCLUSION OF THE CLINICAL STUDY:

The data of the clinical trial confirm that Sauflon Multipurpose Soft (hydrophilic) Contact Lens Solution is substantially equivalent to other currently marketed cleaning, rinsing, disinfecting and storage products, specifically Bausch & Lomb Multipurpose solution, when used according to the manufacturer's instructions.

FEB 24 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

John M. Szabocsik, Ph.D.
Official Correspondent for
Sauflon Pharmaceuticals, Inc.
203 North Wabash Avenue
Suite 1200
Chicago, IL 60601

Re: K974485
Trade Name: Sauflon Multipurpose Soft (hydrophilic) Contact Lens Solution
Regulatory Class: II
Product Code: 86 LPN
Dated: November 24, 1997
Received: November 26, 1997

Dear Mr. Szabocsik:

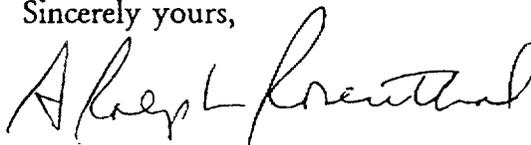
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2

510(k) NUMBER (IF KNOWN) K974485

DEVICE NAME SAUFLON MULTIPURPOSE SOFT
(HYDROPHILIC) CONTACT LENS SOLUTION

INDICATIONS FOR USE

The Sauflon Multipurpose Soft (hydrophilic) Contact Lens Solution is indicated for use in chemical (not heat) disinfection, daily cleaning, rinsing and storage of daily and extended wear soft contact lenses as recommended by your eye care practitioner.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Ming-Chuan Shu *js*

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use
(Optional Format 1-2-96)