

SEP 14 1999

K991125

510(K) SUMMARY FOR FREEDOM OF INFORMATION

SAUFLON AEROTAB DISINFECTING SYSTEM  
FOR SOFT (HYDROPHILIC) CONTACT LENSES

1. Submitted by: Sauflon Pharmaceuticals, Ltd  
49-53 York St  
Twickenham, Middlesex TW1 3LP  
United Kingdom  
  
Contact Person: John M. Szabocsik, Ph.D.  
Szabocsik and Associates  
203 N. Wabash, Ste 1200  
Chicago, IL 60601  
TEL: 312-553-0828
2. Date Prepared July 16, 1999
3. Common/Usual Name Sauflon AEROTAB Disinfecting System:  
Sauflon AEROTAB Disinfecting Tablet with  
AEROSOLV Unpreserved Buffered Saline  
Solution and Sauflon Barrel Lens Case
4. Trade/ Proprietary Sauflon AEROTAB Disinfecting System:  
Sauflon AEROTAB Disinfecting Tablet with  
AEROSOLV Unpreserved Buffered Saline  
Solution and Sauflon Barrel Lens Case
5. FDA Classification Class II (Performance Standards) 21 CFR  
886.5928 Soft (hydrophilic) contact lens  
disinfecting tablet with saline and lens  
case.  
Sauflon AEROTAB Disinfecting System:  
Product code 86LPN
6. Substantial equivalence This product is substantially  
equivalent to PD 1343 Disinfecting  
Tablet with Unisol®, approved PMA  
P890059.

I. INDICATIONS FOR USE

The SAUFLON AEROTAB DISINFECTING SYSTEM is indicated for chemical disinfection and storage of clear (untinted) soft (hydrophilic) contact lenses.

The AEROSOLV UNPRESERVED BUFFERED SALINE SOLUTION is indicated for the rinsing of soft contact lenses after cleaning, dissolving of the Sauflon AEROTAB Disinfecting Tablet to make the disinfecting/ storage solution, and rinsing of the soft contact lenses prior to insertion onto the eye.

The SAUFLON Barrel Lens Case is to be used with the AEROSOLV UNPRESERVED BUFFERED SALINE SOLUTION and Sauflon AEROTAB Disinfecting Tablets as the lens case for chemical disinfection and storage of clear (untinted) soft (hydrophilic) contact lenses.

The SAUFLON barrel lens case may also be used as the lens case for storage of soft (hydrophilic) contact lenses during chemical disinfection only. DO NOT USE WITH HEAT OR HYDROGEN PEROXIDE SYSTEMS.

## II. PRODUCT DESCRIPTION AND CHEMISTRY

### Sauflon AEROTAB Disinfecting System

The Sauflon Aerotab Disinfecting Tablet contains halazone (4-carboxyphenyl N-chloro sulphonamide) as the active ingredient, with an effervescent base of adipic acid and anhydrous sodium carbonate. There is no preservative in the tablet. AEROSOLV Unpreserved Buffered Saline Solution is a sterile, aqueous, isotonic solution of sodium chloride buffered with boric acid and sodium borate.

The Sauflon AEROTAB disinfecting system was shown to be compatible with clear (untinted) soft (hydrophilic) contact lenses.

## III. TOXICOLOGY

Hydrophilic lenses representative of all four groups disinfected for 30 cycles with the Sauflon AEROTAB Disinfecting System showed no cytotoxicity and no ocular irritation.

All toxicology concerning the AEROSOLV Unpreserved Buffered Saline Solution is contained in P850074 and its supplements.

The components of the lens case have passed the requirements for Plastics for Ophthalmic Products (USP XXIII).

## IV. MICROBIOLOGY

The Sauflon AEROTAB Disinfecting Tablet is a non-sterile tablet, and the system contains no preservative. The Sauflon AEROTAB Disinfecting System meets the requirements of the Stand-Alone Procedure for Disinfecting Products, and maintains efficacy throughout the labeled shelf-life.

All microbiology concerning the AEROSOLV Unpreserved Buffered Saline Solution is contained in P850074 and its supplements.

**V. CLINICAL STUDIES**

**A. AEROTAB Disinfecting Tablet**

A 6 month clinical trial of 334 subjects (276 test, 58 control) compared the safety and efficacy of the Sauflon AEROTAB Disinfecting Tablet when used with commercially available saline, daily cleaners and wetting solutions to that of a commercial peroxide disinfecting system.

There were no adverse reactions with the Sauflon AEROTAB Disinfecting System, and there were no positive slit lamp findings at 90% of the eye examinations, compared to 67% with no findings with peroxide. No symptoms were reported at 81% of visits, compared to 85% in the peroxide controls, a difference considered not significantly different. The most common symptoms were lens awareness and discomfort in both test and control groups. Appropriate visual acuity (within 2 Snellen lines of original best corrected acuity) was obtained by 95% of the test eyes and all of the control eyes. Wear time was not affected by the care regimen. Evaluation of lens cleanliness showed 93% of test lenses and 94% of control lenses were clinically clean at scheduled visits. There were no significant gender differences in the findings.

All clinical information concerning the AEROSOLV Unpreserved Buffered Saline Solution is contained in P850074 and its supplements.



SEP 14 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Sauflon Pharmaceuticals, Ltd.  
c/o John Szabocsik, Ph.D.  
Szabocsik and Associates  
203 North Wabash Avenue  
Suite 1200  
Chicago, Illinois 60601

Re: K991125

Trade Name: Sauflon Aerotab Disinfecting System (Sauflon Aerotab Disinfecting Tablet, Aerosolv Unpreserved Buffered Saline Solution, Sauflon Barrel Lens Case)

Regulatory Class: II  
Product Code: 86 LPN, 86 LRX  
Dated: July 19, 1999  
Received: July 30, 1999

Dear Dr. 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.

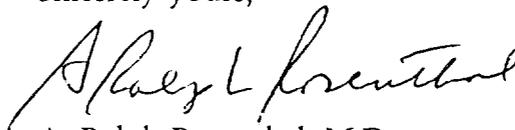
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - John Szabocsik, Ph.D.

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

If you desire specific advice for your devices 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 devices, 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

Enclosures

510(k) NUMBER (IF KNOWN) K991125

DEVICE NAME SAUFLON AEROTAB DISINFECTING SYSTEM  
(SAUFLON AEROTAB DISINFECTING TABLET,  
AEROSOLV UNPRESERVED BUFFERED SALINE,  
SAUFLON BARREL LENS CASE)

INDICATIONS FOR USE

The preservative-free SAUFLON AEROTAB DISINFECTING SYSTEM is indicated for chemical disinfection and storage of clear (untinted) soft (hydrophilic) contact lenses.

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_ OR Over-The-Counter-Use X  
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

*Mym Smith*  
(Division Sign-Off)  
Division of Ophthalmic Devices  
510(k) Number K991125

*JS*

510(k) NUMBER (IF KNOWN) K991125

DEVICE NAME AEROSOLV UNPRESERVED BUFFERED SALINE

INDICATIONS FOR USE

The AEROSOLV UNPRESERVED BUFFERED SALINE is indicated for the rinsing of soft contact lenses after cleaning, dissolving of the AEROTAB tablet to make the disinfecting/ storage solution, and rinsing of the soft contact lenses prior to insertion onto the eye.

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_ OR Over-The-Counter-Use X  
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

*M. Smith*  
(Division Sign-Off)  
Division of Ophthalmic Devices  
510(k) Number K991125

*JS*

510(k) NUMBER (IF KNOWN) K991125

DEVICE NAME SAUFLON BARREL LENS CASE

INDICATIONS FOR USE

The SAUFLON Barrel Lens Case is to be used with the AEROSOLV UNPRESERVED BUFFERED SALINE and Sauflon AEROTAB Disinfecting Tablets as the lens case for chemical disinfection and storage of clear, untinted soft (hydrophilic) contact lenses.

The SAUFLON Barrel Lens Case may also be used as the lens case for storage of soft (hydrophilic) contact lenses during chemical disinfection only. DO NOT USE WITH HEAT OR HYDROGEN PEROXIDE SYSTEMS.

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_ OR Over-The-Counter-Use X  
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Megan Smith  
(Division Sign-Off)  
Division of Ophthalmic Devices  
510(k) Number K991125

*JS*