

ATTACHMENT 1

Copy of Electronic Orange Book
(<http://www.fda.gov/cder/ob/default.htm>)
of the RLD under NDA 20-832

<u>019422</u>	Yes	CHLORHEXIDINE GLUCONATE	SOLUTION; TOPICAL	2%	EXIDINE	XTTRIUM
<u>019125</u>	No	CHLORHEXIDINE GLUCONATE	SOLUTION; TOPICAL	4%	EXIDINE	XTTRIUM
<u>072525</u>	No	CHLORHEXIDINE GLUCONATE	SPONGE; TOPICAL	4%	CHLORHEXIDINE GLUCONATE	DESERET
<u>019822</u>	No	CHLORHEXIDINE GLUCONATE	SPONGE; TOPICAL	4%	BIOSCRUB	GRIFFEN
<u>072295</u>	No	CHLORHEXIDINE GLUCONATE	SPONGE; TOPICAL	4%	MICRODERM	J AND J
<u>019490</u>	No	CHLORHEXIDINE GLUCONATE	SPONGE; TOPICAL	4%	CHLORHEXIDINE GLUCONATE	KENDALL IL
<u>019793</u>	No	CHLORHEXIDINE GLUCONATE	SPONGE; TOPICAL	4%	PHARMASEAL SCRUB CARE	PHARMASEAL
<u>018423</u>	Yes	CHLORHEXIDINE GLUCONATE	SPONGE; TOPICAL	4%	HIBICLENS	REGENT
<u>020832</u>	Yes	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SPONGE; TOPICAL	2%;70%	CHLORAPREP ONE-STEP FREPP	MEDI FLEX HOSP
<u>021555</u>	Yes	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	SWAB; TOPICAL	2%;70%	CHLORAPREP ONE-STEP SEPP	MEDI FLEX HOSP

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Search results from the "OB_OTC" table for query on "020832."

Active Ingredient:	CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL
Dosage Form;Route:	SPONGE; TOPICAL
Proprietary Name:	CHLORAPREP ONE-STEP FREPP
Applicant:	MEDI FLEX HOSP
Strength:	2%;70%
Application Number:	020832
Product Number:	001
Approval Date:	Jul 14, 2000
Reference Listed Drug	Yes
RX/OTC/DISCN:	OTC
Patent and Exclusivity Info for this product:	View

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FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
 Orange Book Data - **Monthly**
 Orange Book Data Updated Through December,
2004
 Orange Book Patent Data Only - **Daily**
 Patent Data Last Updated: February 14, 2005

Patent and Exclusivity Search Results from query on Appl No 020832 Product 001 in the 3_OTC list.

Patent Data

There are no unexpired patents for this product in the Orange Book Database.

[Note: Title I of the 1984 Amendments does not apply to drug products submitted or approved under the former Section 507 of the Federal Food, Drug and Cosmetic Act (antibiotic products). Drug products of this category will not have patents listed.]

Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration
<u>020832</u>	001	<u>NC</u>	JUL 14,2003

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