DERMAL WOUND CLEANSER- benzethonium chloride spray
Smith & Nephew Medical Ltd.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Dermal Wound Cleanser

DRUG FACTS

ACTIVE INGREDIENTS

benzethonium chloride 0.13%

PURPOSE

First aid antiseptic

USES

- first aid to help reduce the risk of infection in minor cuts, scrapes and burns
- for washing small superficial wounds
- aids in the removal of foreign materials such as dirt and debris

WARNINGS

- **For external use only**
- **Do not use in the eyes** or apply over large areas of the body
- **In case of deep or puncture wounds, animal bites, or serious burns, contact a doctor**
- **Stop use and contact a doctor** if the condition persists or gets worse. Do not use longer than 1 week unless directed by a doctor
- **Keep out of reach of children**. If swallowed, get medical help or contact a Poison Control Center immediately

DIRECTIONS

- clean the affected area
- apply a small amount of this product on the area 1 to 3 times daily
- rinse as per normal protocol
- cover wound with sterile dressing or bandage as needed
- if applying dressing or bandage, let dry first

OTHER INFORMATION

- contains antimicrobial ingredient

INACTIVE INGREDIENTS

benzyl alcohol, citric acid, disodium EDTA, glycerin, polyquaternium-10, polysorbate 20, sodium

citrate, water

QUESTION OR COMMENTS?

1 800 876-1261

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - DERMAL WOUND CLEANSER BOTTLE, SPRAY (473mL)

Smith&Nephew

#449000
NDC 69740-490-00

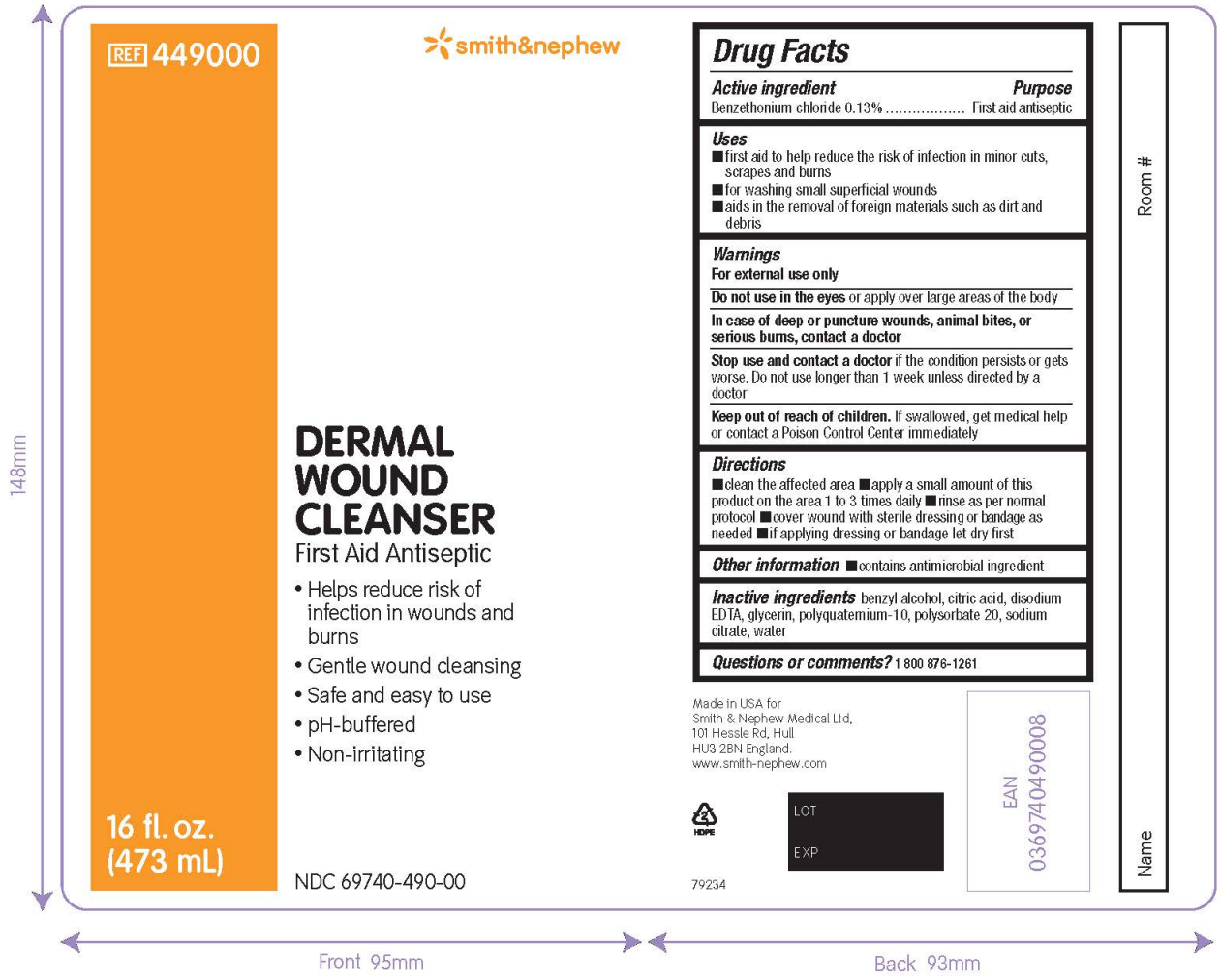
Dermal
Wound
Cleanser

First Aid Antiseptic

- Helps reduce risk of infection in wounds and burns
- Gentle wound cleansing
- Safe and easy to use
- pH-buffered
- Non-irritating

16 fl. oz. (473mL)

Made in the USA for Smith & Nephew Medical Ltd
101 Hessle Road
Hull
HU3 2BN
England
www.smith-nephew.com



PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - DERMAL WOUND CLEANSER BOTTLE, SPRAY (236mL)

Smith&Nephew

#59449200

NDC 69740-492-00

Dermal
Wound
Cleanser

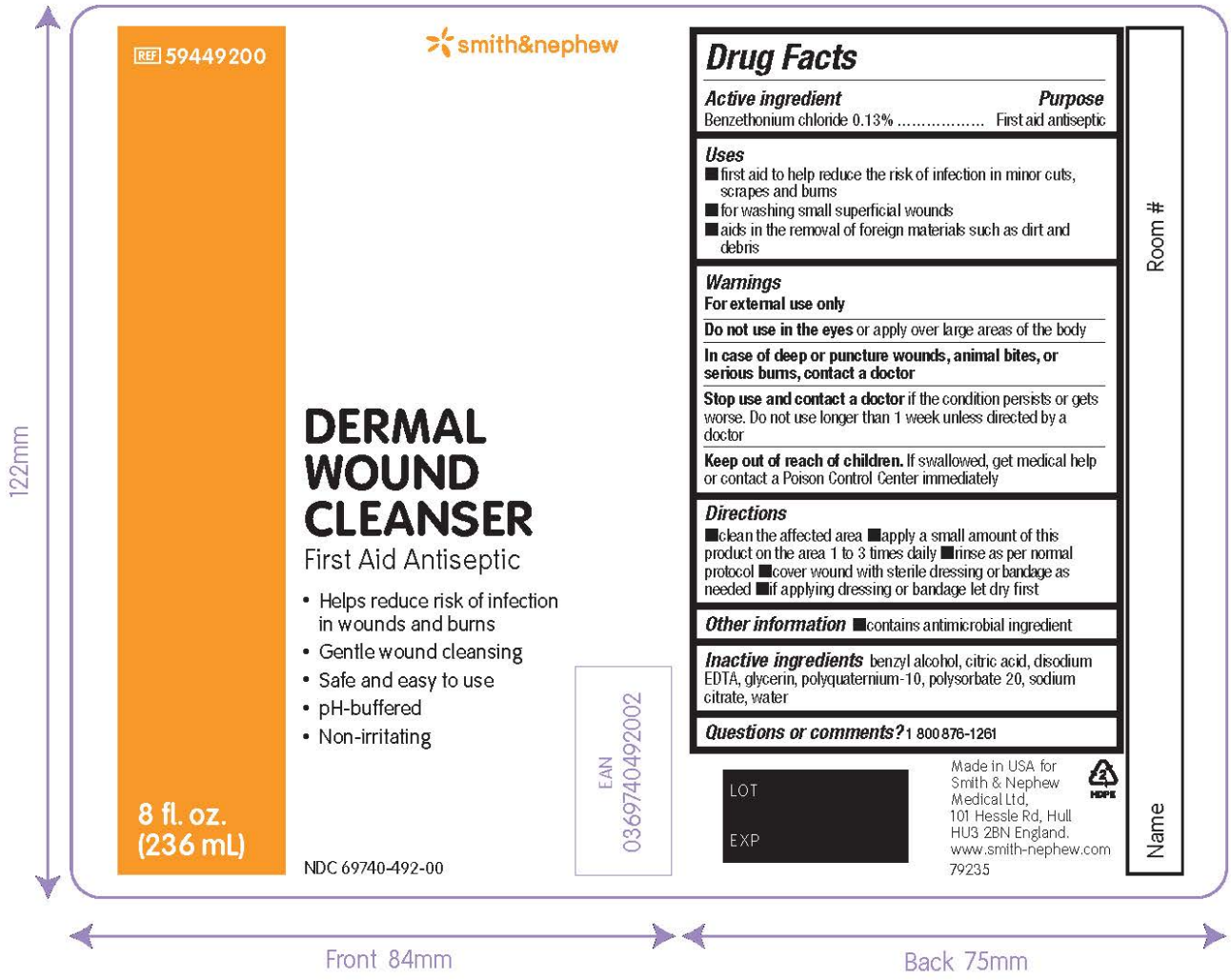
First Aid Antiseptic

- Helps reduce risk of infection in wounds and burns
- Gentle wound cleansing
- Safe and easy to use
- pH-buffered
- Non-irritating

8 fl. oz. (236mL)

Made in the USA for Smith & Nephew Medical Ltd
101 Hessle Road
Hull

HU3 2BN
England
www.smith-nephew.com



DERMAL WOUND CLEANSER

benzethonium chloride spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69740-490
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	1.3 g in 981 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69740-490-00	473 mL in 1.0 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/01/1994	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/01/1994	

DERMAL WOUND CLEANSER

benzethonium chloride spray

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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69740-492-00	236 mL in 1.0 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/01/1991	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/01/1991	

Labeler - Smith & Nephew Medical Ltd. (216344051)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	MANUFACTURE(69740-490, 69740-492)

Revised: 8/2017 Smith & Nephew Medical Ltd.