OCEAN POTION INSTANT BURN RELIEF ICE- lidocaine gel
Sun & Skin Care Research, LLC

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.

DRUG FACTS

Active Ingredient

Lidocaine 0.5%

Purpose

Temporarily Relieves pain due to:
- sunburn
- minor burns

Uses

Temporarily Relieves pain and itching due to:
- sunburn
- minor burns

Warnings

For external use only. Do not swallow. Avoid contact with eyes. If contacted, flush eyes with water. Should a rash or irritation develops, discontinue use. If condition worsens, or if symptoms persist for more than 7 days, consult a physician. Do not use in large quantities, particularly over raw surfaces or blistered areas. Keep out of the reach of children.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

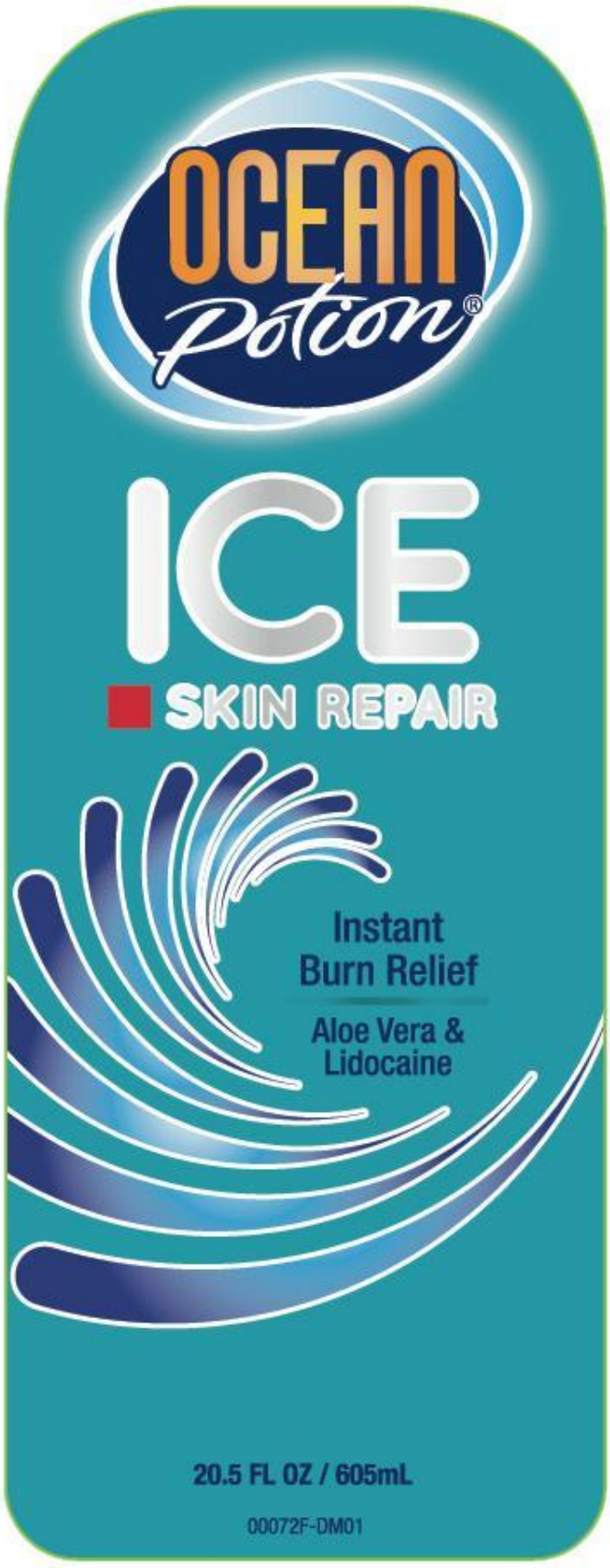
INACTIVE INGREDIENT SECTION

Inactive Ingredients: Acrylates / C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Extract, Arnica Montana Flower Extract, CI 42090, DMDM Hydantoin, Fragrance, Glycerin, Isoceteth-20, Melaleuca Alternifolia (Tea Tree Oil), Menthol, Methylparaben, Phenoxyethanol, Propylene Glycol, Propylparaben, Symphytum Officinale (Comfrey) Extract, Triethanolamine, Water

Directions

Adults and children 2 years of age and older, apply to the affected area not more than 3 to 4 times daily. Children under 2 years of age, consult a physician.

- protect this product from excessive heat and direct sun
- for use on skin only



Enriched with aloe vera and cooling lidocaine, Ocean Potion® Ice +Skin Repair helps to prevent peeling and aid in the healing and replenishment of the skin's natural moisture.

Provides temporary pain relief from sunburn, scrapes, windburns, minor burns, insect bites and other skin irritations.

Drug Facts

Active Ingredients

Lidocaine Hydrochloride 0.5%	**Purpose** Topical Anesthetic

Uses

- temporary relief of pain and itching
- helps to relieve and soothe pain from sunburn, minor burns, skin irritations, scrapes, insect bites

Warnings

For external use only.

Do not use in large quantities, particularly over raw surfaces or areas with blisters.

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- condition worsens or symptoms last more than 7 days
- symptoms clear up and occur again within a few days

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 2 years or older: apply to affected area not more than 3-4 times daily
- Children under 2 years of age: do not use, ask a doctor

Inactive Ingredients Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Extract, Arnica Montana Flower Extract, CI 42090 (FD&C Blue #1), DMDM Hydantoin, Fragrance, Glycerin, Isoceteth-20, Melaleuca Alternifolia (Tea Tree Oil), Menthol, Methylparaben, Phenoxyethanol, Propylene Glycol, Propylparaben, Symphytum Officinale (Comfrey) Extract, Triethanolamine, Water

Questions or Comments?
Call toll free 800-715-3485

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Manufactured and Distributed by
Sun & Skin Care Research, LLC
851 Greensboro Rd., Cocoa, FL 32926
oceanpotion.com 800-715-3485

NO ANIMAL TESTING

Made in USA

OCEAN POTION INSTANT BURN RELIEF ICE

lidocaine gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62802-172
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOCETETH-20 (UNII: O020065R7Z)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TROLAMINE (UNII: 9O3K93S3TK)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
COMFREY LEAF (UNII: DG4F8T839X)	
TEA TREE OIL (UNII: VIF565UC2G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62802-172-65	605 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/01/2012	

Labeler - Sun & Skin Care Research, LLC (849772207)

Establishment

Name	Address	ID/FEI	Business Operations
Sun & Skin Care Research, LLC		849772207	manufacture(62802-172)