

H2OCEAN NOTHING TATTOO GLIDE AND SOOTHING BALM- lidocaine ointment
Aidance Skincare & Topical Solutions, 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 Ingredients

Lidocaine HCL 4%

Purpose

Lidocaine HCL - Topical Anesthetic

Uses

Temporarily relieves pain and itching associated with minor burns, minor cuts or skin irritations

Warnings

For external use only. Stop use and ask a doctor if condition worsens or if symptoms persist for more than 7 days, or clear up and occur again within a few days. **When using this product** avoid contact with eyes. Flush with water if contact occurs. **Do not apply** over large areas of the body, particularly over raw surfaces or blistered areas.

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 and older: Apply externally to the affected area up to 3 to 4 times a day.
Children under 2 years: Consult a doctor.

Inactive Ingredients

beeswax (organic), bentonite (volcanic clay), chamomile oil, cotton seed oil, glycerine (vegetable), jojoba seed oil (golden), magnesium oxide, purified water, sea salt, silver oxide, zinc oxide.

PRINCIPAL DISPLAY PANEL - 200g Label

H2Ocean® First in First Aid™

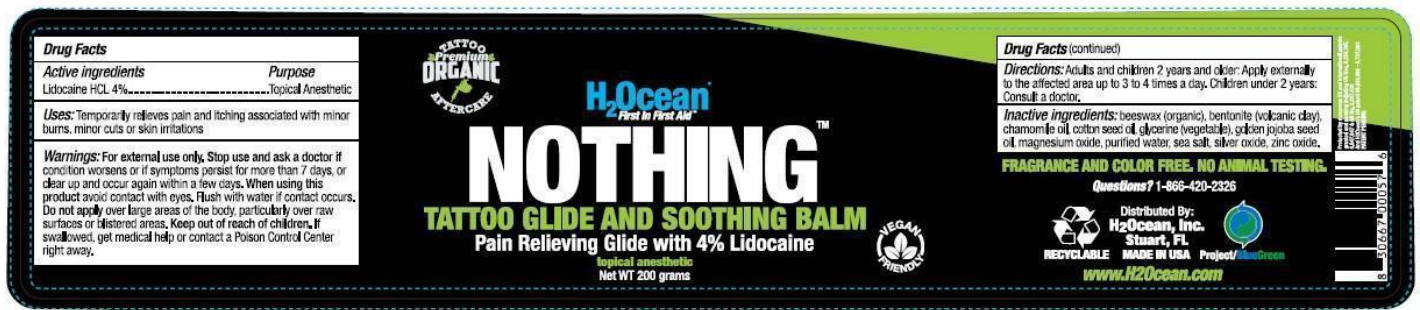
NOTHING

TATTOO GLIDE AND SOOTHING BALM

Pain Relieving Glide with 4% Lidocaine

topical anesthetic

Net WT 200 grams



H2OCEAN NOTHING TATTOO GLIDE AND SOOTHING BALM

lidocaine ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-901
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BENTONITE (UNII: A3N5ZCN45C)	
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	
COTTONSEED OIL (UNII: H3E878020N)	
GLYCERIN (UNII: PDC6A3C0OX)	
JOJOBA OIL (UNII: 724GKU717M)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
SEA SALT (UNII: 87GE52P74G)	
SILVER OXIDE (UNII: 897WUN6G6T)	
WATER (UNII: 059QF0K00R)	
WHITE WAX (UNII: 7G1J5DA97F)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-901-20	200 g in 1 JAR; Type 0: Not a Combination Product	06/29/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/29/2015	

Labeler - Aidance Skincare & Topical Solutions, LLC (018950611)

Establishment

Name	Address	ID/FEI	Business Operations
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-901) , label(24909-901)

Revised: 1/2020

Aidance Skincare & Topical Solutions, LLC