

SKIN PROTECTANT - sodium bicarbonate liquid
Shanghai Kejing Cleaning Products Co., 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.

Drug Facts

Active ingredient

Sodium Bicarbonate (Baking Soda) 5%

Purpose

Skin Protectant

Uses temporary relief of itching and irritation due to

-insect bites and stings -poison ivy, oak or sumac

Warnings

For external use only

Do not use

-over large areas of body

-other than as directed

When using this product

-avoid contact with eyes

Stop use and ask a doctor if

-symptoms last for more than 7 days

-the condition becomes worse

-symptoms clear up and then 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 over 2 years of age:

-apply a small amount directly to the bite, sting or affected area and rub gently

-re-apply as needed

children under 2 years of age: ask a doctor before use

Other information

store at room temperature 59 - 86F (15 - 30C)

Inactive ingredients ammonia, cyclohexasiloxane, cyclopentasiloxane, glycerin, water

0.5 FL OZ (14mL) Insect Bite & Sting Relief

Drug Facts	
Active Ingredient	Purpose
Sodium Bicarbonate (Baking Soda) 5%.....	Skin Protectant
Uses temporary relief of itching and irritation due to insect bites and stings; as poison ivy, oak or sumac.	
Warnings	
For external use only.	
Do not use	
■ over large areas of the body	
■ other than as directed	
When using this product	
■ avoid contact with eyes	
Stop use and ask a doctor if	
■ symptoms last for more than 7 days	
■ the condition becomes worse	
■ symptoms clear up and then 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 over 2 years of age:	
■ apply a small amount directly to the bite, sting or affected area and rub gently	
■ re-apply as needed	
children under 2 years of age: ask a doctor before use	
Other information	
store at room temperature 59° - 86° F (15° - 30° C).	
Inactive Ingredients ammonia, cyclohexasiloxane, cyclopentasiloxane, glycerin, water	

Distributed By: 0007 - Farmingdale, NY 11735
NFC-30507 Made in China

SKIN PROTECTANT

sodium bicarbonate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:31190-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
CYCLOMETHICONE 5 (UNII: 0THI5PC10R)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:31190-101-01	14 g in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/18/2016	

Labeler - Shanghai Kejing Cleaning Products Co., Ltd. (526877847)

Establishment

Name	Address	ID/FEI	Business Operations
Shanghai Kejing Cleaning Products Co., Ltd.		526877847	manufacture(31190-101)

Revised: 1/2016

Shanghai Kejing Cleaning Products Co., Ltd.