

SAFeway - dimethicone lotion
SAFeway INC.

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

DIMETHICONE 1.25%

PURPOSE

SKIN PROTECTANT

USES

TEMPORARILY PROTECTS AND HELPS RELIEVE CHAPPED SKIN.

WARNINGS

FOR EXTERNAL USE ONLY.

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE WITH WATER.

STOP USING THIS PRODUCT AND ASK DOCTOR IF

IRRITATION OR REDNESS DEVELOPS AND LASTS. IF CONDITION WORSENS OR SYMPTOMS LAST FOR MORE THAN SEVEN DAYS OR CLEARS UP AND RE-OCCURS WITHIN A FEW DAYS.

KEEP OUT OF REACH OF CHILDREN

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

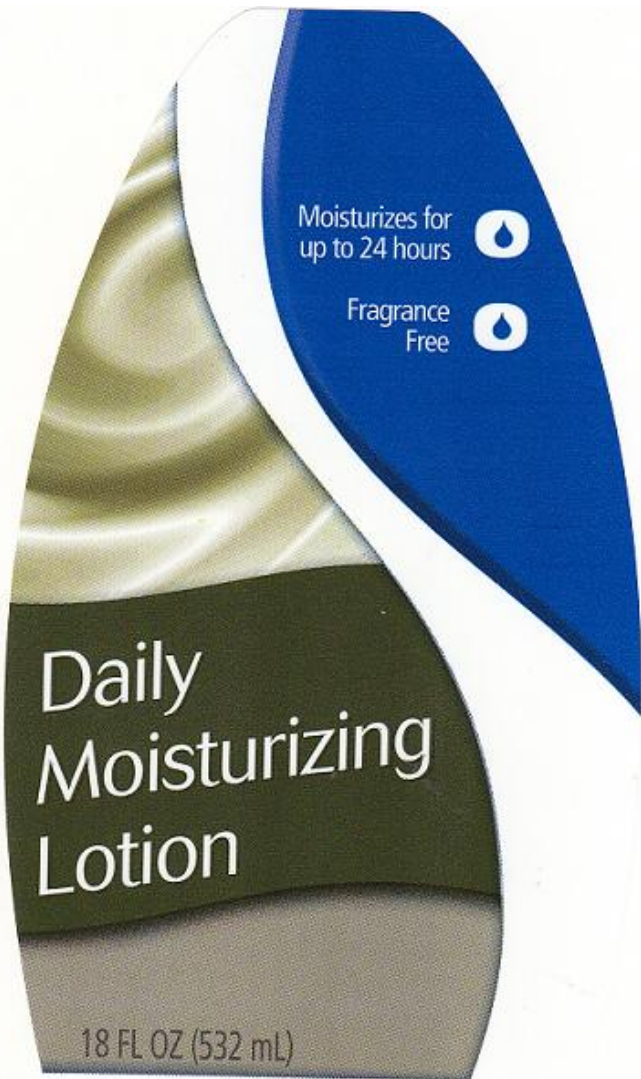
DIRECTIONS

ADULTS AND CHILDREN OVER 2 YEARS. APPLY AS NEEDED.

INACTIVE INGREDIENTS:

WATER (AQUA), GLYCERIN, DISTEARYLDIMONIUM CHLORIDE, PETROLATUM, ISOPROPYL PALMITATE, CETYL ALCOHOL, AVENA SATIVA (OAT) KERNEL FLOUR, BENZYL ALCOHOL, SODIUM CHLORIDE, DMDM HYDANTOIN, METHYLPARABEN, PROPYLPARABEN.

LABEL COPY



SAFeway  TM
06-17761

Drug Facts	
Active ingredient	Purpose
Dimethicone 1.25 %	Skin protectant
Uses	
Temporarily protects and helps relieve chapped skin.	
Warnings	
For external use only.	
When using this product ■ avoid contact with eyes. If contact occurs, rinse with water.	
Stop using this product and ask doctor if ■ irritation or redness develops and lasts. If condition worsens or symptoms last for more than seven days or clears up and re-occurs within a few days.	
Keep out of reach of children ■ In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.	
Directions	
■ Adults and children over 2 years. Apply as needed.	
Inactive ingredients:	
Water (Aqua), Glycerin, Distearyltrimonium Chloride, Petrolatum, Isopropyl Palmitate, Cetyl Alcohol, Avena Sativa (Oat) Kernel Flour, Benzyl Alcohol, Sodium Chloride, DMDM Hydantoin, Methylparaben, Propylparaben.	

DISTRIBUTED BY SAFEWAY INC.
P.O. BOX 99
PLEASANTON, CA 94566-0009
1-888-SAFEWAY / www.safeway.com
MADE IN CANADA



06-17762

RD 11333



SAFeway
dimethicone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-320
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	1.25 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)	
PETROLATUM (UNII: 4T6H12BN9U)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
OATMEAL (UNII: 8PI54V663Y)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-320-18	532 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/03/2012	

Labeler - SAFEWAY INC. (009137209)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture

Revised: 12/2011

SAFEWAY INC.