EQUALINE- dimethicone lotion
SUPERVALU 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 1.3%

PURPOSE

SKIN PROTECTANT

USES

TEMPORARILY PROTECTS AND HELPS RELIEVE CHAPPED OR CRACKED SKIN AND HELPS PROTECT FROM THE DRYING EFFECTS OF WIND AND COLD.

WARNINGS

FOR EXTERNAL USE ONLY.

WHEN USING THIS PRODUCT

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

STOP USING THIS PRODUCT AND ASK A DOCTOR IF

CONDITION WORSENS, OR IF SYMPTOMS LAST MORE THAN 7 DAYS, OR IF THEY CLEAR UP AND OCCUR AGAIN 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

APPLY AS NEEDED.

OTHER INFORMATION

STORE AT ROOM TEMPERATURE.

INACTIVE INGREDIETNS:

AVENA SATIVA (OAT) KERNEL FLOUR, BENZYL ALCOHOL, CETYL ALCOHOL, DISTEARYLDIMONIUM CHLORIDE, ETHYLHEXYLGLYCERIN, GLYCERIN, ISOPROPYL PALMITATE, PETROLATUM, PHENOXYETHANOL, SODIUM CHLORIDE, WATER (AQUA).

QUESTIONS OR COMMENTS?

1-877-932-7948

LABEL COPY

EQUALINE

dimethicone lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41163-358
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	13 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
OATMEAL (UNII: 8PI54V663Y)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
PETROLATUM (UNII: 4T6H12BN9U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:41163-358-18	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	01/15/2013	

Labeler - SUPERVALU INC. (006961411)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(41163-358)

Revised: 1/2013 SUPERVALU INC.