

MISS SPA - hand sanitiser gel
Oriental Home Sense 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.

Miss Spa Hand Sanitiser

ACTIVE INGREDIENT: ETHYL ALCOHOL 55.4% **PURPOSE** ANTISEPTIC
ANTISEPTIC

USES: TO HELP REDUCE BACTERIA ON THE HANDS.

WARNING: FOR EXTERNAL USE ONLY. FLAMMABLE, **KEEP AWAY** FROM FIRE OR FLAME.

WHEN USING THIS PRODUCT, AVOID CONTACT WITH EYES AND LIPS. IF CONTACT OCCURS, RINSE WITH WATER.

STOP USING THIS PRODUCT AND ASK DOCTOR IF IRRITATION OR REDNESS DEVELOPS AND LASTS

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

DIRECTIONS: WET HANDS THOROUGHLY AND RUB TOGETHER UNTIL DRY.

INACTIVE INGREDIENTS: WATER, PROPYLENE GLYCOL, FRAGRANCE, POLYACRYLIC ACID, HYDROGENATED JOJOBA OIL, ALOE BARBADENSIS LEAF EXTRACT, TOCOPHERYL ACETATE, DISODIUM EDTA, SODIUM HYDROXIDE. MAY CONTAIN: FD&C BLUE NO. 1(CI 42090), D&C RED NO. 33(CI 17200), FD&C RED NO. 40(CI 16035), FD&C YELLOW NO. 5 (CI 19140)

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DRUG FACTS
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 Not Tested On Animals
 MADE IN CHINA
 Distributed by:
 miss spa®
 Northbrook, IL 60062
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 EXP: 07/2015

MISS SPA

hand sanitiser gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:6 1238 -1125
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	554 mL in 554 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
HYDROGENATED JOJOBA OIL/JOJOBA OIL, RANDOMIZED (IODINE VALUE 57-61) (UNII: 12GIN16K1G)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TOCOPHERYL RETINOATE (UNII: 0WN694NBMM)	
DISODIUM (ETHOXYCARBONYL)PHOSPHONATE (UNII: 0YFB1C22IN)	

SODIUM HYDRIDE (UNII: 23J3BHR95O)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61238-1125-1	29 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	11/15/2013	

Labeler - Oriental Home Sense Co., Ltd. (668448004)

Establishment

Name	Address	ID/FEI	Business Operations
Oriental Home Sense Co., Ltd.		668448004	manufacture(61238-1125)

Revised: 11/2013

Oriental Home Sense Co., Ltd.