SMART SENSE ALCOHOL FREE- sodium fluoride liquid KMART CORPORATION

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 FLUORIDE 0.05% (0.02% W/V FLUORIDE ION)

PURPOSE

ANTICAVITY

USES

AIDS IN THE PREVENTION OF DENTAL CAVITIES.

WARNINGS

KEEP OUT OF REACH OF CHILDREN. IF MORE THAN USED FOR RINSING IS ACCIDENTALLY SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY (1-800-222-1222).

KEEP OUT OF REACH OF CHILDREN.

IF MORE THAN USED FOR RINSING IS ACCIDENTALLY SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY (1-800-222-1222).

DIRECTIONS

ADULTS AND CHILDREN 6 YEARS OF AGE AND OLDER: USE ONCE A DAY AFTER BRUSHING YOUR TEETH WITH A TOOTHPASTE. VIGOROUSLY SWISH 10 ML OF RINSE BETWEEN YOUR TEETH FOR 1 MINUTE AND THEN SPIT OUT. DO NOT SWALLOW THE RINSE. DO NOT EAT OR DRINK FOR 30 MINUTES AFTER RINSING. SUPERVISE CHILDREN AS NECESSARY UNTIL CAPABLE OF USING WITHOUT SUPERVISION. CHILDREN UNDER 6 YEARS OF AGE: CONSULT A DENTIST OR DOCTOR.

OTHER INFORMATION

STORE AT CONTROLLED ROOM TEMPERATURE 20-25C (68-77F). COLD WEATHER MAY CLOUD THIS PRODUCT.

INACTIVE INGREDIENTS:

WATER (AQUA), SORBITOL, PROPYLENE GLYCOL, POLYSORBATE 20, FLAVOR, SODIUM PHOSPHATE, POLOXAMER 407, SODIUM BENZOATE, CALCIUM DISODIUM EDTA, POTASSIUM SORBATE, DISODIUM PHOSPHATE, SODIUM SACCHARIN, CETYLPYRIDINIUM CHLORIDE, MENTHOL, METHYL SALICYLATE, GREEN 3 (CI 42053), YELLOW 5 (CI 19140).

QUESTIONS OR COMMENTS?

LABEL COPY



Drug Facts

Active ingredient

Sodium Fluoride 0.05% (0.02% w/v Fluoride ion)

Purpose Anticavity

Uses ■ Aids in the prevention of dental cavities.

Keep out of reach of children. ■ If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center immediately (1-800-222-1222).

Directions ■ Adults and children 6 years of age and older: ■

Use once a day after brushing your teeth with a toothpaste.

Vigorously swish 10 mL of rinse between your teeth for 1 minute and then spit out. Do not swallow the rinse. Do not eat or drink for 30 minutes after rinsing.

- Supervise children as necessary until capable of using without supervision.
- Children under 6 years of age: consult a dentist or doctor.

Other Information
Store at controlled room temperature 20"-25" (68"-77°F). Cold weather may cloud this product.

Inactive ingredients: Water (Aqua), Sorbitol, Propylene Glycol, Polysorbate 20, Flavor, Sodium Phosphate, Poloxamer 407, Sodium Benzoate, Calcium Disodium EDTA, Potassium Sorbate, Disodium Phosphate, Sodium Saccharin, Cetylpyridinium Chloride, Menthol, Methyl Salicylate, Green 3 (Cl 42053), Yellow 5 (Cl 19140).

Questions or comments? 1-800-842-7886

Do not use if band around cap is broken or missing. To open: Squeeze smooth areas on cap and turn. To close: Turn cap until it locks.

Distributed by: Kmart Corporation Hoffman Estates, IL 60179

Shop kmart.com Made in Canada

SATISFACTION GUARANTEE

If you are unsatisfied for any reason, return the unused portion to the store for a full refund or call 1-800-842-7886.

*This product is not manufactured or distributed by Chattern, Inc., owner of the registered trademark

SMART SENSE ALCOHOL FREE

ORAL

sodium fluoride liquid

Product Information

Route of Administration

HUMAN OTC DRUG Product Type

Item Code (Source)

NDC:49738-554

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	0.5 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
SORBITOL (UNII: 506T60A25R)		
PROPYLENE GLYCOL (UNII: 6 DC9 Q167V3)		
POLYSORBATE 20 (UNII: 7T1F30V5YH)		
SODIUM PHO SPHATE (UNII: SE337SVY37)		
POLOXAMER 407 (UNII: TUF2IVW3M2)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)		
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)		
SO DIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: 22ADO53M6F)		
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)		
CETYLPYRIDINIUM CHLORIDE (UNII: D9 OM4SK49 P)		
MENTHOL (UNII: L7T10EIP3A)		
METHYL SALICYLATE (UNII: LAV5U5022Y)		
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49738-554-18	532 mL in 1 BOTTLE, PLASTIC		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	05/09/2013		

Labeler - KMART CORPORATION (008965873)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment				
Name	Address	ID/FEI	Business Operations	
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(49738-554)	

Revised: 5/2013 KMART CORPORATION