

SUNSCREEN SPF30- sunscreen spf30 liquid
NINGBO JIANGBEI OCEAN STAR TRADING 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.

Active Ingredients

Active ingredients-----purpose

PEG-100 STEARATE----- Sunscreen SPF30

TITANIUM DIOXIDE

ETHYLHEXYL METHOXYCINNAMATE

BUTYL METHOXYDIBENZOYLMETHANE

Warnings:

Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging. For external use only. Keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash or irritation develops and lasts. Keep out of reach of children. If swallowed: seek medical help or contact a poison control center right away.

Directions:

Apply liberally 15 minutes before sun exposure and reapply as need.

Children under 6 months: ask a doctor before use.

Inactive Ingredients:

MINERAL OIL, SILICON, 4-HYDROXYBENZOIC ACID, PROPYL ACETATE, MONOGLYCERIDE CITRATE, GETOSTEARYL ALCOHOL, SODIUM DODECYLBENZENESULFONATE, CYCLOMETHICONE, ETHYLENE GLYCOL, WATER, XANTHAN GUM, CARBOMER 940, ALLANTOIN, GLYCERIN, 1,2-BUTANEDIOL, GPL

50.00 mm

13.00 mm

Drug Facts	0.27oz. Exp. XX/XX	Drug Facts (continued)
Active Ingredients PEG-100 STEARATE, TITANIUM DIOXIDE ETHYLHEXYL METHOXYCINNAMATE BENZOPHENONE-3 BUTYL METHOXYDIBENZOYLMETHANE	Purpose Sunscreen SPF 30	Directions • Apply liberally 15 minutes before sun exposure and reapply as needed. • Children under 6 months: ask a doctor before use.
Inactive Ingredients MINERAL OIL, SILICON, 4-HYDROXYBENZOIC ACID, PROPYL ACETATE, MONOGLYCERIDE CITRATE, GETOSTEARYL ALCOHOL, SODIUM DODECYLBENZENESULFONATE, CYCLOMETHICONE, ETHYLEBE GLYCOL, WATER, XANTHAN GUM, CARBOMER 940, ALLANTOIN, GLYCETIN, 1, 2-BUTANEDIOL, GPL	Ariel Premium Supply Inc Made in China ▶	Warnings: Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging. For external use only. Keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash or irritation develops and lasts. Keep out of reach of children. If swallowed: seek medical help or contact a poison control center right away.

sunscreen spf30 liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:47993-216
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PEG-100 STEARATE (UNII: YD01N1999R) (PEG-100 STEARATE - UNII:YD01N1999R)	PEG-100 STEARATE	2.5 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	4 g in 100 g
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8) (ETHYLHEXYL METHOXYCRYLENE - UNII:S3KFG6Q5X8)	ETHYLHEXYL METHOXYCRYLENE	1.25 g in 100 g
BENZOPHENONE (UNII: 701M4TTV9O) (BENZOPHENONE - UNII:701M4TTV9O)	BENZOPHENONE	0.5 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.75 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	5 g in 100 g
SILICON (UNII: Z4152N8IU)	1 g in 100 g
4-HYDROXYBENZOIC ACID (UNII: JG8Z55Y12H)	0.2 g in 100 g
PROPYL ACETATE (UNII: 4AWM8C91G6)	0.1 g in 100 g
GLYCERYL MONOOLEATE CITRATE (UNII: NLE5KIG74K)	1.5 g in 100 g
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	2 g in 100 g
SODIUM DODECYLBENZENESULFONATE (UNII: 554127163Y)	5 g in 100 g
CYCLOMETHICONE (UNII: NMQ347994Z)	2 g in 100 g
ETHYLENE GLYCOL (UNII: FC72KVT52F)	0.8 g in 100 g
WATER (UNII: 059QF0K00R)	59.7 g in 100 g
XANTHAN GUM (UNII: TTV12P4NEE)	0.25 g in 100 g
CARBOMER 940 (UNII: 4Q93RCW27E)	10 g in 100 g
ALLANTOIN (UNII: 344S277G0Z)	0.3 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	2 g in 100 g
1,2-BUTANEDIOL (UNII: RUN0H01QEU)	3 g in 100 g
DMDM HYDANTOIN (UNII: BYR0546TOW)	0.15 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47993-216-01	10 g in 1 TUBE; Type 0: Not a Combination Product	06/01/2015	
2	NDC:47993-216-02	15 g in 1 TUBE; Type 0: Not a Combination Product	06/01/2015	
3	NDC:47993-216-03	20 g in 1 TUBE; Type 0: Not a Combination Product	06/01/2015	
4	NDC:47993-216-04	30 g in 1 TUBE; Type 0: Not a Combination Product	06/01/2015	
5	NDC:47993-216-05	50 g in 1 TUBE; Type 0: Not a Combination Product	06/01/2015	
6	NDC:47993-216-06	60 g in 1 TUBE; Type 0: Not a Combination Product	06/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/20/2015	

Labeler - NINGBO JIANGBEI OCEAN STAR TRADING CO.,LTD (529334491)

Registrant - NINGBO JIANGBEI OCEAN STAR TRADING CO.,LTD (529334491)

Establishment

Name	Address	ID/FEI	Business Operations
NINGBO OCEANSTAR CHEMICAL PRODUCTS CO.,LTD		544493972	manufacture(47993-216)

Revised: 1/2018

NINGBO JIANGBEI OCEAN STAR TRADING CO.,LTD