

**HAWAIIAN BLEND EXTREME ZINC SPF 50- zinc oxide, titanium dioxide aerosol
Inspec Solutions LLC.**

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.

Hawaiian Blend Extreme Zinc Broad Spectrum SPF 50 Sunscreen Spray

Active Ingredient

Zinc Oxide

Titanium Dioxide

Zinc Oxide - 19.5% Sunscreen

Titanium Dioxide - 4.0%..... Sunscreen

WARNINGS

For external use only

Do not use on damaged or broken skin

when using this product keep out of eyes-rinse with water to remove.

Stop use and ask a doctor if rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Apply liberally 15 minutes before sun exposure

Reapply:

- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours

Helps prevent sunburn

Higher SPF gives more sunburn protection

If used as directed with other sun protection measures, decreases the risk of skin cancer and early skin aging caused by the sun

Caprylic/Capric Triglyceride

Caprylyl Glycol

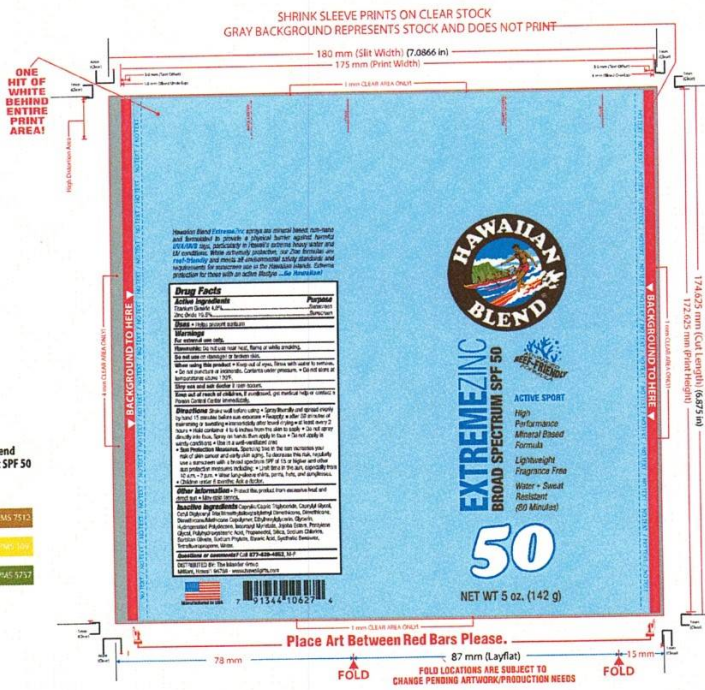
Cetyl Diglyceryl Tris(trimethylsiloxy)silylethyl Dimethicone

Dimethicone

Dimethicone/Methicone Copolymer

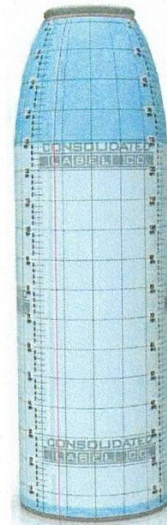
Sodium Phytate
Ethylhexylglycerin
Glycerin
Hydrogenated Polydecene
Isopropyl Myristate
Jojoba Esters
Pentylene Glycol
Polyhydroxystearic Acid
Propanediol
Silica
Sodium Chloride
Sorbitan Olivatate
Stearic Acid
Synthetic Beeswax
Tetrafluoropropene
Fragrance
Water

Hawaiian Blend Extreme Zinc SPF 50 Spray



220721
Spray Template
8 Spot Colors
Hawaiian Blend
ExtremeZinc: SPF 50

BLACK
PMS 4623 PMS 7512
PMS 187 PMS 134
PMS 3005 PMS 5737



GRID TEST MODEL
251775-LF87x174p625

Material: 180g Stock	PVC-58%
SW: 30	SLANT: 100%
Color: 17	Q: 110
Color: 17	Q: 110
Color: 17	Q: 110
Color: 17	Q: 110

17/07/2017 Rev-03

HAWAIIAN BLEND EXTREME ZINC SPF 50

zinc oxide, titanium dioxide aerosol

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72667-061
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	4 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	19.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL DIGLYCERYL TRIS(TRIMETHYLSILOXY)SILYLETHYL DIMETHICONE (3500 MM2/S) (UNII: KB7T6C99UP)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HYDROGENATED POLYDECENE TYPE I (UNII: U333RI6EB7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0KO0R)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
SYNTHETIC BEESWAX (UNII: 08MNR5YE2R)	
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)	
GLYCERIN (UNII: PDC6A3C0OX)	
2,3,5,6-TETRAFLUOROPHENOL (UNII: TNA118I5TG)	
PROPANEDIOL (UNII: 5965N8W85T)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72667-061-01	142 g in 1 CAN; Type 0: Not a Combination Product	01/03/2023	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph not final	part352	01/03/2023	

Labeler - Inspec Solutions LLC. (081030372)

Establishment

Name	Address	ID/FEI	Business Operations
Inspec Solutions		081030372	manufacture(72667-061)

Revised: 1/2023

Inspec Solutions LLC.