

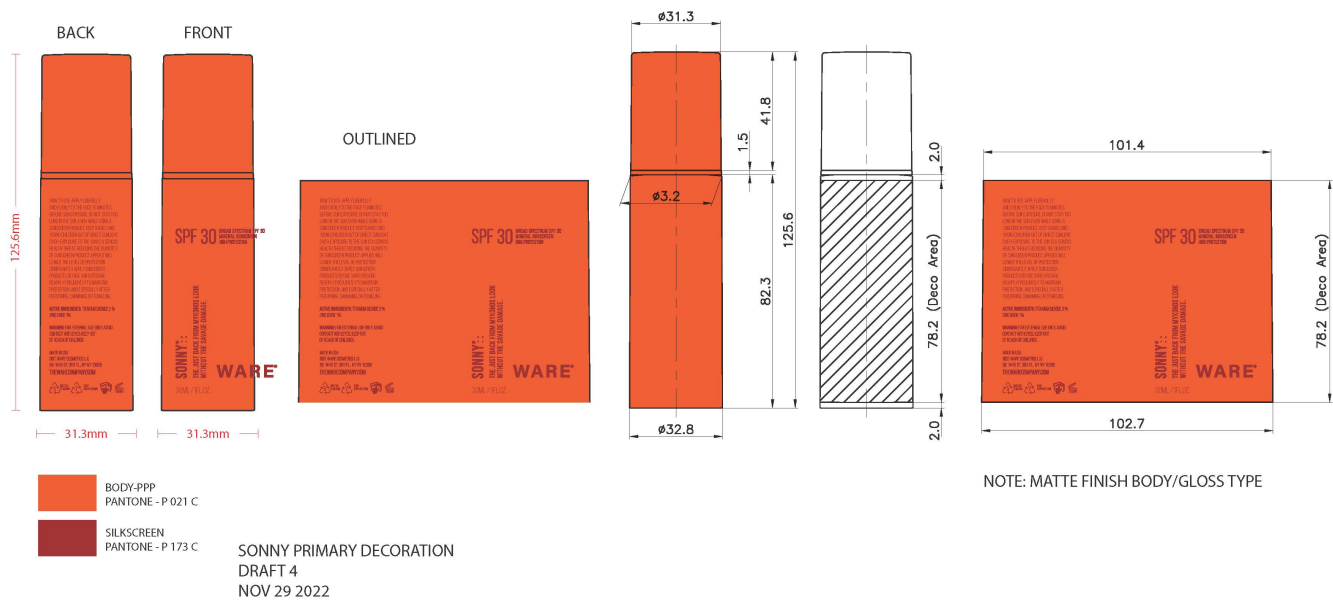
WARE SONNY UNIVERSAL- titanium dioxide, zinc oxide lotion

Ware Cosmetics

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.

Ware Sonny Universal

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titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83510-400
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	9.7 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	19.4 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE RED (UNII: 1K09F3G675)	

FERROSFERRIC OXIDE (UNII: XM0M87F357)
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)
POLYESTER-7 (UNII: 0841698D2F)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)
ALLANTOIN (UNII: 344S277G0Z)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
AVENA SATIVA WHOLE (UNII: 5P8D0Z74RG)
DICRATERIA ROTUNDA OIL (UNII: Z0DWJ9R4GM)
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)
CAMELLIA SINENSIS WHOLE (UNII: C5M4585ZBZ)
TRICETARETH-4 PHOSPHATE (UNII: 69534Y66NO)
PULLULAN (UNII: 8ZQ0AYU1TT)
XANTHAN GUM (UNII: TTV12P4NEE)
STEARETH-20 (UNII: L0Q8IK9E08)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
TRILAURETH-4 PHOSPHATE (UNII: M96W2OLL2V)
SODIUM ASCORBATE (UNII: S033EH8359)
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)
CETYL ALCOHOL (UNII: 936JST6JCN)
SQUALANE (UNII: GW89575KF9)
PEG-75 STEARATE (UNII: OT38R0N74H)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
DIMETHICONOL/PROPYLSILSESQUIOXANE/SILICATE CROSSPOLYMER (450000000 MW) (UNII: 9KB5R958PB)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
ETHYLHEXYL ISONONANOATE (UNII: I6KB4GE3K4)
CETETH-20 (UNII: I835H2IHHX)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
TOCOPHEROL (UNII: R0ZB2556P8)
RUTTNERA LAMELLOSA OIL (UNII: 5XZ38R4SUT)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)

Product Characteristics

Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83510-	1 in 1 CARTON	05/09/2022	

400-02	1 III 1 CARTON	05/08/2023	
1 NDC:83510-400-01	30 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/08/2023	

Labeler - Ware Cosmetics (118890352)

Revised: 6/2023

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