CREAM- octinoxate, oxybenzone cream
Oxygen Development

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.

Studiomakeup smooth perfection BB cream SPF 15 broad spectrum

Active Ingredient

Octinoxate 7.5

Oxybenzone 2.0

Purpose

Sunscreen

Uses

helps prevent sunburn. Provides moderate protection against sunburn.

Directions

Apply and blend evenly onto the face. Use over Studiomakeup soft illusion Face Primer for a flawless and smooth finish

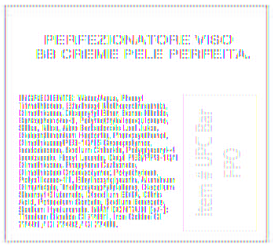
Ingredients

Water/Aqua, phenyl trimethicone, ethylhexyl methoxycinnamate, dimethicone, dicaprylyl ether, boron nitride, benzophenone-3, polymethylsilsesquioxane, silica, mica, aloe barbadensis leaf juice, disteardimonium hectorite, phenoxyethanol, dimethicone/PEG-10/15 crosspolymer, isododecane, sodium chloride, polyglyceryl-4 isostearate, hexyl laurate, cetyl PEG/PPG-10/1 dimethicone, propylene carbonate, dimethicone crosspolymer, polyethylene, polysilicone-11, ethylhexyglycerin, aluminum dimyristate, triehoxycaprylylsilane,disodium stearoyl glutamate, disodium EDTA, citric acid, potassium sorbate, sodium benzoate, sodium hyaluronate. May contain [+/-]: titanium dioxide CI 77891, iron oxides CI 77491/ CI 77492/ CI 77499

package

Customer Name	Prestige Cosmetics/STUDIOMAKEUP
Job description	BB CREAM OVER LABEL EU
Date	09.13.12- Revision 1: IL ITALY (11/21/12)-Revision 2: Size/Layout
File Name	PRESTIGE-LBL-BB CREAM-EU
Scale	100 %

Component #	000-L
Label Size:	1.25"
Label Color:	WHIT
Text Print:	BLAC
Label Type:	COVE
Label Finish:	Semi-as sar
Label Location:	Back ingred
Adhesive:	PERM
Unwind:	#2



PRINT BAR CODE,
ITEM NUMBER AND SHADE NAME

PBB-01E Light
0-80672-86101-7

PBB-02E Medium
0-80672-86102-4

PBB-03E Deep
0-80672-86103-1

LABEL MUST
as sample B provide
on Jan.

OVER LABEL FOR MARKETS FOLLOWING REGULATIONS

INGREDIENTS: Water/Aqua, Phenyl Trimethicone, Ethylhexy Methoxycinnamate, Dimethicone, Dicaprylyl Ether, Boron Nitric Benzophenone-3, Polymethylsilsesquioxane, Silica, Mica, Alo Barbadensis Leaf Juice, Disteardimonium Hectorite, Phenoxyethanol, Dimethicone/PEG-10/15 Crosspolymer, Isododecane, Sodium Chloride, Polyglyceryl-4 Isostearate, He Laurate, Cetyl PEG/PPG-10/1 Dimethicone, Propylene Carbona Dimethicone Crosspolymer, Polyethylene, Polysilicone-11, Ethylhexylglycerin, Aluminum Dimyristate, Triethoxycaprylylsila Disodium Stearoyl Glutamate, Disodium EDTA, Citric Acid, Potassium Sorbate, Sodium Benzoate, Sodium Hyaluronate. M CONTAIN [+/-]: Titanium Dioxide CI 77891, Iron Oxides CI 77 / CI 77492 / CI 77499.

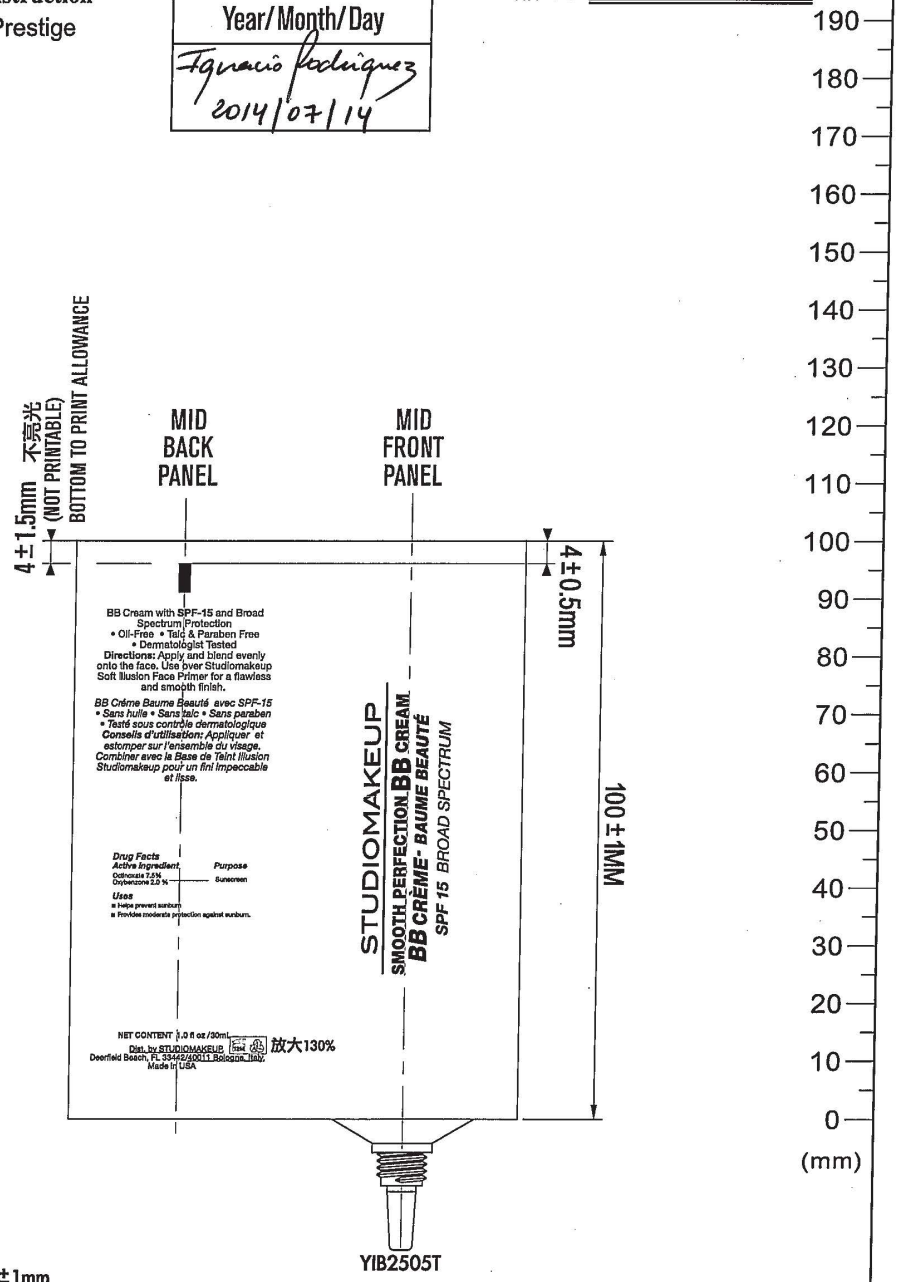
Approval: _____ Date: _____

Comments: _____

ø25 印刷示意圖
Printing Instruction
客戶別：Prestige

Signature for Approval Year/Month/Day
Ignacio Rodriguez 2014/07/14

品名：PSBB031T



正背中心偏移值±1mm

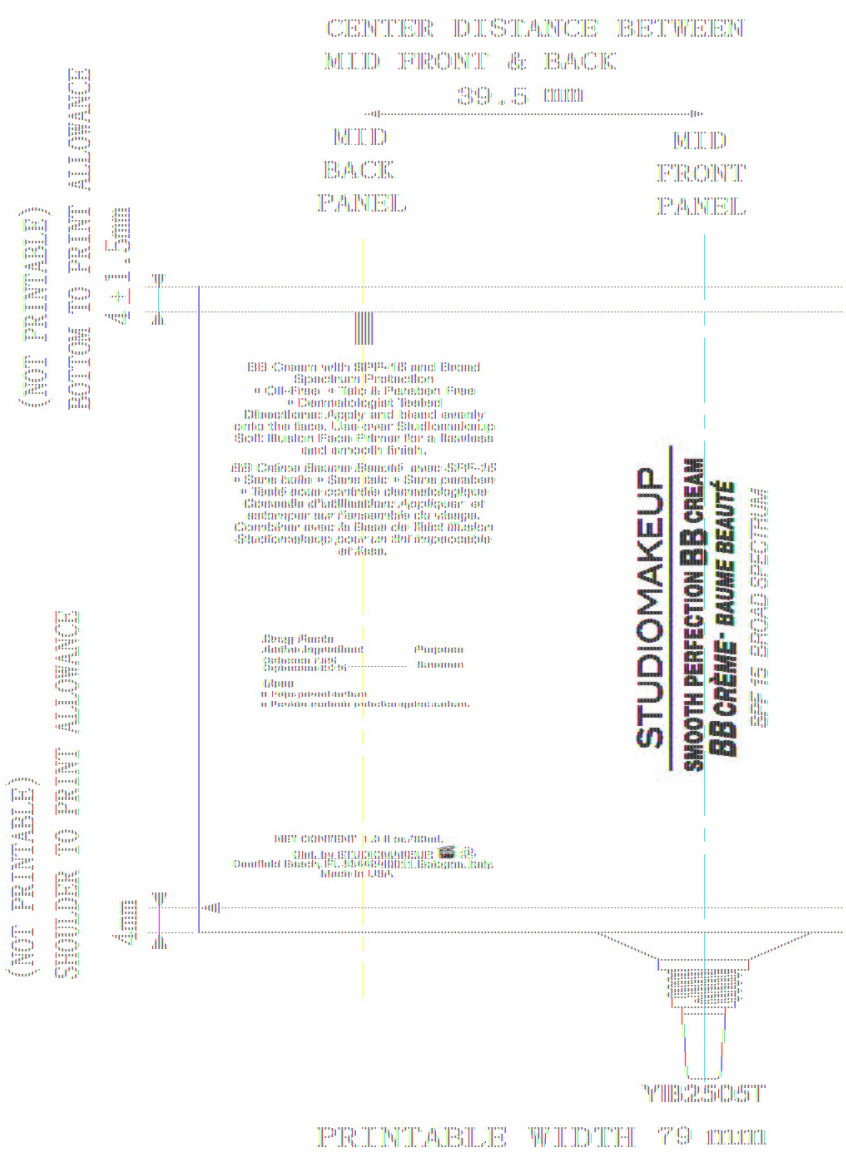
offset	1	2	3	4	5	6
COLOR NO.	BLACK					
STANDARD COLOR	黑					

製表：黃 奘 展 PTE：_____ 軟管廠：_____ 主管：_____ 2014年07月08日

Customer Name	STUDIO MAKEUP
Job Description	BB Cream Tube
REVISION	07/03/2014 Weight/Underline
File Name	SMU-Deco-BBCreamTube
Scale	100%

Component #:	YOM
Tube Color:	Cust
Deco Print:	Blac
Cap Color:	Blac

FINAL



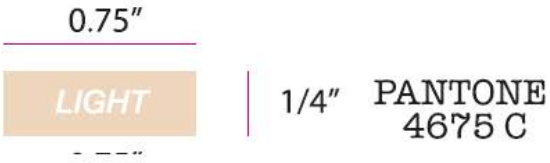
Approval: ..... Date:

Comments: .....

.....

.....

LIGHT



CREAM

octinoxate, oxybenzone cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61354-025
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	2 mg in 100 mg
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.49 mg in 100 mg

Inactive Ingredients	
Ingredient Name	**Strength**
DIMETHICONE (UNII: 92RU3N3Y1O)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
ISODODECANE (UNII: A8289P68Y2)	
DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
MICA (UNII: V8A1AW0880)	
DICAPRYLYL ETHER (UNII: 77JZM5516Z)	
BORON NITRIDE (UNII: 2U4T60A6YD)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61354-025-01	30 mg in 1 TUBE; Type 0: Not a Combination Product	02/23/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/23/2021	

Labeler - Oxygen Development (137098492)

Establishment

Name	Address	ID/FEI	Business Operations
Oxygen Development		137098492	manufacture(61354-025)

Revised: 2/2023