COSMEDIX SPF50- sunscreen emulsion
Universal Packaging Systems, Inc. DBA: PakLab

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.

Avobenzone 3.0%

Octinoxate 7.5%

Octisalate 5.0%

Oxybenzone 5.0%

Helps prevent sunburn

Apply liberally 15 minutes before sun exposure.

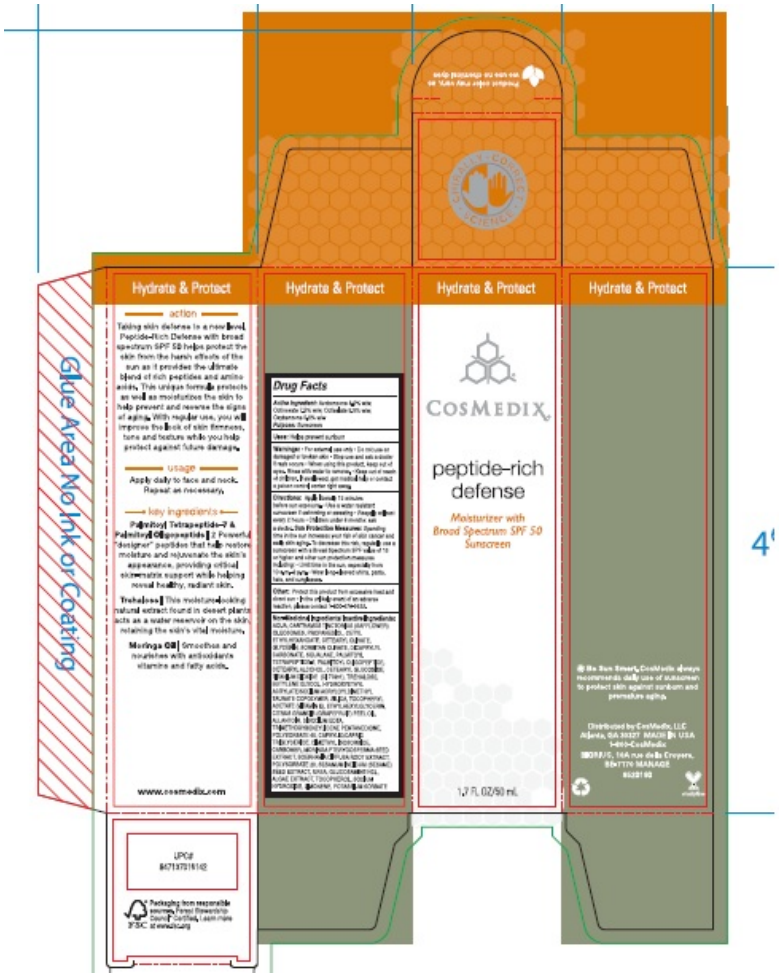
Water (Aqua), Propanediol, Dicaprylyl Carbonate, Carthamus Tinctorius (Safflower) Oleosomes, Cetyl Ethylhexanoate, Glycerin, Cetearyl Olivate, Squalane, Sorbitan Olivate, Silica, Trehalose, Trimethoxybenzylidene Pentanedione, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Butylene Glycol, Cetearyl Alcohol, Cetearyl Glucoside, Tocopheryl Acetate, Ethylhexylglycerin, Citrus Grandis (Grapefruit) Peel Oil, Limonene, Potassium Sorbate, Polysorbate 60, Allantoin, Disodium EDTA, Titanium Dioxide (CI 77891), Caprylic/Capric Triglyceride, Sodium Hydroxide, Dimethyl Isosorbide, Carbomer, Moringa Pterygosperma Seed Extract, Boerhavia Diffusa Root Extract, Polysorbate 20, Sesamum Indicum (Sesame) Seed Extract, Urea, Glucosamine HCl, Algae Extract, Palmitoyl Oligopeptide, Tocopherol, Palmitoyl Tetrapeptide-7.

In the unlikely event of an adverse reaction, please contact 1-800-676-9522

For external use only. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs.

Helps protect against sunburn.

Topical emulsion



COSMEDIX SPF50

sunscreen emulsion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61531-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.05 g in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.03 g in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	0.05 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61531-103-01	50 g in 1 TUBE; Type 0: Not a Combination Product	11/24/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/24/2015	

Labeler - Universal Packaging Systems, Inc. DBA: PakLab (790530976)

Establishment

Name	Address	ID/FEI	Business Operations
Universal Packaging Systems, Inc. DBA: PakLab		790530976	MANUFACTURE(61531-103)