

**ELROEL PANG PANG BIG SUN CUSHION S7- zinc oxide, titanium dioxide, octinoxate, octisalate, bemotrizinol cream
MONOGLLOT HOLDINGS Inc.**

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.

83154-001_ELROEL Pang Pang Big Sun Cushion S7

ZINC OXIDE 9.70%

OCTINOXATE 7.00%

OCTISALATE 3.00%

BEMOTRIZINOL 2.50%

TITANIUM DIOXIDE 1.52%

Sunscreen

Helps prevent sunburn

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply at least every two hours
- use a water resistant sunscreen if swimming or sweating
- Sun Protection Measures.

Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 a.m. - 2 p.m.
- wear long-sleeved shirts, pants, hats and sunglasses
- children under 6 months of age: ask a doctor

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.

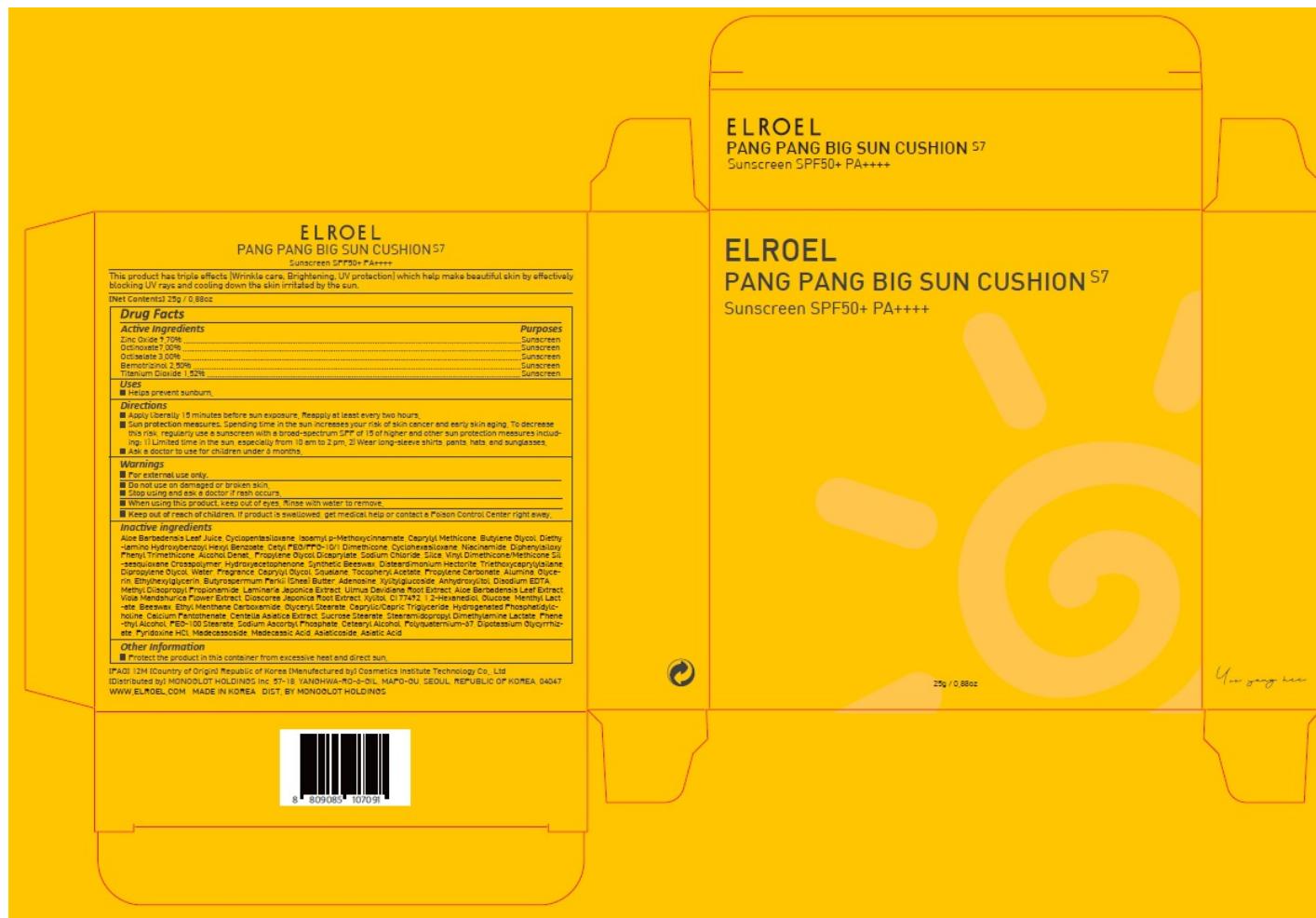
Stop using and ask a doctor if rash occurs.

Keep out of reach of the children. If product is swallowed, get medical help or contact a poison control center right away.

Aloe Barbadensis Leaf Juice, Cyclopentasiloxane, Isoamyl p-Methoxycinnamate, Caprylyl Methicone, Butylene Glycol, Diethylamino Hydroxybenzoyl Hexyl Benzoate, Cetyl PEG/PPG-10/1 Dimethicone, Cyclohexasiloxane, Niacinamide, Diphenylsiloxy Phenyl Trimethicone, Alcohol Denat., Propylene Glycol Dicaprylate, Sodium Chloride, Silica, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer, Hydroxyacetophenone, Synthetic Beeswax, Distearidimonium Hectorite, Triethoxycaprylylsilane, Dipropylene Glycol, Water, Fragrance, Caprylyl Glycol, Squalane, Tocopheryl Acetate, Propylene Carbonate, Alumina, Glycerin, Ethylhexylglycerin, Butyrospermum Parkii (Shea) Butter, Adenosine, Xylitylglucoside, Anhydroxylitol, Disodium EDTA, Methyl Diisopropyl Propionamide, Laminaria Japonica Extract, Ulmus Davidiana Root Extract, Aloe Barbadensis Leaf Extract, Viola Mandshurica Flower Extract, Dioscorea Japonica Root Extract, Xylitol, CI

77492, 1,2-Hexanediol, Glucose, Menthyl Lactate, Beeswax, Ethyl Menthane Carboxamide, Glyceryl Stearate, Caprylic/Capric Triglyceride, Hydrogenated Phosphatidylcholine, Calcium Pantothenate, Centella Asiatica Extract, Sucrose Stearate, Stearamidopropyl Dimethylamine Lactate, Phenethyl Alcohol, PEG-100 Stearate, Sodium Ascorbyl Phosphate, Cetearyl Alcohol, Polyquaternium-67, Dipotassium Glycyrrhizate, Pyridoxine HCl, Madecassoside, Madecassic Acid, Asiaticoside, Asiatic Acid

Protect the product in this container from excessive heat and direct sunlight



ELROEL PANG PANG BIG SUN CUSHION S7

zinc oxide, titanium dioxide, octinoxate, octisalate, bemotrizinol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83154-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.52 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	9.7 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	3 g in 100 g

BEMOTRIZINOL (UNII: PWZ1720CBH) (BEMOTRIZINOL - UNII:PWZ1720CBH)	BEMOTRIZINOL	2.5 g in 100 g
---	--------------	----------------

Inactive Ingredients		
	Ingredient Name	Strength
	ALOE VERA LEAF (UNII: ZY81Z83H0X)	
	CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
	AMILOXATE (UNII: 376KTP06K8)	
	CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
	DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE (UNII: ANQ870JD20)	
	CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
	CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
	NIACINAMIDE (UNII: 25X51I8RD4)	
	DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)	
	ALCOHOL (UNII: 3K9958V90M)	
	PROPYLENE GLYCOL DICAPRYLATE (UNII: 581437HWX2)	
	SODIUM CHLORIDE (UNII: 451W47IQ8X)	
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
	VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
	HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
	SYNTHETIC BEESWAX (UNII: 08MNR5YE2R)	
	DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
	TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
	DIPROPYLENE GLYCOL (UNII: E107L85C40)	
	WATER (UNII: 059QF0KO0R)	
	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
	SQUALANE (UNII: GW89575KF9)	
	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
	PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
	ALUMINUM OXIDE (UNII: LMI26O6933)	
	GLYCERIN (UNII: PDC6A3C0OX)	
	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
	SHEA BUTTER (UNII: K49155WL9Y)	
	ADENOSINE (UNII: K72T3FS567)	
	XYLITYLGLUCOSIDE (UNII: 00IEZ166FB)	
	ANHYDROXYLITOL (UNII: 8XWR7NN42F)	
	EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
	METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)	
	LAMINARIA JAPONICA (UNII: WE98HW412B)	
	ULMUS DAVIDIANA ROOT (UNII: URQ79U8261)	
	VIOLA MANDSHURICA FLOWER (UNII: 46MR945M6X)	
	DIOSCOREA JAPONICA TUBER (UNII: I43FCF3356)	
	XYLITOL (UNII: VCQ006KQ1E)	
	FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
	1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
	ANHYDROUS DEXTROSE (UNII: 5SLOG7R0OK)	
	MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)	
	YELLOW WAX (UNII: 2ZA36H0S2V)	
	ETHYL MENTHANE CARBOXAMIDE (UNII: 6S7S02945H)	

GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
CALCIUM PANTOTHENATE (UNII: 568ET80C3D)
CENTELLA ASIATICA TRITERPENOIDS (UNII: 4YS74Q4G4J)
SUCROSE STEARATE (UNII: 274KW0050M)
STEARAMIDOPROPYL DIMETHYLAMINE LACTATE (UNII: 31Q9363QSX)
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)
PEG-100 STEARATE (UNII: YD01N1999R)
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
GLICYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)
MADECASSOSIDE (UNII: CQ2F5O6YIY)
MADECASSIC ACID (UNII: M7O1N24J82)
ASIATICOSIDE (UNII: PKO39VY215)
ASIATIC ACID (UNII: 9PA5A687X5)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83154-001-02	1 in 1 CARTON	01/04/2023	
1	NDC:83154-001-01	25 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/04/2023	

Labeler - MONOGLOT HOLDINGS Inc. (694628175)

Registrant - MONOGLOT HOLDINGS Inc. (694628175)

Establishment

Name	Address	ID/FEI	Business Operations
Cit Co., Ltd.		690081646	manufacture(83154-001)