OUTBACK 2 IN 1 PROTECTION- octinoxate,avobenzone and zinc oxide cream
Ultra Mix (Aust) Pty Ltd

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.

Outback 2 in 1 Protection

Active Ingredients

OCTINOXATE : 7.5 % AVOBENZONE : 1.3% ZINC OXIDE :9.5%

Inactives

TEA TREE OIL

EUCALYPTUS POLYBRACTEA LEAF OIL

CITRONELLA OIL

LEPTOSPERMUM PETERSONII LEAF OIL

VANILLA

ACTILASTIN 1000

Purpose

Sunscreen, helps prevent sunburn.

Directions of Usage

Apply liberally 15 minutes before sun exposure, reapply after 40 minutes of swimming or sweating immediately after towel drying at least every 2 hours.

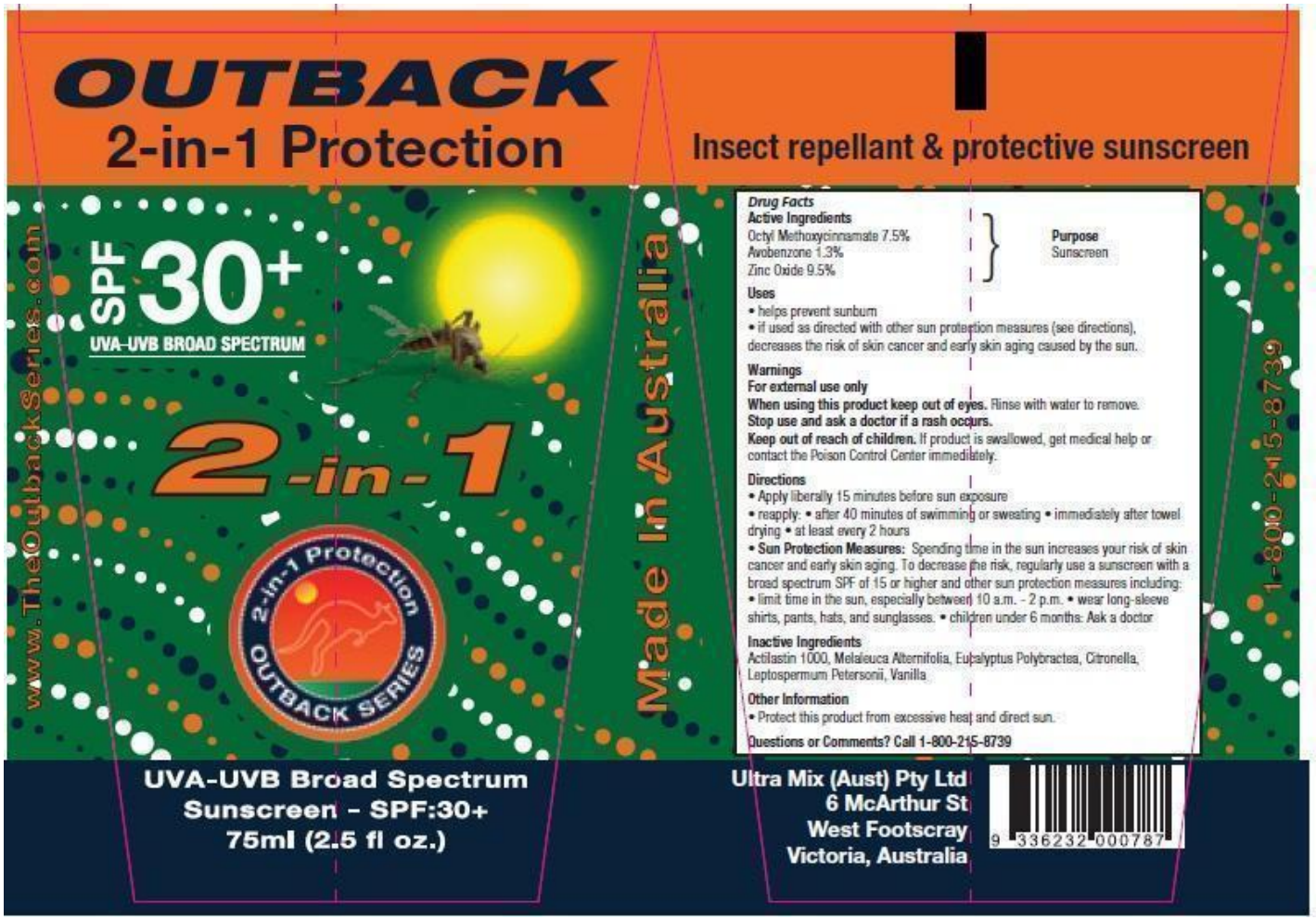
Warnings

For external use only.

When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if a rash occurs. Keep out of reach of children. If product is swallowed, get medical help or contact the Poison Control Center immediately.

Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including: limit time in the sun, especially between 10 a.m – 2 p.m. wear long-sleeve shirts, pants, hats and sunglasses. Children under 6 months: Ask a doctor

Product Label



OUTBACK 2 IN 1 PROTECTION

octinoxate,avobenzone and zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69594-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	13 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	95 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
TEA TREE OIL (UNII: VIF565UC2G)	
EUCALYPTUS POLYBRACTEA LEAF OIL (UNII: J1XGA6WROO)	
CITRONELLA OIL (UNII: QYO8Q067D0)	
LEPTOSPERMUM PETERSONII LEAF OIL (UNII: N37UWG52T3)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	VANILLA	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69594-005-01	75 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/16/2015	

Labeler - Ultra Mix (Aust) Pty Ltd (752254649)

Establishment

Name	Address	ID/FEI	Business Operations
Ultra Mix (Aust) Pty Ltd		752254649	manufacture(69594-005) , label(69594-005)

Revised: 2/2015 Ultra Mix (Aust) Pty Ltd