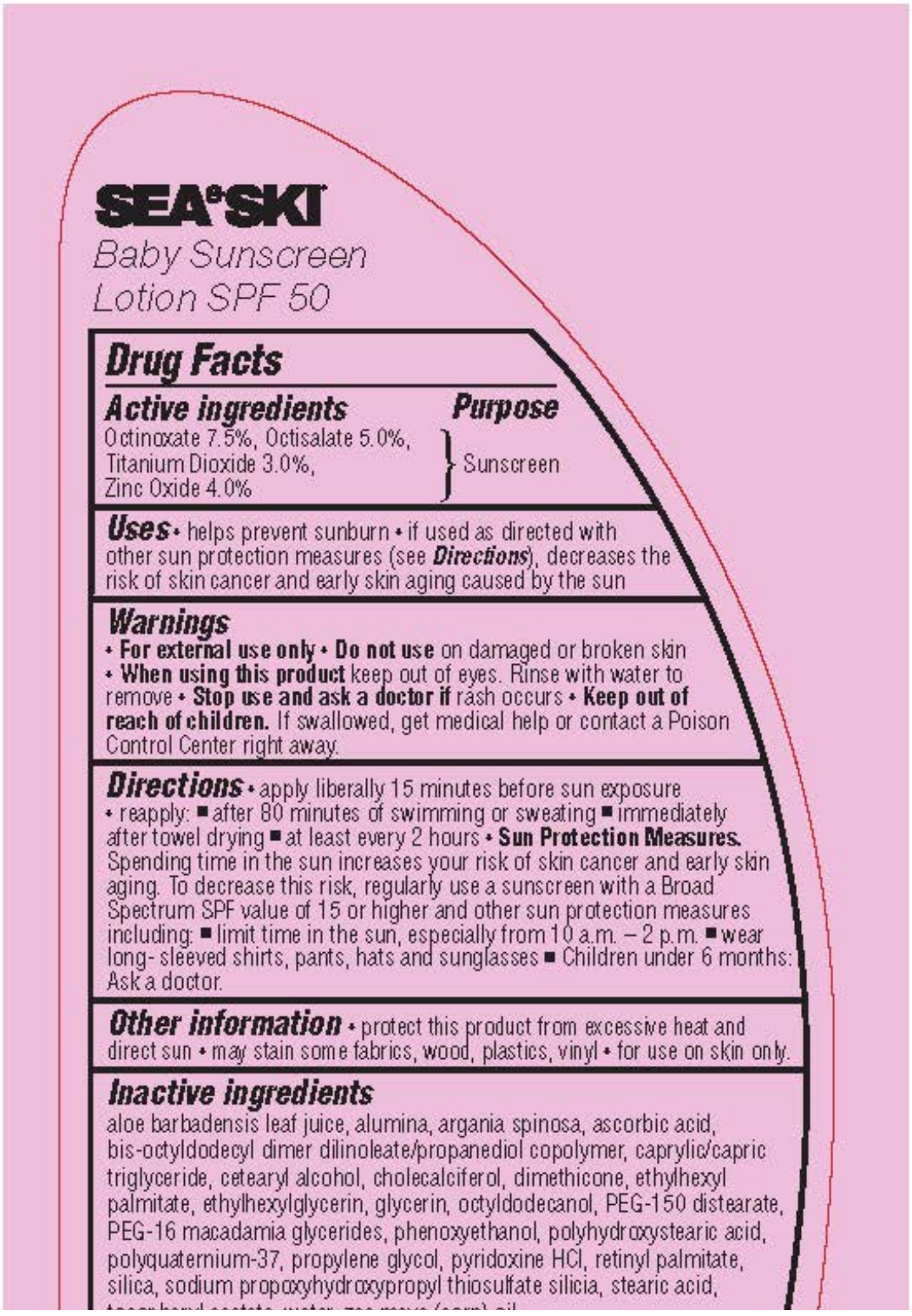
GENERAL PROTECTION- avobenzone,octisalate,homosalate,octocrylene,octinoxate lotion
Cross-Brand Manufacturing, LLC

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.

Sea & Ski Baby SPF 50 Lotion

Sea & Ski SPF 50 Baby



GENERAL PROTECTION

avobenzone,octisalate,homosalate,octocrylene,octinoxate lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71153-2005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71153-2005-1	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/23/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/23/2016	

Labeler - Cross-Brand Manufacturing, LLC (080319350)

Establishment

Name	Address	ID/FEI	Business Operations
Cross-Brands Manufacturing, LLC		080319350	manufacture(71153-2005) , label(71153-2005)

Revised: 12/2016 Cross-Brand Manufacturing, LLC