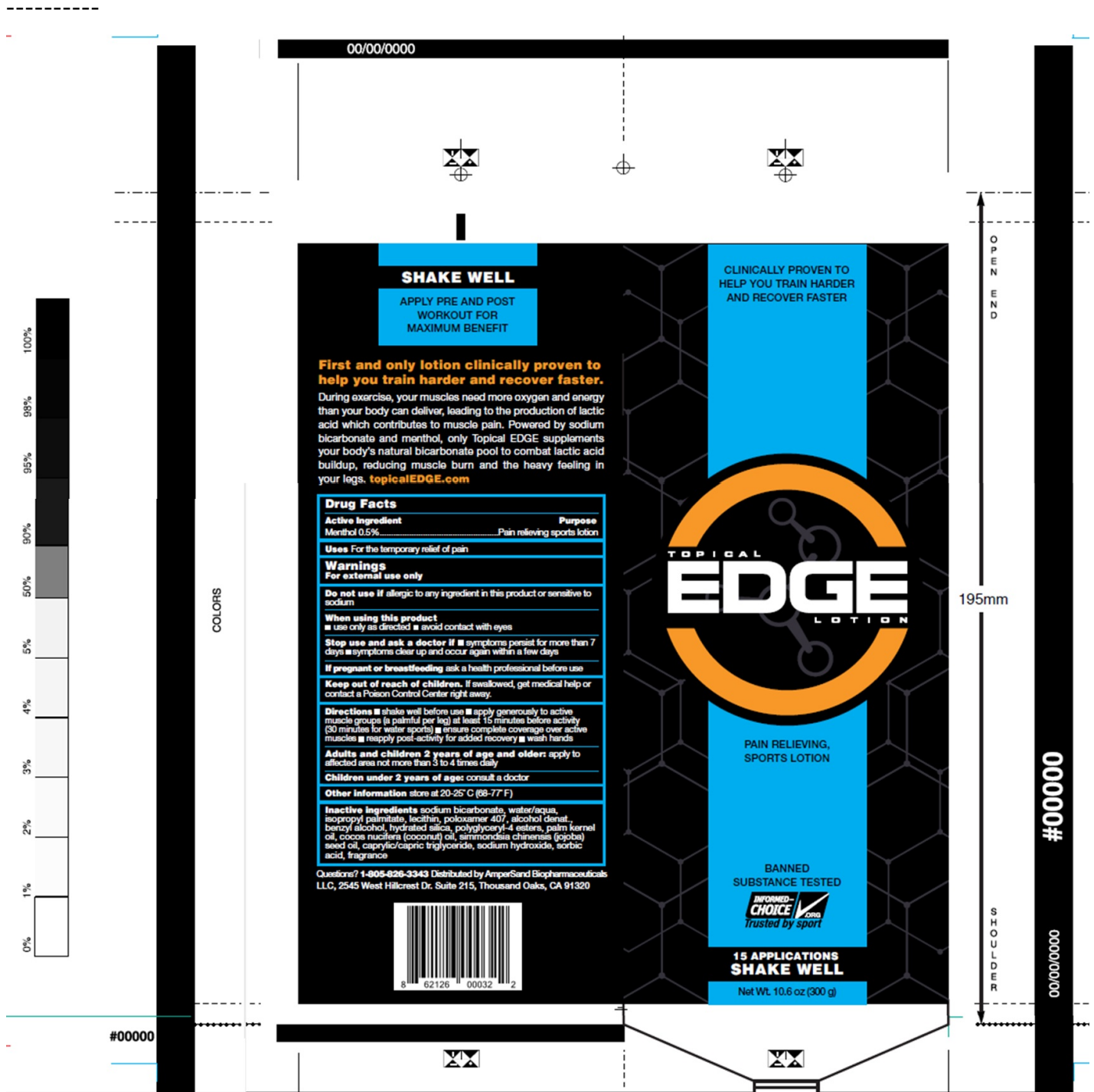


TOPICAL EDGE- menthol lotion
AmperSand Biopharma

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.



TOPICAL EDGE			
menthol lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70458-500

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
JOJOBA OIL (UNII: 724GKU717M)	
SORBIC ACID (UNII: X045WJ989B)	
POLYGLYCERYL-4 OLEATE (UNII: 15B05TY4GX)	
POLYGLYCERYL-4 STEARATE (UNII: VLC3W3U1PE)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
COCONUT OIL (UNII: Q9L0O73W7L)	
PALM KERNEL OIL (UNII: B0S90M0233)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
ALCOHOL (UNII: 3K9958V90M)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70458-500-02	300 g in 1 TUBE; Type 0: Not a Combination Product	09/25/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/25/2017	

Labeler - AmperSand Biopharma (080111681)

Revised: 8/2017

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