

**ECZEMA RELIEF SOOTHING 2% COLLOIDAL OATMEAL- colloidal
oatmeal cream**

Three Dog Beauty 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.

**THREE DOG BEAUTY - NAKERY BEAUTY - ECZEMA RELIEF SOOTHING CREAM
(83092-105)**

ACTIVE INGREDIENT

COLLOIDAL OATMEAL 2%

PURPOSE

SKIN PROTECTANT

USES

TEMPORARILY PROTECTS AND HELPS RELIEVE MINOR SKIN IRRITATION AND ITCHING DUE TO ECZEMA.

WARNINGS

- FOR EXTERNAL USE ONLY.

WHEN USING THIS PRODUCT

- AVOID CONTACT WITH EYES.

STOP USE AND ASK A DOCTOR IF

- CONDITION WORSENS
- SYMPTOMS LAST MORE THAN 7 DAYS OR CLEAR UP AND OCCUR AGAIN WITHIN A FEW DAYS.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

APPLY AS NEEDED OR AS DIRECTED BY A DOCTOR.

OTHER INFORMATION

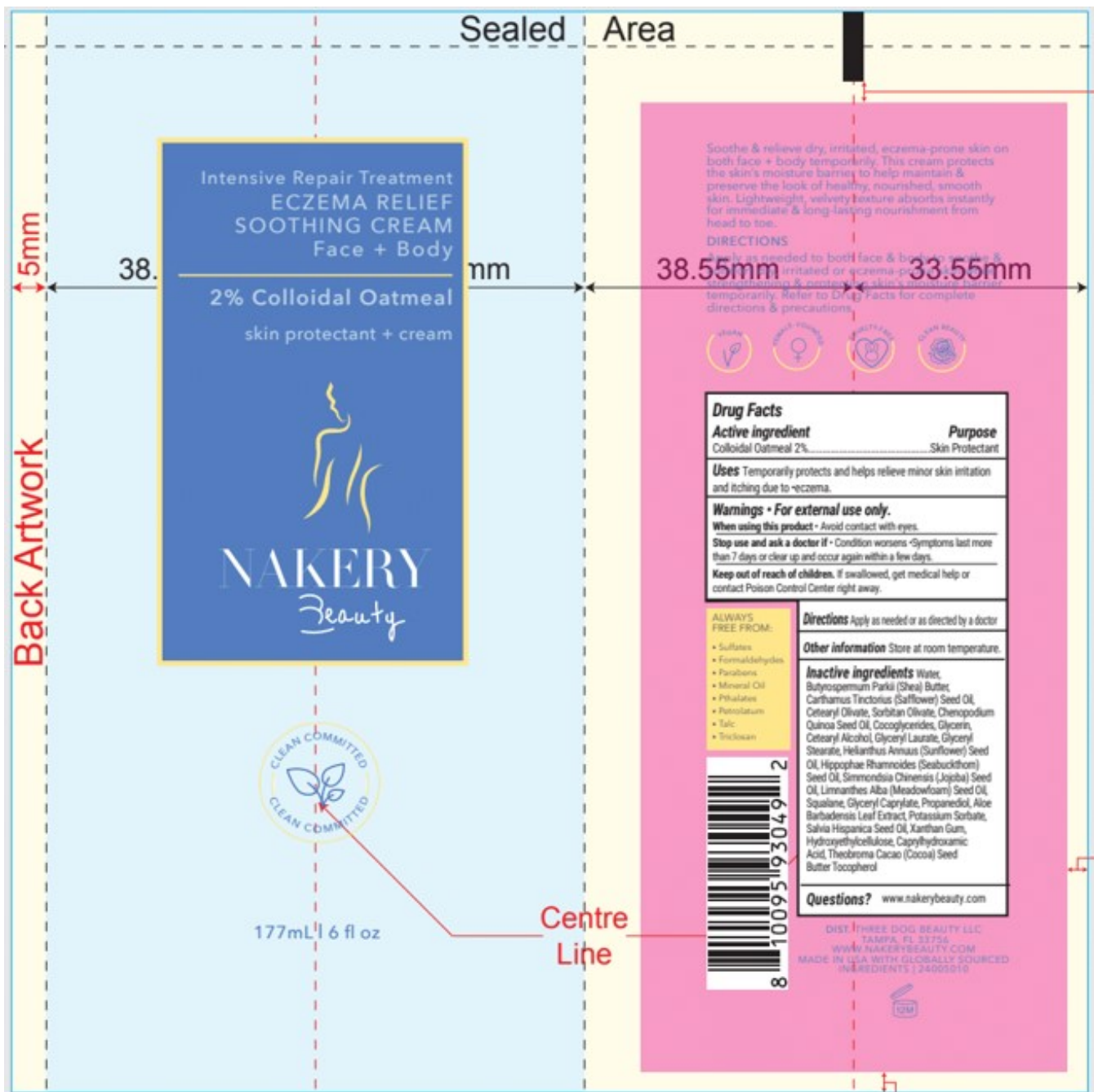
STORE AT ROOM TEMPERATURE.

INACTIVE INGREDIENTS

WATER, BUTYROSPERMUM PARKII (SHEA) BUTTER, CARTHAMUS TINCTORIUS (SAFFLOWER) SEED OIL, CETEARYL OLIVATE, SORBITAN OLIVATE, CHENOPODIUM QUINOA SEED OIL, COCOGLYCERIDES, GLYCERIN, CETEARYL ALCOHOL, GLYCERYL LAURATE, GLYCERYL STEARATE, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, HIPPOPHAE RHAMNOIDES (SEABUCKTHORN) SEED OIL, SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL, LIMNANTHES ALBA (MEADOWFOAM) SEED OIL, SQUALANE, GLYCERYL CAPRYLATE, PROPANEDIOL, ALOE BARBADENSIS LEAF EXTRACT, POTASSIUM SORBATE, SALVIA HISPANICA SEED OIL, XANTHAN GUM, HYDROXYETHYLCELLULOSE, CAPRYLHYDROXAMIC ACID, THEOBROMA CACOA (COCOA) SEED BUTTER, TOCOPHEROL

QUESTIONS?

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ECZEMA RELIEF SOOTHING 2% COLLOIDAL OATMEAL

colloidal oatmeal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83092-105
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
COCOA BUTTER (UNII: 512OYT1CRR)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
SALVIA HISPANICA SEED (UNII: NU00LX06F8)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SHEA BUTTER (UNII: K49155WL9Y)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
CHENOPODIUM QUINOA SEED (UNII: OO4K72NZ2X)	
COCO-GLYCERIDES (UNII: ISE9I7DNUG)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL LAURATE (UNII: Y98611C087)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
TOCOPHEROL (UNII: R0ZB2556P8)	
JOJOBA OIL (UNII: 724GKU717M)	
HIPPOPHAE RHAMNOIDES SEED OIL (UNII: T53SBG6741)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)	
SQUALANE (UNII: GW89575KF9)	
PROPANEDIOL (UNII: 5965N8W85T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83092-105-06	177 mL in 1 TUBE; Type 0: Not a Combination Product	09/28/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M016	09/28/2022	

Labeler - Three Dog Beauty LLC (111157953)

Registrant - Three Dog Beauty LLC (111157953)