# TENACIOUS ERGODYNE KREWD SPF 50 SUNSCREEN STICK- avobenzone, homosalate, octisalate, octocrylene stick Tenacious 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.

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## Tenacious Ergodyne KREWD SPF 50 Sunscreen Stick

## **∏Active ingredients**

Avobenzone 3.0%, Homosalate 15.0%, Octisalate 5.0%, Octocrylene 10.0%

## **Purpose**

Sunscreen

#### Uses

• helps prevent sunburn • if used as directed with other sun protection measures (see  $\square$  **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

## Warnings

## 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 use and ask a doctor if

rash occurs.

## Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

• apply liberally 15 minutes before sun exposure

- reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- children under 6 months of age: Ask a doctor
- **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

#### Other information

- protect the product in this container from excessive heat and direct sun
- may stain or damage some fabrics, materials or surfaces

## Inactive ingredients

beeswax (apis mellifera), ozokerite, cetearyl behenate, lauryl lactate, polybutene, butyloctyl salicylate, cetyl alcohol, styrene/acrylates copolymer, myristyl myristate, theobroma cacao (cocoa) seed butter, phenoxyethanol, tetrahexyldecyl ascorbate (vitamin C ester), tocopherol (natural vitamin E).

#### Label





#### Drug Facts (continued)

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0.25" Hinge Area

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## **Product Information**

**Product Type** HUMAN OTC DRUG Item Code (Source) NDC:73620-004

**Route of Administration TOPICAL** 

## **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	30 mg in 1 g	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	150 mg in 1 g	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 g	

Inactive Ingredients			
Ingredient Name	Strength		
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)			
WHITE WAX (UNII: 7G1J5DA97F)			
LAURYL LACTATE (UNII: G5SU0BFK7O)			
CERESIN (UNII: Q1LS2UJO3A)			
STEARYL BEHENATE (UNII: A68S9UI39D)			
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)			
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)			
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)			
CETYL ALCOHOL (UNII: 936JST6JCN)			
.ALPHATOCOPHEROL, DL- (UNII: 7QWA1RIO01)			
COCOA BUTTER (UNII: 5120YT1CRR)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			

l	P	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1		42 g in 1 CONTAINER; Type 0: Not a Combination Product	02/14/2020		

Marketing In	formation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	02/14/2020	

## Labeler - Tenacious Holdings, Inc. (108665142)

Revised: 2/2023 Tenacious Holdings, Inc.