

**TIEGE HANLEY MOISTURIZING LIP BALM SPF 30- zinc oxide stick**  
**Raining Rose, 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.*

-----

**Tiege Hanley Moisturizing Lip Balm SPF 30**

***Drug Facts***

***Active Ingredients***

Zinc Oxide 7.5%

***Purpose***

Sunscreen

***Uses*** • Helps prevent sunburn and chapped lips

***Warnings***

**For External Use Only • Do not use** on damaged or broken skin • **Stop use and ask a doctor if** rash occurs • **When using this product** keep out of eyes.  
• Rinse with water to remove • If swallowed get medical help or contact Poison Control Center right away.  
• **Keep out of reach of children.**

***Directions*** • Apply generously 15 minutes before sun exposure

- Reapply at least every two hours
- Use a water resistant sunscreen if swimming or sweating
- Children under 6 months ask a doctor

***Other Information:*** Protect this product from excessive heat and sun. This product is sealed with a tamper evident label. Do not use if label is missing or broken.

***Inactive Ingredients*** Pentaerythrityl Tetraistearate, Oryza Sativa (Rice) Bran Wax, Prunus Amygdalus Dulcis

(Almond) Oil, Helianthus Annuus (Sunflower) Seed Oil, Butyloctyl Salicylate, Glyceryl Stearate, Squalene, Behenyl

Alcohol, Moringa Oleifera Seed Oil, Caprylic/Capric Triglyceride, C18-38 Alkyl Hydroxystearoyl Stearate, Simmondsia

Chinensis (Jojoba) Seed Oil, Citrus Reticulata Blanco (Tangerine) Oil, Polyhydroxystearic Acid, Undaria Pinnatifida

Extract, Mentha Piperita (Peppermint) Oil

**Package Labeling**

**TIEGE**

**HANLEY**

**Uncomplicated**

**Skin Care for Men<sup>®</sup>**

□

**LIP**

**Moisturizing Lip Balm**

**with SPF 30**

**Net Wt 0.15 oz (4.2 g)**

**Made in the USA**

**MFD for Tiege Hanley LLC**

**Chicago, IL 60612**

**Tiege.com**

Tube Label

**TIEGE HANLEY**

Uncomplicated  
Skin Care for Men®

**LIP**

Moisturizing Lip Balm  
Zinc Oxide SPF 30

Net Wt 0.15 oz (4.2 g)

**Active Ingredients**  
Zinc Oxide 7.5% Sunscreen

**Inactive Ingredients** Prunus Amygdalus Dulcis (Almond) Oil, Helianthus Annuus (Sunflower) Seed Oil, Butyric Acid, Caprylic/Capric Triglyceride, C18-38 Alkyl Hydroxystearate, Simmondsia Chinensis (Jojoba) Seed Oil, Citrus Reticulata Blanco (Tangerine) Oil, Polyhydroxystearic Acid, Undaria Pinnatifida Extract, Mentha Piperita (Peppermint) Oil

**Purpose** Sunscreen

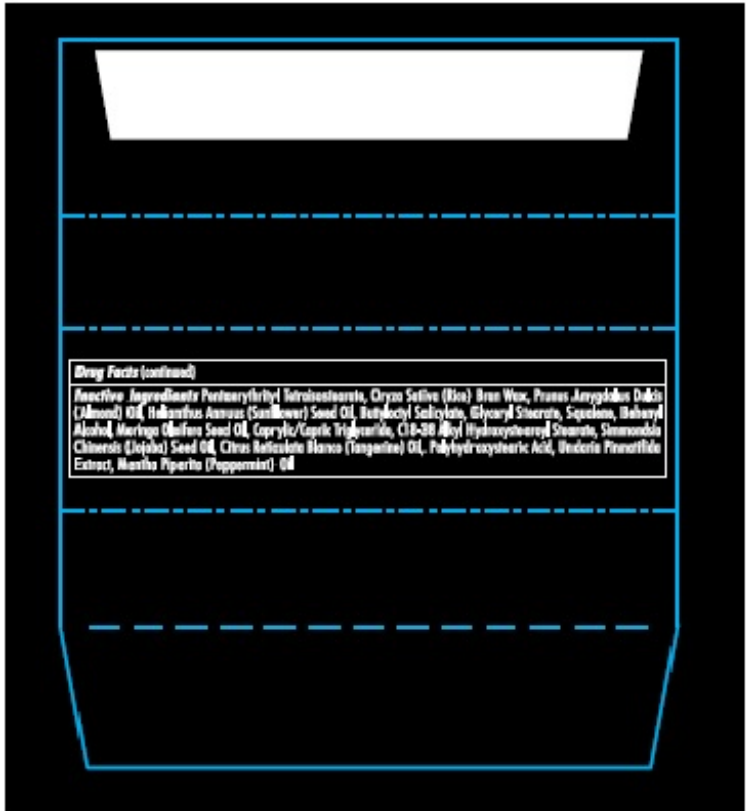
Lot code: 980897 EXP: 12/2021

**Tear Here**  
Tamper Resistant Seal

**Made in the USA**  
MFD for Tiege Hanley LLC  
Chicago, IL 60612  
Tiege.com

L331758

Box Label



res

**TIEGE HANLEY MOISTURIZING LIP BALM SPF 30**  
zinc oxide stick

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65692-1004
<b>Route of Administration</b>	TOPICAL		

<b>Active Ingredient/Active Moiety</b>		
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	75 mg in 1 g

<b>Inactive Ingredients</b>	
<b>Ingredient Name</b>	<b>Strength</b>
PENTAERYTHRITYL TETRAISO STEARATE (UNII: 9D7IK5483F)	
RICE BRAN (UNII: R60QEP13IC)	
ALMOND OIL (UNII: 66YXD4DKO9)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
SQUALENE (UNII: 7QWM220FJH)	
DOCOSANOL (UNII: 9G1OE216XY)	
MORINGA OLEIFERA SEED OIL (UNII: REM6A5QMC0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SYNTHETIC WAX (1200 MW) (UNII: Q3Z4BCH099)	
JOJOBA OIL (UNII: 724GKU717M)	
MANDARIN OIL (UNII: NJO720F72R)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
UNDARIA PINNATIFIDA (UNII: ICV1OK7M1S)	
PEPPERMINT OIL (UNII: AV092KU4JH)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65692-1004-1	1 in 1 PACKAGE	04/01/2020	
1		4.2 g in 1 TUBE; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/28/2020	

**Labeler** - Raining Rose, Inc. (083819404)

**Registrant** - Raining Rose, Inc. (083819404)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Raining Rose, Inc.		083819404	manufacture(65692-1004) , label(65692-1004) , pack(65692-1004)

