BARRIER BALM- barrier balm ointment Autumn Harp, Inc.

Skin Barrier Balm

Active Ingredient

Petrolatum 41.9%

Dimethicone 13.0%

Helps prevent, temporarily protects and helps relieve chafed, chapped or cracked skin

Helps prevent and protect from the drying effects of wind and cold weather

Temporarily protects minor cuts, scrapes, burns

Directions

Apply as needed

Warnings

For external use only

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Do not use on deep or puncture wounds, animal bites, serious burns

When using this product do not get into eyes

Stop use and ask doctor if condition worsens, symptoms last more than 7 days or clear up and occur again within a few days

Caprylic/Capric triglyceride, Butyrospermum Parkii (Shea Butter), Aluminum Starch Octenylsuccinate, Synthetic Wax, Polyhydroxystearic Acid, Sodium Hyaluronate, Water, Zinc Oxide, Tocopheryl Acetate, Triethoxycaprylylsilane

Questions?

858-859-1188

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Apply as needed





 FILE NAME:
 SR23026-A01-Carton_A

 DESIGNER:
 Enrique Mondragon

 SALESPERSON:
 Sean Roberts

 PROJECT MGR:
 O7/11/2023

 LAYOUT SIZE:
 0 x 0

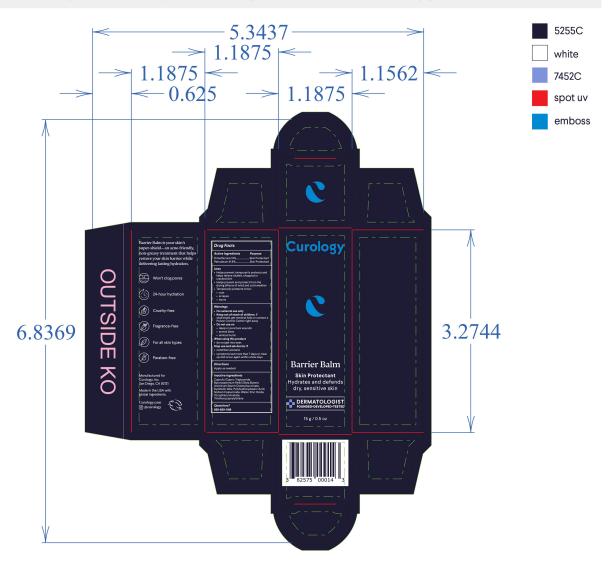
 STOCK TYPE:
 O18 Candesce C1S

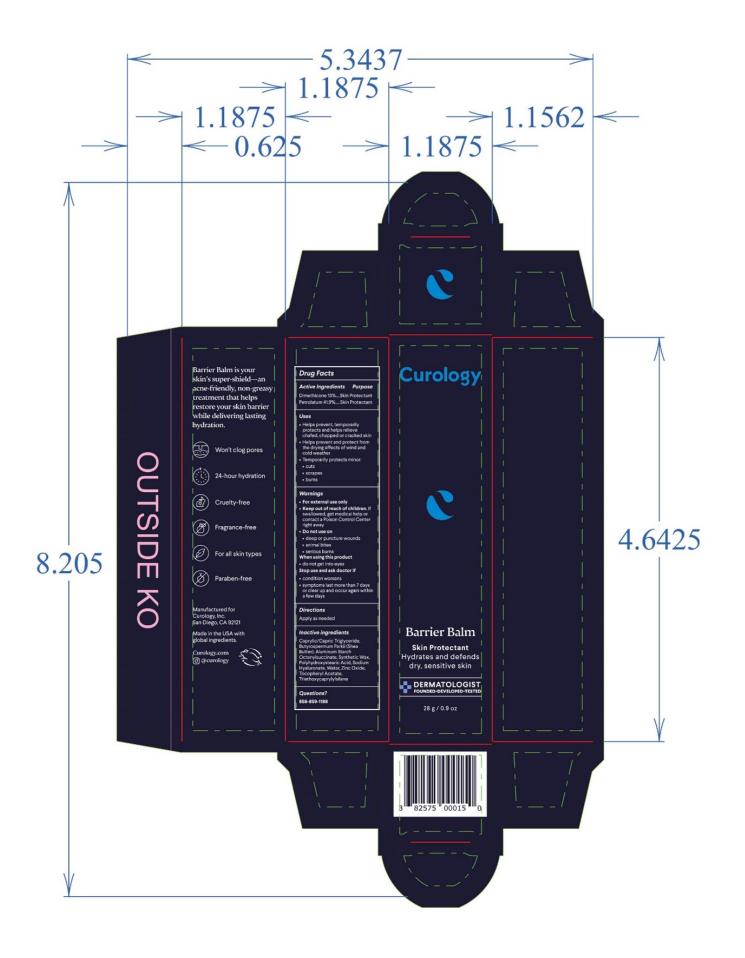
 NOTES:
 Candesce C1S

SHEET SIZE:	0 × (0)
GRAIN OR FLUTE:	(horizontal)
SHEET WASTE:	0%
INCHES OF RULE:	54.97
REVISION:	A
DESIGN VIEW:	outside

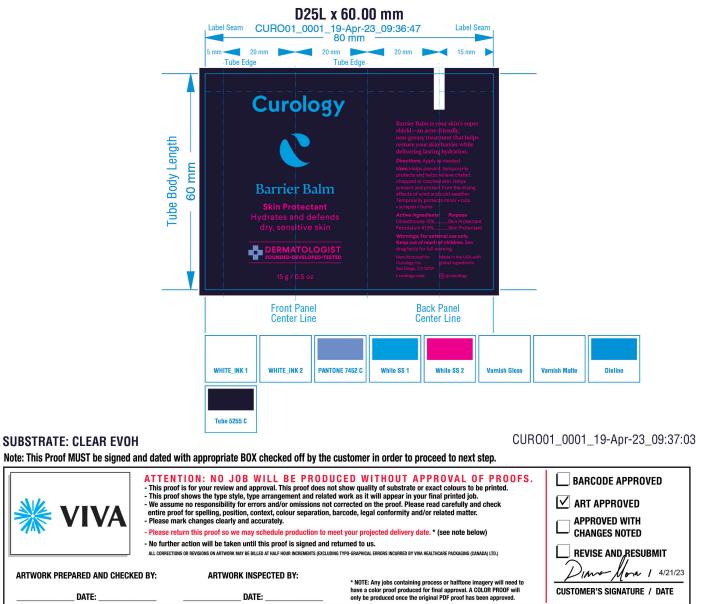
SEE CORRESPONDING "DESIGN REQUEST FORM" & SUPPORTING DOCUMENTS FOR ADDITIONAL ACCEPTANCE CRITERIA

This design remains the exclusive property of JohnsByrne Co. and may not be copied or reproduced without written permission from JohnsByrne Co. Any unauthorized use or reproduction of this design constitutes violation of United States copyright law.





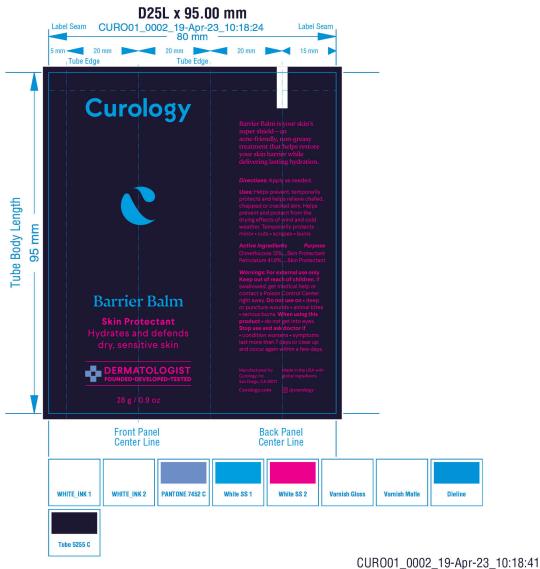
TO REVIEW THIS PDF PROOF PLEASE USE OVERPRINT PREVIEW



DATE:

DATE:

TO REVIEW THIS PDF PROOF PLEASE USE OVERPRINT PREVIEW

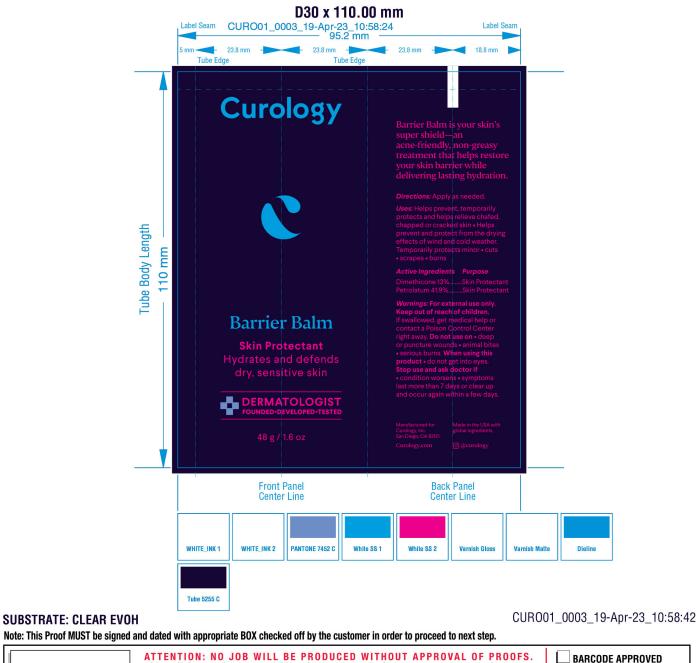


SUBSTRATE: CLEAR EVOH

Note: This Proof MUST be signed and dated with appropriate BOX checked off by the customer in order to proceed to next step.

ATTENTION: NO JOB WILL BE PRODUCED WITHOUT APPROVAL OF PROOFS. BARCODE APPROVED This proof is for your review and approval. This proof does not show quality of substrate or exact colours to be printed.
 This proof shows the type style, type arrangement and related work as it will appear in your final printed job.
 We assume no responsibility for errors and/or omissions not corrected on the proof. Please read carefully and check
 entire proof for spelling, position, context, colour separation, barcode, legal conformity and/or related matter.
 Please mark changes clearly and accurately. ✓ ART APPROVED IVA APPROVED WITH **CHANGES NOTED** - Please return this proof so we may schedule production to meet your projected delivery date. * (see note below) - No further action will be taken until this proof is signed and returned to us. **REVISE AND RESUBMIT** ALL CO TIONS OR REVISIONS ON ARTWORK MAY BE BILLED AT HALF HOUR IN IENTS (EXCLUDING TYPO-GRAPHICAL ERRORS INCURRED BY VIVA HEALTHCARE PACKAGING (CANADA) LTD.) **/** 4/21/23 ma **ARTWORK PREPARED AND CHECKED BY: ARTWORK INSPECTED BY:** in * NOTE: Any jobs containing process or halftone imagery will need to have a color proof produced for final approval. A COLOR PROOF will only be produced once the original PDF proof has been approved. CUSTOMER'S SIGNATURE / DATE DATE: DATE:

TO REVIEW THIS PDF PROOF PLEASE USE OVERPRINT PREVIEW



BARCODE APPROVED This proof is for your review and approval. This proof does not show quality of substrate or exact colours to be printed.
 This proof is hows the type style, type arrangement and related work as it will appear in your final printed job.
 We assume no responsibility for errors and/or omissions not corrected on the proof. Please read carefully and check
 entire proof for spelling, position, context, colour separation, barcode, legal conformity and/or related matter.
 Please mark changes clearly and accurately. ART APPROVED VA **APPROVED WITH** CHANGES NOTED - Please return this proof so we may schedule production to meet your projected delivery date. * (see note below) - No further action will be taken until this proof is signed and returned to us. **REVISE AND RESUBMIT** RRECTIONS OR REVISIONS ON ARTWORK MAY BE BILLED AT HALF HOUR INC ALL CO ENTS (EXCLUDING TYPO-GRAPHICAL ERRORS INCL RED BY VIVA HEALTHCARE PACKAGING (CANADA) LTD.) / 4/21/23 ARTWORK PREPARED AND CHECKED BY: ARTWORK INSPECTED BY: ma * NOTE: Any jobs containing process or halftone imagery will need to have a color proof produced for final approval. A COLOR PROOF will only be produced once the original PDF proof has been approved. CUSTOMER'S SIGNATURE / DATE DATE: DATE:

BARRIER BALM barrier balm ointment				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51514-0363	
Route of Administration	TOPICAL			

A . I				
Active Ingredient/Active M	loiety			
Ingred	ient Name		Basis of Strength	Strength
DIMETHICONE 20 (UNII: H8YMB5QY UNII:H8YMB5QY0D)	0D) (DIMETHICONE	20 -	DIMETHICONE 20	13 g in 100 g
PETROLATUM (UNII: 4T6H12BN9U)	PETROLATUM - UNI	:4T6H12BN9U)	PETROLATUM	41.9 g in 100 g
Inactive Ingredients				
	Strength			
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)				
ZINC OXIDE (UNII: SOI2LOH54Z)				
.ALPHATOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)				
SYNTHETIC WAX (1800 MW) (UNII: 248P1AUJ90)				
WATER (UNII: 059QF0KO0R)				
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)				
MEDIUM-CHAIN TRIGLYCERIDES (JNII: C9H2L21V7U)			
SHEA BUTTER (UNII: K49155WL9Y)				
ALUMINUM STARCH OCTENYLSUC	CINATE (UNII: 19PJ	006294)		
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)				
HYALURONATE SODIUM (UNII: YSE9PPT4TH)				
Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor	•			

Flavor Contains

-		-
Dac	VDA	Ina
Pac	NGU	

# Item Code Package Description Marketing Start Market				Marketing End
#	item code	Package Description	Date	Date
1	NDC:51514- 0363-2	1 in 1 CARTON	10/02/2023	
1	NDC:51514- 0363-1	15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51514- 0363-4	1 in 1 CARTON	10/02/2023	
2	NDC:51514- 0363-3	28 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:51514- 0363-6	1 in 1 CARTON	10/02/2023	
3	NDC:51514- 0363-5	48 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing

Application Number or Monograph Marketing Start Marketing End

Category	Citation	Date	Date
OTC Monograph Drug	M016	10/02/2023	

Labeler - Autumn Harp, Inc. (064187883)

Establishment			
Name	Address	ID/FEI	Business Operations
Autumn Harp		064187883	manufacture(51514-0363)

Revised: 8/2023

Autumn Harp, Inc.