

**CONTROLLING BALM WITH TEA TREE OIL- salicylic acid emulsion**  
**CA-BOTANA INTERNATIONAL**

*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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**Controlling Balm with Tea Tree Oil**

**Warnings:**

For external use only.

Do not use on wounds or damaged skin

When using this product: use only as directed. Avoid contact with eyes. Do not bandage tightly

Stop use and ask a doctor if: redness is present. Irritation develops. Condition worsens or symptoms persist more than 7 days. Symptoms clear up and occur again within a few days.

Store at room temperature. Lot number and expiration date see crimp or see box.

cleanse the skin thoroughly with soft foam deep cleanse before applying. cover the entire affected area with a thin layer 1 to 2 times daily. because too much drying of the skin may occur, start with 1 application daily, then gradually increase to 2 times daily if needed or as directed by a doctor. if bothersome dryness or peeling occurs, reduce application to once a day or every other day.

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Acrilates/Acrylamine Copolymer  
Aloe barbadensis (Aloe vera) extract  
Alpha Copper Tripeptide-4 TM  
Argania Spinosa (Argan) extract  
Benzyl Alcohol  
Camellia sinensis (White tea) extract  
Chamomilla recutita (Chamomile) extract  
Cinnamomum Zeylanicum  
Citrus medica lemonum (Lemon) Peel Oil  
Copper Gluconate  
Ethanol  
Ethylhexylglycerin  
Euterpe oleracea (Acai) extract  
Ginkgo Biloba extract  
Glycine  
Hamamelis virginiana (Witchhazel) extract  
Hypericum perforatum (St John's wort) extract  
Juniperus communis (Juniper) extract  
Lactic acid  
Lavandula angustifolia oil  
Malpighia glabra (Acerola) extract  
Melaleuca Alternifolia (Tea tree) leaf oil  
Olea europaea (Olive) leaf extract  
Phenoxyethanol  
Phosphatidylcholine  
Pinus Taeda (Pine tree) extract  
Polysorbate 20  
Potassium Sorbate  
Propanediol  
Punica granatum (Pomegranate) extract  
Rosa canina extract

Rosmarinus officinalis (Rosemary) extract  
Sodium Hyaluronate  
Sodium Hydroxide  
Sodium PC  
Tetra sodium  
Vitis Vinifera ( Grape) extract  
Water (Aqua)  
Xanthan Gum

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Keep out of reach of children. If swallowed get medical help or contact a Posion Control Center immediately.

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DOCTOR D.  
SCHWAB®

# CONTROLLING BALM

WITH TEA TREE OIL

BAUME DE CONTRÔLE  
BALSAMO CONTROLANTE

 **ACNE +  
OILY SKIN**



1 FL OZ / 30 ML



### Drug Facts

Active ingredient	Purpose
Salicylic Acid 0.8%	Acne Treatment

**Uses** •clears acne pimples •helps prevent new acne pimples •penetrates pores to eliminate most acne blemishes, blackheads, and whiteheads

### Warnings For external use only

**Do not use** •on broken skin •on large areas of the body

**When using this product** •apply to affected areas only •do not use in or near eyes •using other topical acne drugs at the same time or right after use of this product may increase dryness or irritation of the skin. Only one drug should be used unless directed by a doctor.

NDC # 35192-016-05

DOCTOR D. SCHWAB®  
[www.DoctorSchwabCA.com](http://www.DoctorSchwabCA.com)

A division of CA BOTANICA  
San Diego, CA 92121, USA  
Made in USA

REF #850

Peel  
Here

### Drug Facts (continued)

**Stop use and ask a doctor if** too much skin irritation or sensitivity develops or increases

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

**Directions** •cleanse the skin thoroughly with Soft Foam Deep Cleanse before applying •cover the entire affected area with a thin layer 1 to 2 times daily •because too much drying of the skin may occur, start with 1 application daily, then gradually increase to 2 times daily if needed or as directed by a doctor •if bothersome dryness or peeling occurs, reduce application to once a day or every other day

**Inactive ingredients:** Acilates/Acylamine copolymer, Aloe barbadensis (Aloe vera) extract, Alpha copper tripeptide-4™, Argania spinosa (Argan) extract, Benzyl alcohol, Camellia sinensis (White tea)

**Drug Facts** *(continued)*

extract, Chamomilla recutita (Chamomile) extract, Cinnamomum zeylanicum, Citrus medica lemonum (Lemon) peel oil, Copper gluconate, Ethanol, Ethylhexylglycerin, Euterpe oleracea (Acai) extract, Ginkgo biloba extract, Glycine, Hamamelis virginiana (Witchhazel) extract, Hypericum perforatum (St. John's wort) extract, Juniperus communis (Juniper) extract, Lactic acid, Lavandula angustifolia oil, Malpighia glabra (Acerola) extract, Melaleuca alternifolia (Tea tree) leaf oil, Olea europaea (Olive) leaf extract, Phenoxyethanol, Phosphatidylcholine, Pinus taeda (Pine tree) extract, Polysorbate 20, Potassium sorbate, Propanediol, Punica granatum (Pomegranate) extract, Rosa canina extract, Rosmarinus officinalis (Rosemary) extract, Sodium hyaluronate, Sodium hydroxide, Sodium PCA, Tetrasodium EDTA, Vitis vinifera (Grape) fruit cell extract, Water (Aqua), Xanthan gum.

**Other information:** Store at room temperature.

**Package Label Display Panel****CONTROLLING BALM WITH TEA TREE OIL**

salicylic acid emulsion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:35192-016
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	0.24 mg in 29.6 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
GLATIRAMER ACETATE (UNII: 5M691HL4BO)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
COPPER (UNII: 789U1901C5)	
ARGANIA SPINOSA LEAF (UNII: 51XV5WTF7E)	
.ALPHA.,.ALPHA.-DIMETHYLBENZYL ALCOHOL (UNII: JE030BGE05)	

CAMELLIA SINENSIS FLOWER (UNII: 9I2BJY2J17)
CHAMOMILE (UNII: FGL3685T2X)
CINNAMON (UNII: 5S29HWU6QB)
LEMON OIL (UNII: I9GRO824LL)
COPPER GLUCONATE (UNII: RV823G6G67)
ALCOHOL (UNII: 3K9958V90M)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
ACAI (UNII: 46AM2VJ0AW)
GINKGO (UNII: 19FUJ2C58T)
GLYCINE (UNII: TE7660XO1C)
HAMAMELIS VIRGINIANA BARK (UNII: IH3063S9MY)
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB)
JUNIPER BERRY OIL (UNII: SZH16H44UY)
LACTIC ACID (UNII: 33X04XA5AT)
LAVENDER OIL (UNII: ZBP1YXW0H8)
MALPIGHIA EMARGINATA SEED (UNII: 1X7L93686M)
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
PINUS TAEDA BARK (UNII: 9I1F994SVG)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
PUNICA GRANATUM FLOWER (UNII: D9B634V4GP)
ROSA CANINA FLOWER (UNII: 81MCR2UQ6Q)
ROSEMARY (UNII: IJ67X351P9)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
VITIS VINIFERA FLOWERING TOP (UNII: 6TG3V35HTV)
WATER (UNII: 059QF0K00R)
XANTHAN GUM (UNII: TTV12P4NEE)
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
PROPYLENE GLYCOL, (R)- (UNII: 602HN5L69H)
1,2-DIOLEOYL-SN-GLYCERO-3-PHOSPHOCHOLINE (UNII: H026DM5V6U)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35192-016-05	29.4 mg in 1 TUBE; Type 0: Not a Combination Product	11/02/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	11/09/2014	

**Labeler** - CA-BOTANA INTERNATIONAL (106276728)

**Registrant** - RODOLFO UGELSTAD (106276728)

## Establishment

Name	Address	ID/FEI	Business Operations
CA-BOTANA INTERNATIONAL		106276728	manufacture(35192-016)

Revised: 12/2019

CA-BOTANA INTERNATIONAL