

MARK. BREAK OUT PLAN- salicylic acid gel
Avon Products 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.

DRUG FACTS

See attached 1092906 breakout plan FC.jpg

Active ingredient	Purpose
Salicylic Acid 1.5%.....	Acne Treatment

Uses

- helps in the treatment of acne
- helps prevent new acne blemishes from forming
- clears up acne blemishes
- penetrates pores to eliminate most blackheads and acne pimples

Warnings

For external use only

When using this product

- avoid contact with eyes. If product contacts eyes, rinse thoroughly with water. If irritation persists, seek medical attention
- using other topical acne products at the same time or immediately after use of this product may increase dryness or irritation of the skin. If this occurs, only one product should be used unless directed by a doctor.

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

Directions

- cleanse skin thoroughly before applying medication
- because excessive drying of the skin may occur, start with one application daily, then gradually increase to two to three 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/Non-medicinal ingredients

WATER/EAU

SD ALCOHOL 40-B

DIMETHICONE

POLYSORBATE 20

GLYCERIN

PYRUS MALUS (APPLE) FRUIT EXTRACT

VANILLA PLANIFOLIA FRUIT EXTRACT

ROSMARINUS OFFICINALIS (ROSEMARY) LEAF EXTRACT

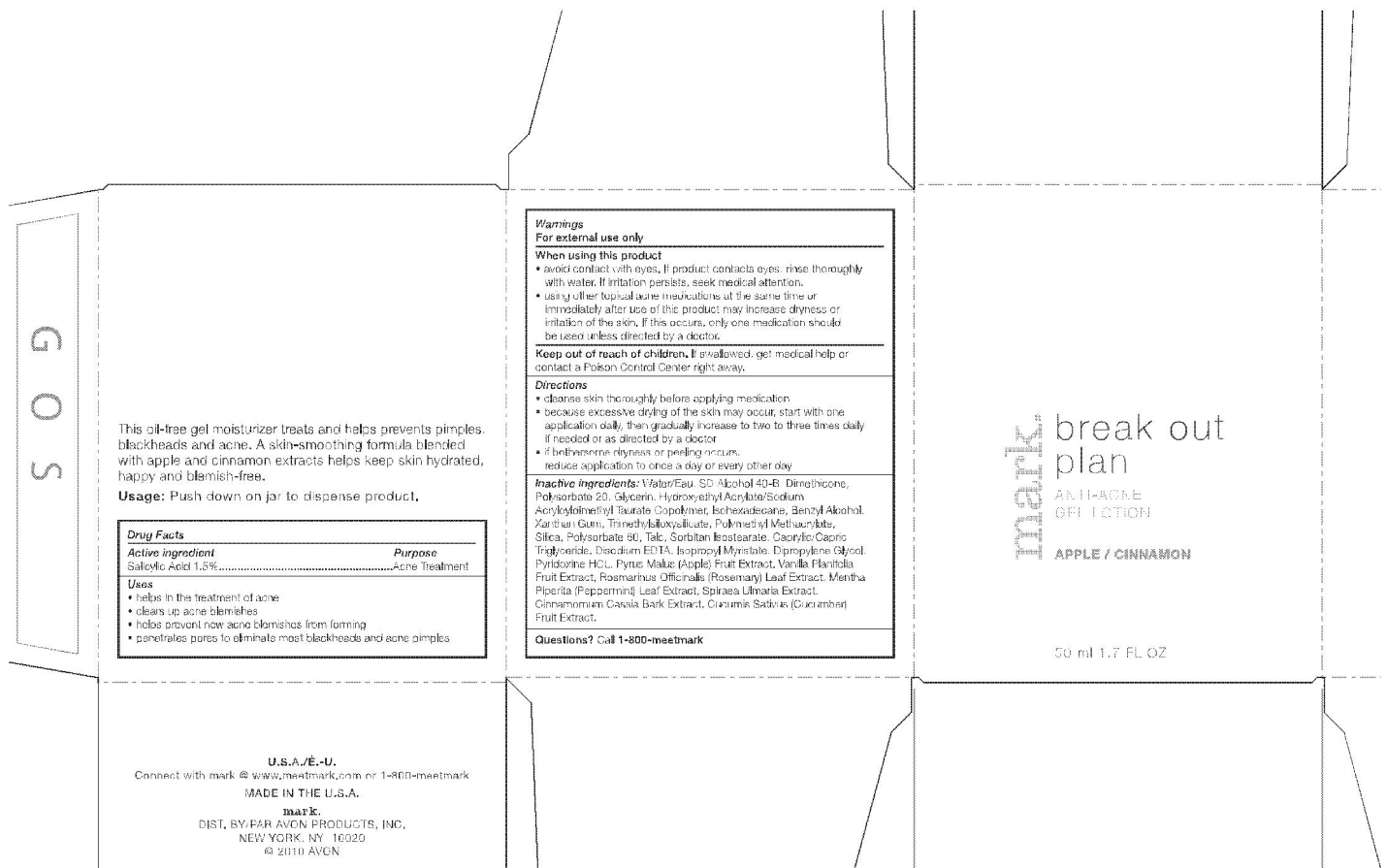
MENTHA PIPERITA (PEPPERMINT) LEAF EXTRACT

SPIRAEA ULMARIA EXTRACT

CINNAMOMUM CASSIA BARK EXTRACT

CUCUMIS SATIVUS (CUCUMBER) FRUIT EXTRACT
 HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER
 ISOHEXADECANE
 XANTHAN GUM
 TRIMETHYLSILOXYSILICATE
 POLYMETHYL METHACRYLATE
 SILICA
 POLYSORBATE 60
 TALC
 SORBITAN ISOSTEARATE
 CAPRYLIC/CAPRIC TRIGLYCERIDE
 ISOPROPYL MYRISTATE
 DIPROPYLENE GLYCOL
 PYRIDOXINE HCL
 DISODIUM EDTA
 BENZYL ALCOHOL

Questions? Call 1-800-meetmark



MARK. BREAK OUT PLAN

salicylic acid gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10096-0195
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	.75 mL in 50 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10096-0195-1	50 mL in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333	12/29/2009	

Labeler - Avon Products Inc. (001468693)

Establishment

Name	Address	ID/FEI	Business Operations
Avon products, Inc.		005149471	manufacture

Revised: 12/2009

Avon Products Inc.