

ACNE BODY WASH- salicylic acid soap

Curology

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

Active Ingredient

Salicylic acid 2%

Purpose

Acne treatment

Uses

For the treatment of acne

Warnings

- For external use only.
- When using this product using other topical acne drugs at the same time or right after use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by doctor.
- Keep out of reach of children.
- If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Dampen skin and massage a thin layer onto the entire affected area, then rinse thoroughly.
- Because drying of skin may occur, start with one daily application, then gradually increase to two or three times daily, if needed or directed by a doctor.
- If excessive dryness or peeling occurs, reduce application to once a day or every other day.

Other Information

Store at 20-25°C (68-77°F)

Inactive Ingredients

Water, Sodium C14-16 Olefin Sulfonate, Glycerin, Cocamidopropyl Betaine, Cocamidopropyl Dimethylamine, Polyglyceryl-4 Caprate, Polyglyceryl-6 Caprylate, Hydroxypropyl Methylcellulose, Phenoxyethanol, Sodium Chloride, Zinc Pyrithione, Sodium Hydroxide, Polyquaternium-7, Ethylhexylglycerin, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Disodium EDTA, Sodium Benzoate

Principal Display Panel - 100 ml Bottle Label

Curology

Acne Body Wash

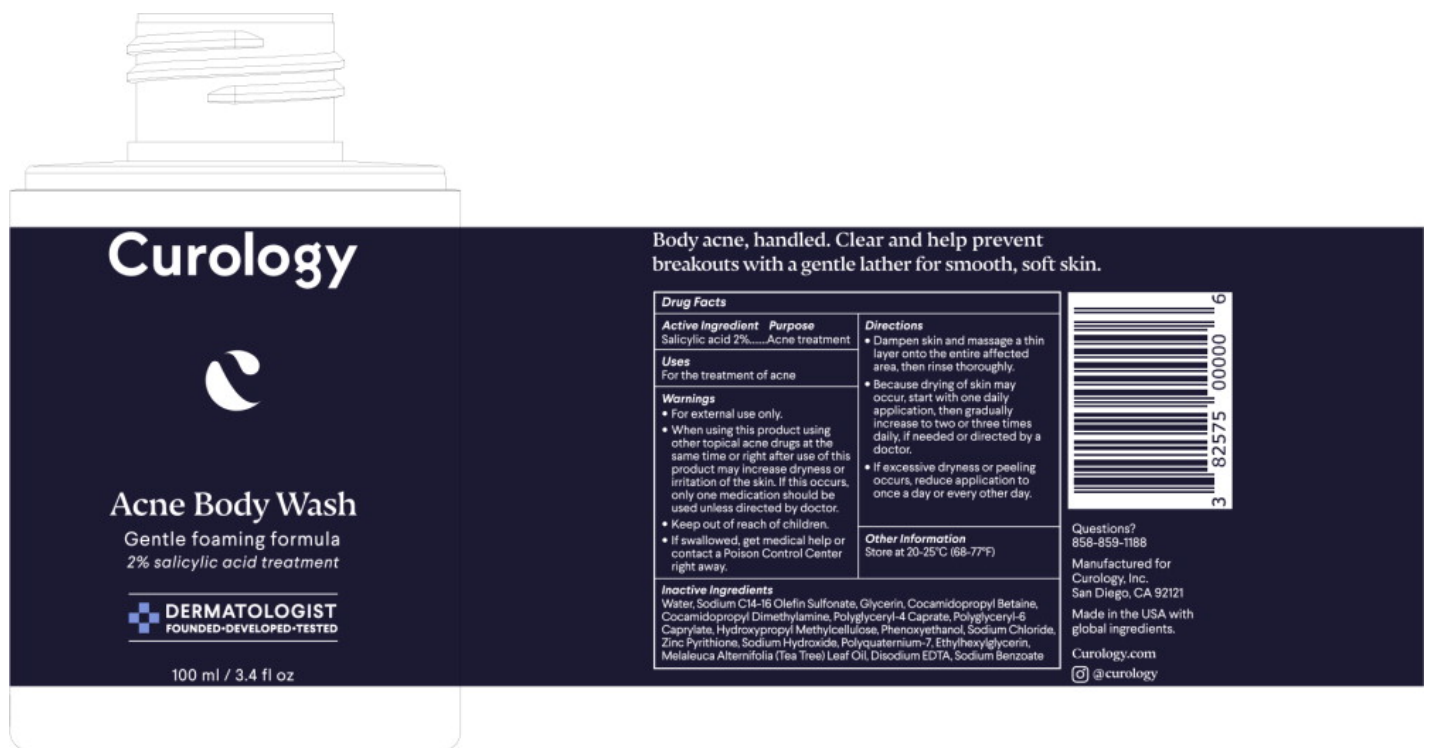
Gentle foaming formula

2% salicylic acid treatment

DERMATOLOGIST

FOUNDED DEVELOPED TESTED

100 ml/3.4 fl oz



Principal Display Panel - 200 ml Bottle Label

Curology

Acne Body Wash

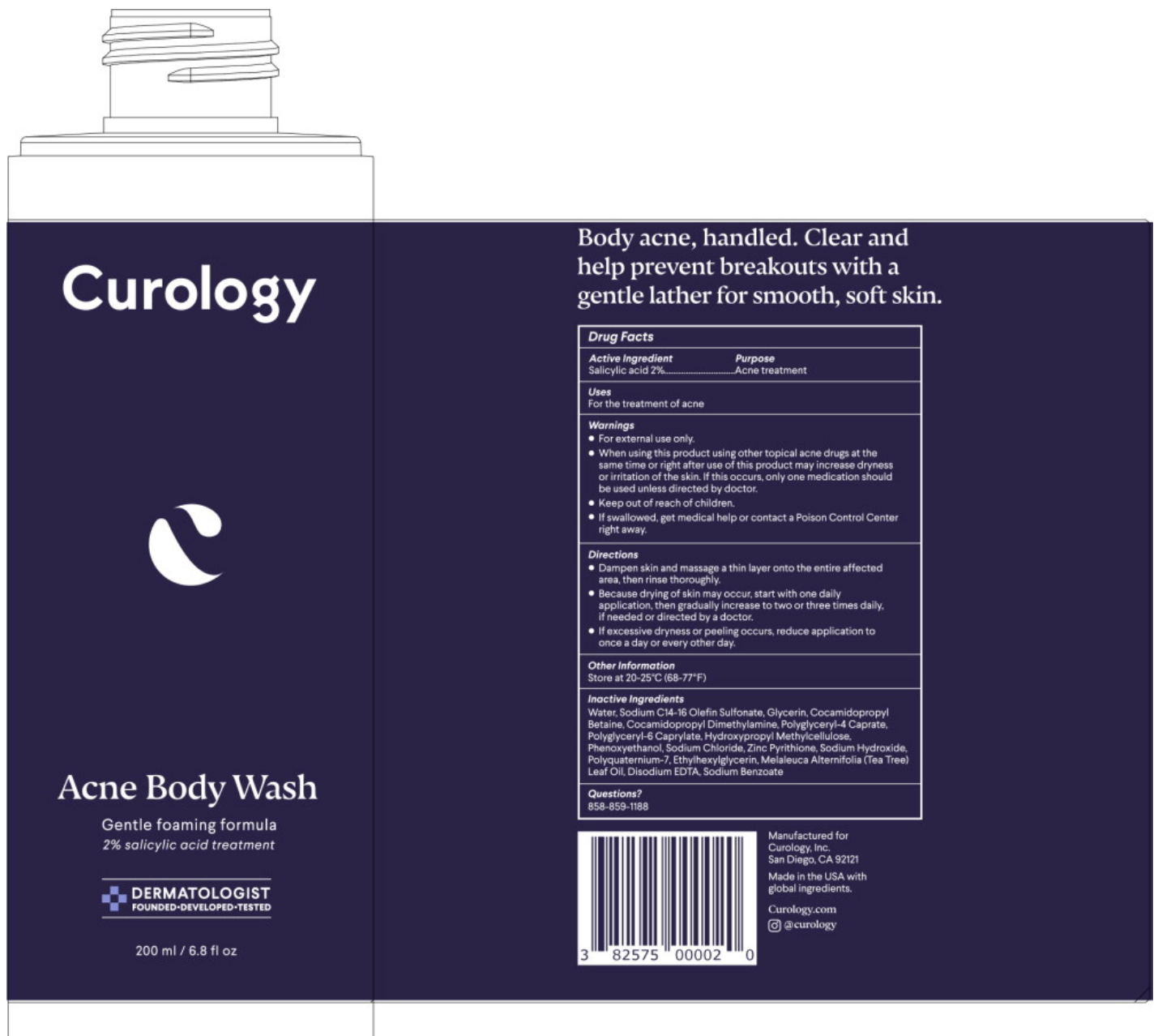
Gentle foaming formula

2% salicylic acid treatment

DERMATOLOGIST

FOUNDED DEVELOPED TESTED

200 ml/6.8 fl oz



ACNE BODY WASH

salicylic acid soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82575-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Salicylic Acid (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ)	Salicylic Acid	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Sodium C14-16 Olefin Sulfonate (UNII: O9W3D3YF5U)	
Glycerin (UNII: PDC6A3C0OX)	
Cocamidopropyl Betaine (UNII: 5OCF3O11KX)	
Cocamidopropyl Dimethylamine (UNII: L36BM7DG2T)	
Hypromellose, Unspecified (UNII: 3NXW29V3WO)	
Polyglyceryl-4 Caprate (UNII: 3N873UN885)	
Polyglyceryl-6 Caprylate (UNII: DGV8R54VG7)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Pyrrhione Zinc (UNII: R953O2RHZ5)	
Polyquaternium-7 (70/30 Acrylamide/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Edetate Disodium Anhydrous (UNII: 8NLQ36F6MM)	
Tea Tree Oil (UNII: VIF565UC2G)	
Sodium Chloride (UNII: 451W47IQ8X)	
Edetic Acid (UNII: 9G34HU7RV0)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Formaldehyde/Sodium Naphthalenesulfonate Copolymer (3000 MW) (UNII: 90D834OZUI)	
Xanthan Gum (UNII: TTV12P4NEE)	
Magnesium Nitrate (UNII: 77CBG3UN78)	
Methylchloroisoithiazolinone (UNII: DEL7T5QRPN)	
Magnesium Chloride (UNII: 02F3473H9O)	
Methylisothiazolinone (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82575-100-10	100 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	12/05/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	12/05/2022	

ACNE BODY WASH

salicylic acid soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82575-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Salicylic Acid (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ)	Salicylic Acid	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Sodium C14-16 Olefin Sulfonate (UNII: O9W3D3YF5U)	
Glycerin (UNII: PDC6A3C00X)	
Cocamidopropyl Betaine (UNII: 5OCF3O11KX)	
Cocamidopropyl Dimethylamine (UNII: L36BM7DG2T)	
Hypromellose, Unspecified (UNII: 3NXW29V3WO)	
Polyglyceryl-4 Caprate (UNII: 3N873UN885)	
Polyglyceryl-6 Caprylate (UNII: DGV8R54VG7)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Pyrrithione Zinc (UNII: R953O2RHZ5)	
Polyquaternium-7 (70/30 Acrylamide/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Edetate Disodium Anhydrous (UNII: 8NLQ36F6MM)	
Tea Tree Oil (UNII: VIF565UC2G)	
Sodium Chloride (UNII: 451W47IQ8X)	
Edetic Acid (UNII: 9G34HU7RV0)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Formaldehyde/Sodium Naphthalenesulfonate Copolymer (3000 MW) (UNII: 90D834OZUI)	
Xanthan Gum (UNII: TTV12P4NEE)	
Magnesium Nitrate (UNII: 77CBG3UN78)	
Methylchloroisoithiazolinone (UNII: DEL7T5QRPN)	
Magnesium Chloride (UNII: 02F3473H9O)	
Methylisothiazolinone (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82575-200-20	200 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	12/05/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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Labeler - Curology (104103284)

Revised: 12/2022

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