AQUA PLUS ACNE TREATMENT SYSTEM- salicylic acid Totally Clear 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.

Aqua Plus Acne Treatment System

daily CLEANSER

Drug Facts

Active Ingredients

Salicylic Acid 2.0%

Purpose

Acne Treatment

Uses

For The Treatment of Acne

Warnings - For External Use Only

When Using This Product:

- Avoid contact with eyes and mouth. If contact occurs, rinse thoroughly with water.
- Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.
- Limit use to face and neck.

Keep Out Of Reach Of Children

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

Wet your skin and massage the Aqua+ Daily Cleanser over your entire face, avoiding your eyes. Use the Aqua+ Daily Cleanser only once a day until your skin acclimates, after which you can move to twice-per-day applications. Rinse with water and gently pat your skin with a clean towel.

Water, Sodium Laureth Sulfate, Cetyl Alcohol, Glycerin, Aloe Barbadensis Leaf Extract, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Glyceryl Stearate, Green Tea (Camellia Sinensis) Leaf Extract, Sodium Ascorbic Phosphate, dl-Panthenol, Tocopheryl Acetate, Retinyl Palmitate, Xanthum Gum, Steareth-21, Squalane, Dimethicone, Polysorbate-60, Cprylyl Glycol, Steareth-2, Versene Na, Phosphoric Acid, Propylene Glycol, Hydrobromic Acid, Citric Acid, Glutaric Acid, Methylisothiazolinone

Other Information

Store in a cool, dry place. Do not freeze.

refreshing TONER

Drug Facts

Active Ingredients

Salicylic Acid 1.0%

Purpose

Acne Treatment

Uses

For The Treatment Of Acne

Warnings - For External Use Only

When Using This Product:

- Avoid contact with eyes and mouth. If contact occurs, rinse thoroughly with water.
- Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.
- Limit use to face and neck.

Keep Out Of Reach Of Children

• If product is swallowed, get medical help or contact a Poison Control Center right away.

Water, Propylene Glycol, SD Alcohol 40B, Cocamidopropyl Dimethylamine, Isoceteh-20, Salix Alba (Willow) Bark Extract, Methyl Gluceth-20, Caprylyl Glycol, Tetrasodium EDTA, Sodium Hydroxide, Phosphoric Acid, Hydrobromic Acid, Citric Acid, Glutaric Acid, Methlisothiazolinone

Other Information

Store in a cool, dry place. Do not freeze.

spotter GEL

Drug Facts

Active Ingredients

Salicylic Acid 1.5%

Purpose

Acne Treatment

Uses

For The Treatment Of Acne

Warnings - For External Use Only

When Using This Product:

- Avoid contact with eyes and mouth. If contact occurs, rinse thoroughly with water.
- Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.
- Limits use to face and neck.

Keep Out Of Reach Of Children

• If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

Clean the skin thoroughly before applying the Aqua+ Spotter Gel. Cover the entire affected area with a thin layer, one to three times daily. Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or 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.

Water, Propylene Glycol, SD Alcohol 40B, Cocamidopropyl Dimethylamine, Butylene Glycol, Polyquaternium-10, Spirea ulmaria (Meadowsweet) Flower Extract, Triticum Vuldare (Wheat) Germ Extract, Tetrasodium ETDA, Caprylyl Glycol, Phosphoric Acid, Hydrobromic Acid, Citric Acid, Glutaric Acid, Methylisothiazolinone

Other Information

Store in a cool, dry place. Do not freeze.

System Labeling



Aqua Plus Daily Cleanser

ТМ	Drug Facts		
	Active Ingredients Salicylic Acid 2.0%	Purpose Acne Treatment	Uses For the Treatment Of Acne
QUAPLUS SERIES	 Skin irritation and dryne 	nd mouth. If contact occu ss is more likely to occur i ime. If irritation occurs, o k. ren	rs, rinse thoroughly with water. f you use another topical acne nly use one topical acne medi– t a Poison Control Center
daily		aily Cleanser only once a o twice-per-day applicati	over your entire face, avoiding day until your skin acclimates, ons. Rinse with water and
LEANSER	Hydroxyethyl Acrylate/Sodiu Green Tea (Camellia Sinensis Tocopheryl Acetate, Retinyl cone, Polysorbate-60, Capry	um Acryloyldimethyl Taura s) Leaf Extract, Sodium Asc Palmitate, Xanthan Gum, S /lyl Glycol, Steareth-2, Vers	Aloe Barbadensis Leaf Extract, te Copolymer, Glyceryl Stearate, orbic Phosphate, dl-Panthenol, teareth-21, Squalane, Dimethi- sene Na, Phosphoric Acid, ic Acid, Methylisothiazolinone
	Other Information Store in a cool, dry place. D	o not freeze.	
50 m l	Questions?	1-888-407-8330	www.aqplus.com
NDC 71471-561-27	Totally Clear Products, Inc. Lake Worth, FL 33463		Made in the USA

Aqua Plus Refreshing Toner Label

ТМ	Drug Facts
Aqs	Active Ingredients Salicylic Acid 1.0%Purpose Acne TreatmentUses For The Treatment Of Acne
QUAPLUS SERIES	 Warnings - For External Use Only When Using This Product: Avoid contact with eyes and mouth. If contact occurs, rinse thoroughly with water. Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medi- cation at a time. Limit use to face and neck. Keep Out Of Reach Of Children If product is swallowed, get medical help or contact a Poison Control Center right away.
efreshing	Directions After cleansing your face with the Aqua+ Daily Cleanser, apply the Aqua+ Refreshing Toner with a cotton ball or soft tissue. Start to rub cotton ball over entire face. Pay extra attention to acne prone areas such as nose and cheeks. Let dry. Do not rinse. Will reduce oil and impurities and restores natural balance to skin.
TONER	Water, Propylene Glycol, SD Alcohol 40B, Cocamidopropyl Dimethylamine, Isoceteth-20, Salix Alba (Willow) Bark Extract, Methyl Gluceth-20, Caprylyl Glycol, Tetrasodium EDTA, Sodium Hydroxide, Phosphoric Acid, Hydrobromic Acid, Citric Acid, Glutaric Acid, Methylisothiazolinone
Salicylic Acid 1%	Other Information Store in a cool, dry place. Do not freeze.
	Questions? 1-888-407-8330 www.aqplus.com
50ml	
NDC 71471-416-27	Totally Clear Products, Inc. Made in the US Lake Worth, FL 33463

Aqua Plus Spotter Gel Label

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	Drug Facts	Active Ingredients Salicylic Acid 1.5%	Purpose Acne Treatment	Uses For The Treatment Of Acne
	If contact occurs, rinse t another topical acne me a time. • Limit use to f	ernal Use Only • WHEN USIN horoughly with water. • Skin ir edication at the same time. If irri ace and neck. • KEEP OUT OF RE a Poison Control Center right aw	ritation and dryness is m itation occurs, only use o ACH OF CHILDREN: • If p	ore likely to occur if you use ne topical acne medication at
spotter	area with a thin layer, o application daily, then	he skin thoroughly before applyi me to three times daily. • Becau gradually increase to two or thre ss or peeling occurs, reduce appli	ise excessive drying of the times daily if needed o	ne skin may occur, start with one r as directed by a doctor.
GEL Salicylic Acid 1.5%	Spiraea Ulmaria (Meado	l, SD Alcohol 40B, Cocamidoprop wsweet) Flower Extract, Triticun oric Acid, Hydrobromic Acid, Citr	n Vuldare (Wheat) Germ	Extract, Tetrasodium ETDA,
30ml	Other Information Store in a cool, dry place	e. Do not freeze.	Questions? 1-888-407-8330	www.aqplus.com
NDC 71471-312-27	Totally Clear Products, In	c. • Lake Worth, FL 33463		Made in the U

AQUA PLUS ACNE TREATMENT SYSTEM

salicylic acid kit

Product Information

Product Type	HUMAN O	TC DRUG	Item Code	(Source)	Ν	IDC:7147	71-269
Packaging							
# Item Code	F	Package Description	l	Marketin	ig Start Date	Marke	eting End Date
1 NDC:71471-269-27		e 1: Convenience Kit of		09/01/2017	-		-
			-				
Quantity of Parts							
Part #	Package Qua	ntity		Total	Product Qua	ntity	
Part 1 1 BOTTLE		-	50 mL			-	
Part 2 1 BOTTLE			30 mL				
Part 3 1 BOTTLE			50 mL				
Part 1 of 3							
AQUA PLUS I		EANSER					
salicylic acid solutio	n						
Product Informat	tion						
Item Code (Source)		NDC:71471-561					
Route of Administra	tion	TOPICAL					
	tion						
		TOPICAL					
Route of Administra	t/Active Moi	TOPICAL			Basis of Str	ength	Strength
Route of Administra Active Ingredient	t/Active Moie Ingi	TOPICAL	II:O414PZ4LPZ)		Basis of Str SALICYLIC ACI	_	Strength 20 mg in 1 mL
Route of Administra Active Ingredient	t/Active Moie Ingi	TOPICAL ety redient Name	II:O414PZ4LPZ)			_	
Route of Administra Active Ingredient SALICYLIC ACID (UN	t/ Active Moie Ingı II: 0414PZ4LPZ)	TOPICAL ety redient Name	II:O414PZ4LPZ)			_	
Route of Administra Active Ingredient SALICYLIC ACID (UN	t/ Active Moie Ingı II: 0414PZ4LPZ)	TOPICAL ety redient Name (SALICYLIC ACID - UN				_	20 mg in 1 mL
Route of Administra Active Ingredient	t/ Active Moie Ingı II: 0414PZ4LPZ)	TOPICAL ety redient Name				_	
Route of Administra Active Ingredient SALICYLIC ACID (UN Inactive Ingredie WATER (UNII: 059QF0	t/Active Moie Ingi II: 0414PZ4LPZ) nts	TOPICAL ety redient Name (SALICYLIC ACID - UN Ingredient Nar				_	20 mg in 1 mL
Route of Administra Active Ingredient SALICYLIC ACID (UN Inactive Ingredie WATER (UNII: 059QF0 SODIUM LAURETH-3	t/Active Moie Ingr II: 0414PZ4LPZ) nts PKO0R) SULFATE (UNI	TOPICAL ety redient Name (SALICYLIC ACID - UN Ingredient Nam				_	20 mg in 1 mL
Route of Administra Active Ingredient SALICYLIC ACID (UN Inactive Ingredie WATER (UNII: 059QF0 SODIUM LAURETH-3 CETYL ALCOHOL (U	t/Active Moie Ing II: 0414PZ4LPZ) nts KOOR) SULFATE (UNII NII: 936JST6JCP	TOPICAL ety redient Name (SALICYLIC ACID - UN Ingredient Nam				_	20 mg in 1 mL
Route of Administra Active Ingredient SALICYLIC ACID (UN Inactive Ingredie WATER (UNII: 059QF0 SODIUM LAURETH-3 CETYL ALCOHOL (U GLYCERIN (UNII: PDC	t/Active Moie Ingi II: 0414PZ4LPZ) nts KO0R) SULFATE (UNII NII: 936JST6JCP 6A3C0OX)	TOPICAL ety redient Name (SALICYLIC ACID - UN Ingredient Nam E: BPV390UAP0)				_	20 mg in 1 mL
Route of Administra Active Ingredient SALICYLIC ACID (UN Inactive Ingredie WATER (UNII: 059QF0 SODIUM LAURETH-3 CETYL ALCOHOL (U GLYCERIN (UNII: PDC ALOE VERA LEAF (UI	t/Active Moie Ing II: 0414PZ4LPZ) nts NII: 936JST6JCP 6A3C0OX) NII: ZY81Z83H07	TOPICAL ety redient Name (SALICYLIC ACID - UN Ingredient Nar E: BPV390UAP0) N) K)				_	20 mg in 1 mL
Route of Administra Active Ingredient SALICYLIC ACID (UN Inactive Ingredie WATER (UNII: 059QF0 SODIUM LAURETH-3 CETYL ALCOHOL (U GLYCERIN (UNII: PDC ALOE VERA LEAF (UI GLYCERYL MONOST	t/Active Moie Ing II: 0414PZ4LPZ) nts KO0R) SULFATE (UNII NII: 936JST6JCP 6A3C0OX) NII: ZY8 1Z8 3H0 X	TOPICAL ety redient Name (SALICYLIC ACID - UN Ingredient Nar E: BPV390UAP0) N)				_	20 mg in 1 mL
Route of Administra Active Ingredient SALICYLIC ACID (UN Inactive Ingredie WATER (UNII: 059QF0 SODIUM LAURETH-3 CETYL ALCOHOL (U GLYCERIN (UNII: PDC ALOE VERA LEAF (UI GLYCERYL MONOST GREEN TEA LEAF (UN	t/Active Moie Ing II: 0414PZ4LPZ) nts NII: 0414PZ4LPZ) NII: 0414PZ4LPZ) NII: 0414PZ4LPZ NII: 0414PZ4 NII: 0414PZ4 NII: 0414PZ4 NII: 04128 NII: 04128 N	TOPICAL e ty redient Name (SALICYLIC ACID - UN Ingredient Nar E BPV390UAP0) N) () () () () () () () () () (_	20 mg in 1 mL
Route of Administra Active Ingredient SALICYLIC ACID (UN Inactive Ingredie WATER (UNII: 059QF0 SODIUM LAURETH-3 CETYL ALCOHOL (U GLYCERIN (UNII: PDC ALOE VERA LEAF (UN GLYCERYL MONOST GREEN TEA LEAF (UN	t/Active Moie Ing II: 0414PZ4LPZ) nts NII: 936JST6JCP 6A3C0OX) NII: ZY81Z83H02 FEARATE (UNII: NII: W2ZU1RY8B(PHOSPHATE (U	TOPICAL e ty redient Name (SALICYLIC ACID - UN Ingredient Nar E BPV390UAP0) N) () () () () () () () () () (_	20 mg in 1 mL
Route of Administra Active Ingredient SALICYLIC ACID (UN Inactive Ingredie WATER (UNII: 059QF0 SODIUM LAURETH-3 CETYL ALCOHOL (U GLYCERIN (UNII: PDC ALOE VERA LEAF (UI GLYCERYL MONOST GREEN TEA LEAF (UP SODIUM ASCORBYL PANTHENOL (UNII: W	t/Active Moie Ing II: 0414PZ4LPZ) nts KO0R) SULFATE (UNII NII: 936JST6JCP 6A3C0OX) NII: ZY81Z83H02 FEARATE (UNII: NII: W2ZU1RY8B(PHOSPHATE (U	TOPICAL e ty redient Name (SALICYLIC ACID - UN Ingredient Nar E BPV390UAP0) N) () () 2300U9XXE4) 0) JNIE: 836SJG51DR)				_	20 mg in 1 mL
Route of Administra Active Ingredient SALICYLIC ACID (UN Inactive Ingredie WATER (UNII: 059QF0 SODIUM LAURETH-3 CETYL ALCOHOL (U GLYCERIN (UNII: PDC ALOE VERA LEAF (UN GREEN TEA LEAF (UN SODIUM ASCORBYL PANTHENOL (UNII: W .ALPHATO COPHER	t/Active Moie Ing II: 0414PZ4LPZ) nts NII: 936JST6JCP 6A3C0OX) NII: ZY81Z83H02 CEARATE (UNII: NII: W2ZU1RY8B(PHOSPHATE (U V9CM0067Z) OL ACETATE (U	TOPICAL e ty redient Name (SALICYLIC ACID - UN Ingredient Nar E BPV390UAP0) N) () 2300U9XXE4) 0) JNIE 836SJG51DR) UNII: 9E8X80D2L0)				_	20 mg in 1 mL
Route of Administra Active Ingredient SALICYLIC ACID (UN Inactive Ingredie WATER (UNII: 059QF0 SODIUM LAURETH-3 CETYL ALCOHOL (U GLYCERIN (UNII: PDC ALOE VERA LEAF (UI GLYCERYL MONOST GREEN TEA LEAF (UN SODIUM ASCORBYL PANTHENOL (UNII: W .ALPHATO COPHER(VITAMIN A PALMITA	t/Active Moie Ingi II: 0414PZ4LPZ) nts NII: 0414PZ4LPZ) NII: 0414PZ4LPZ) NII: 936JS16JCN 6A3C00R) SULFATE (UNII NII: 936JS16JCN 6A3C00X) NII: 2Y8 1Z8 3H0 X FEARATE (UNII: NII: W2ZU1RY8 B PHOSPHATE (UNII: V9CM0067Z) OL ACETATE (U	TOPICAL e ty redient Name (SALICYLIC ACID - UN Ingredient Nar E BPV390UAP0) N) () 2300U9XXE4) 0) JNIE 836SJG51DR) UNII: 9E8X80D2L0)				_	20 mg in 1 mL
Route of Administra Active Ingredient SALICYLIC ACID (UN Inactive Ingredie WATER (UNII: 059QF0 SODIUM LAURETH-3 CETYL ALCOHOL (U GLYCERIN (UNII: PDC ALOE VERA LEAF (UI GLYCERYL MONOST GREEN TEA LEAF (UP SODIUM ASCORBYL PANTHENOL (UNII: W	t/Active Moie Ing II: 0414PZ4LPZ) nts NII: 0414PZ4LPZ) NII: 0414PZ4LPZ) NII: 0414PZ4LPZ) NII: 0414PZ4LPZ) NII: 0414PZ4LPZ NII: 0414PZ4 NII: 0412PZ NII: 0414PZ4 NII: 0412PZ NII: 0412P	TOPICAL e ty redient Name (SALICYLIC ACID - UN Ingredient Nar E BPV390UAP0) N) () 2300U9XXE4) 0) JNIE 836SJG51DR) UNII: 9E8X80D2L0)				_	20 mg in 1 mL

DIMETHICO NE (UN	III: 92RU3N3Y1O)					
POLYSORBATE 60	(UNII: CAL22UVI4	4M)				
CAPRYLYL GLYCO	DL (UNII: 00 YIU543	38U)				
STEARETH-2 (UNII:	V56DFE46J5)					
EDETATE DISODIU	M (UNII: 7FLD91C	86K)				
PHO SPHO RIC ACIE) (UNII: E4GA8884	NN)				
PROPYLENE GLYC	C OL (UNII: 6DC9Q	167V3)				
HYDROBROMIC AC	C ID (UNII: 3IY7CNI	28 XJ)				
CITRIC ACID MONO	OHYDRATE (UNII:	2968PHW8QP)				
GLUTARIC ACID (U	JNII: H849F7N00B)	•				
METHYLISOTHIAZ	OLINONE (UNII: 2	229D0E1QFA)				
Packaging						
# Item Code		Package Description	Mar	keting Start Date	Mark	eting End Dat
1 NDC:71471-561- 27	50 mL in 1 BOTT Package	LE; Type 1: Convenience Kit of Co-				
Marketing In	nformation					
Marketing Catego	Applicatio	on Number or Monograph Citation	Market	ing Start Date	Marke	eting End Date
	ny Application		iviai ne e	ing bluit butt		
			09/01/201	_		0
OTC monograph fina		5 F		_		
OTC monograph fina Part 2 of 3				_		
OTC monograph fina Part 2 of 3	ıl part333D			_		
OTC monograph fina Part 2 of 3 AQUA PLUS	ıl part333D			_		
OTC monograph fina Part 2 of 3	ıl part333D			_		
OTC monograph fina Part 2 of 3 AQUA PLUS	ıl part333D			_		
OTC monograph fina Part 2 of 3 AQUA PLUS salicylic acid gel	al part333D SPOTTER			_		
OTC monograph fina Part 2 of 3 AQUA PLUS salicylic acid gel	al part333D SPOTTER			_		
OTC monograph fina Part 2 of 3 AQUA PLUS salicylic acid gel Product Inform	ation			_		
OTC monograph fina Part 2 of 3 AQUA PLUS salicylic acid gel Product Inform Item Code (Source	al part333D SPOTTER ation e)	GEL NDC:71471-312		_		
OTC monograph fina Part 2 of 3 AQUA PLUS salicylic acid gel Product Inform Item Code (Source	al part333D SPOTTER ation e)	GEL		_		
OTC monograph fina Part 2 of 3 AQUA PLUS salicylic acid gel Product Inform Item Code (Source	al part333D SPOTTER ation e)	GEL NDC:71471-312		_		
OTC monograph fina Part 2 of 3 AQUA PLUS salicylic acid gel Product Inform Item Code (Source Route of Administ	ation ration	GEL NDC:71471-312 TOPICAL		_		
OTC monograph fina Part 2 of 3 AQUA PLUS salicylic acid gel Product Inform Item Code (Source Route of Administ	ation e) ration	GEL NDC:71471-312 TOPICAL		.7		
OTC monograph fina Part 2 of 3 AQUA PLUS salicylic acid gel Product Inform Item Code (Source Route of Administ	ation e) ration	GEL NDC:71471-312 TOPICAL		_		Strength
OTC monograph fina Part 2 of 3 AQUA PLUS salicylic acid gel Product Inform Item Code (Source Route of Administ	ation e) ration	GEL NDC:71471-312 TOPICAL		.7	ngth	
OTC monograph fina Part 2 of 3 AQUA PLUS salicylic acid gel Product Inform Item Code (Source Route of Administ	ation e) ration	GEL NDC:71471-312 TOPICAL ety redient Name		7 Basis of Stre	ngth	Strength
OTC monograph fina Part 2 of 3 AQUA PLUS salicylic acid gel Product Inform Item Code (Source Route of Administ Active Ingredie SALICYLIC ACID (U	ation e) ration ent/Active Moi Ing UNII: O414PZ4LPZ)	GEL NDC:71471-312 TOPICAL ety redient Name (SALICYLIC ACID - UNII:O414PZ4LPZ)		7 Basis of Stre	ngth	Strength 15 mg in 1 mL
OTC monograph fina Part 2 of 3 AQUA PLUS salicylic acid gel Product Inform Item Code (Source Route of Administ Active Ingredie SALICYLIC ACID (U	ation e) ration ent/Active Moi Ing UNII: O414PZ4LPZ)	GEL NDC:71471-312 TOPICAL ety redient Name		7 Basis of Stre	ngth	Strength
OTC monograph fina Part 2 of 3 AQUA PLUS salicylic acid gel Product Inform Item Code (Source Route of Administ Active Ingredie SALICYLIC ACID (U Inactive Ingred	ation e) ration ent/Active Moi Ing UNII: 0414PZ4LPZ)	GEL NDC:71471-312 TOPICAL ety redient Name (SALICYLIC ACID - UNII:O414PZ4LPZ)		7 Basis of Stre	ngth	Strength 15 mg in 1 mL
OTC monograph fina Part 2 of 3 AQUA PLUS salicylic acid gel Product Inform Item Code (Source Route of Administ Active Ingredie SALICYLIC ACID (U Inactive Ingred	ation ation ation ation ation ation ation ation brokoor) brokoor)	GEL GEL IDDC:71471-312 TOPICAL GEU GUIDE CAL GUIDE CALICYLIC ACID - UNII:0414PZ4LPZ5		7 Basis of Stre	ngth	Strength 15 mg in 1 mL
OTC monograph fina Part 2 of 3 AQUA PLUS salicylic acid gel Product Inform Item Code (Source Route of Administ Active Ingredie SALICYLIC ACID (U Inactive Ingred WATER (UNII: 059Q PROPYLENE GLYC	ation bit	GEL GEL IDDC:71471-312 TOPICAL GEU GUIDE CAL GUIDE CALICYLIC ACID - UNII:0414PZ4LPZ5		7 Basis of Stre	ngth	Strength 15 mg in 1 mL

WHEAT CEDM (UNII)	VD2C260E5A)					
WHEAT GERM (UNII:)		U)				
EDETATE SODIUM (U						
CAPRYLYL GLYCOL PHO SPHORIC ACID (
HYDROBROMIC ACID		,				
CITRIC ACID MONOH						
GLUTARIC ACID (UN						
METHYLISOTHIAZO						
Packaging						
# Item Code		Package Description	Marke	ting Start Date	Marke	ting End Date
		LE; Type 1: Convenience Kit of Co-		0		8
	ackage					
Marketing Inf	ormation					
Marketing Category	y Applicatio	on Number or Monograph Citation	Market	ing Start Date	Marke	ting End Date
OTC monograph final	part333D		09/01/201	17		
Part 3 of 3						
AQUA PLUS I	REFRESH	ING TONER				
salicylic acid solutio	n					
Product Information	tion					
Item Code (Source)		NDC:71471-416				
Route of Administra	tion	TOPICAL				
Active Ingredient	t/Active Moi	ety				
	Ing	redient Name		Basis of Stre	ngth	Strength
SALICYLIC ACID (UN	III: O414PZ4LPZ)	(SALICYLIC ACID - UNII:O414PZ4LPZ)		SALICYLIC ACIE)	10 mg in 1 mL
Inactive Ingredie	nts					
		Ingredient Name				Strength
WATER (UNII: 059QF0						
PROPYLENE GLYCO						
		INE (UNII: L36BM7DG2T)				
ISOCETETH-20 (UNII:						
WILLOW BARK (UNI						
METHYL GLUCETH-2	:0 (UNII: J3QD0	LD11P)				
CAPRYLYL GLYCOL EDETATE SODIUM (U						

	(UNII: E4GA8884NN)		
HYDROBROMIC AC	ID (UNII: 3IY7CNP8 XJ)		
CITRIC ACID MONO	HYDRATE (UNII: 2968PHW8QP)		
GLUTARIC ACID (U	NII: H849F7N00B)		
METHYLISOTHIAZ	DLINONE (UNII: 229 D0 E1QFA)		
Packaging			
		Marketing Start	Marketing End Dat
# Item Code	Package Description	Date	
NDC:71471 416	Package Description 50 mL in 1 BOTTLE; Type 1: Convenience Kit of Co- Package	Date	
1 NDC:71471-416-	50 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-	Date	
1 NDC:71471-416- 27	50 mL in 1 BOTTLE; Type 1: Convenience Kit of Co- Package	Date	
1 NDC:71471-416- 27 Marketing In	50 mL in 1 BOTTLE; Type 1: Convenience Kit of Co- Package formation		
1 NDC:71471-416- 27	50 mL in 1 BOTTLE; Type 1: Convenience Kit of Co- Package formation	Date Marketing Start Date	Marketing End Date
1 NDC:71471-416- 27 Marketing In Marketing Catego	50 mL in 1 BOTTLE; Type 1: Convenience Kit of Co- Package formation		
1 NDC:71471-416- 27 Marketing In	50 mL in 1 BOTTLE; Type 1: Convenience Kit of Co- Package formation ry Application Number or Monograph Citation	Marketing Start Date	
1 NDC:71471-416- 27 Marketing In Marketing Catego	50 mL in 1 BOTTLE; Type 1: Convenience Kit of Co- Package formation ry Application Number or Monograph Citation	Marketing Start Date	
1 NDC:71471-416- 27 Marketing In Marketing Catego	50 mL in 1 BOTTLE; Type 1: Convenience Kit of Co- Package	Marketing Start Date	
1 NDC:71471-416- 27 Marketing In Marketing Catego OTC monograph fina	50 mL in 1 BOTTLE; Type 1: Convenience Kit of Co- Package	Marketing Start Date	

Labeler - Totally Clear Products, Inc (080687729)

Revised: 12/2017

Totally Clear Products, Inc