

**ANTISEPTIC- benzalkonium chloride, benzocaine spray**  
**JHK 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.*

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**Drug Facts**

**Active Ingredient**

Benzalkonium Chloride 0.1%

Benzocaine 5.0%

**Purpose**

First aid antiseptic

Topical pain relief

**Uses**

First aid to help prevent infection and relieve pain in minor cuts, scrapes and burns.

**Warnings**

**For external use only. Flammable keep away from fire or flame.**

**Do not use**

- near eyes or mucous membranes
- on deep or puncture wounds, animal bites or serious burns
- over large areas of the body
- more than one week unless directed by a doctor

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

**Stop use and ask a doctor if** conditions persist or get worse.

**Directions**

- clean the affected area
- apply a small amount of this product on the area 1 - 3 times daily
- children under 2 ask a doctor

**Other Information**

- store at room temperature

**Inactive ingredients**

isopropyl alcohol, purified water

**Questions?**

1-866-651-3660

Mon-Fri 8:00am-5:00pm EST

Manufactured for American Safety & First Aid Osceola, IN 48561

V1\_11-7-19

**Principal Display Panel – Bottle Label**

0681

NDC 73598-0681-1

**Antiseptic**

First Aid Antiseptic

For Temporary Pain Relief  
and to Help Prevent  
Infection in Minor Cuts,  
Scrapes and Abrasions

**American Safety  
& First Aid**

2 fl. Oz. (59.1 ml)

<b>Drug Facts</b>		0681
<b>Active ingredient</b>	<b>Purpose</b>	NDC 73598-0681-1
Benzalkonium Chloride 0.1%.....	First aid antiseptic	 <p>First Aid Antiseptic</p> <p>For Temporary Pain Relief and to Help Prevent Infection in Minor Cuts, Scrapes and Abrasions.</p> 
Benzocaine 5.0%.....	Topical pain relief	
<b>Uses</b> First aid to help prevent infection and relieve pain in minor cuts, scrapes and burns.		<p>2 fl. oz. (59.1ml)</p>
<b>Warnings</b> For external use only. Flammable keep away from fire or flame.		
<b>Do not use</b> ■ near eyes or mucous membranes ■ on deep or puncture wounds, animal bites or serious burns ■ over large areas of the body ■ more than one week unless directed by a doctor		
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.		
<b>Stop use and ask a doctor if</b> conditions persist or get worse.		
<b>Directions</b> ■ clean the affected area ■ apply a small amount of this product on the area 1 - 3 times daily ■ children under 2 ask a doctor		
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<b>Questions?</b> 1-866-651-3660 Mon-Fri 8:00am-5:00pm EST		
Manufactured for American Safety & First Aid Osceola, IN 46561 V1_11-7-19		

**ANTISEPTIC**  
benzalkonium chloride, benzocaine spray

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73598-0681
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>benzalkonium chloride</b> (UNII: F5UM2KM3W7) (benzalkonium - UNII:7N6JUD5X6Y)	benzalkonium chloride	100 mg in 1 mL
<b>benzocaine</b> (UNII: U3RSY48JW5) (benzocaine - UNII:U3RSY48JW5)	benzocaine	50 mg in 1 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>isopropyl alcohol</b> (UNII: ND2M416302)	
<b>water</b> (UNII: 059QF0K00R)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:73598-0681-1	59.1 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	02/14/2020	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	02/14/2020	

**Labeler** - JHK Inc (867236309)**Registrant** - Safetec of America, Inc. (874965262)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Safetec of America, Inc.		874965262	MANUFACTURE(73598-0681)

Revised: 2/2020

JHK Inc