

**MULTIPURPOSE DISINFECTANT- hydrogen peroxide spray**  
**Amicus Asia Pacific(Hubei) Healthcare Products Pte Ltd**

*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.*

Store between 15-30°C (59-86°F)

Purified Water USP, Fragrance

Place enough product on hands to cover all surfaces. Rub hands together until dry.

Hydrogen peroxide

keep out of reach of children

Disinfection

Sterilization

No Rinseing

For externa/ use only.Do not use in children less than 2 months of age.When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Drug Facts	
<b>Active Ingredient[s]</b>	<b>Purpose</b>
Hydrogen Peroxide (1.2%)W/W.....	Antiseptic
<b>Use[s]</b>	
Multipurpose Disinfectant Spray for Children helps to reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
<ul style="list-style-type: none"> <li>- For external use only.</li> <li>- Do not use in children less than 2 months of age.</li> <li>- When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</li> <li>- Stop use and ask a doctor if irritation or rash occurs. This may be signs of a serious condition.</li> <li>- Keep out of reach of children. If swallowed, get medical help or contact a Posison Control Center right away.</li> </ul>	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>- Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>- Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other Information</b>	
- Store between 15-30C (59-86F)	
<b>Inactive Ingredients</b>	
Purified Water USP, Fragrance.	

**Manufacturer**  
 Amicus Asia Pacific (Hubei) Healthcare Products Pte Ltd  
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 Hubei Province, China  
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<b>MULTIPURPOSE DISINFECTANT</b>			
hydrogen peroxide spray			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54345-001
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	0.48 g in 40 mL

**Inactive Ingredients**

Ingredient Name	Strength
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	
WATER (UNII: 059QF0KO0R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54345-001-01	40 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/03/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/03/2020	

**Labeler** - Amicus Asia Pacific(Hubei) Healthcare Products Pte Ltd (543259254)**Establishment**

Name	Address	ID/FEI	Business Operations
Amicus Asia Pacific(Hubei) Healthcare Products Pte Ltd		543259254	manufacture(54345-001)

Revised: 7/2020

Amicus Asia Pacific(Hubei) Healthcare Products Pte Ltd