

**HS100XG- ethyl alcohol gel**  
**Integrity Bio-Chemicals, LLC**

*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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**Integrity Biochem Hand Sanitizer**

***Drug Facts***

***Active Ingredient[s]*** Alcohol 80% v/v

***Purpose*** Antiseptic

***Use(s)***

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

***Warnings***

For external use only. Flammable. Keep away from heat or flame

***Do not use***

- On children less than 2 months of age
- On open skin wounds

**When using this product** keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.

**Stop use and ask a doctor** if irritation occurs. These may be signs of a serious condition.

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

***Directions***

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using the product to avoid swallowing.

***Other information***

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

***Inactive Ingredients:*** glycerin, hydrogen peroxide, water

**Package Label**

**INTEGRITY**

**BIOCHEM**

**Hand Sanitizer**

**HS100XG**

**80% Alcohol**

3.79 L (1 US gal.)      Moisturizing Solution

Manufactured by: INTEGRITY BIOCHEM

CRESSON, TX 76035

www.integritybiochem.com

NDC: 75512-001-01      0 51497 17031 8

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## HS100XG

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### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75512-001
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75512-001-01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/16/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	04/16/2020	

**Labeler** - Integrity Bio-Chemicals, LLC (080873668)

**Registrant** - Integrity Bio-Chemicals, LLC (080873668)

Establishment			
Name	Address	ID/FEI	Business Operations
Integrity Bio-Chemicals, LLC		080873668	manufacture(75512-001)