

HAND SANITIZER- alcohol gel
Zermat Internacional S.A. de C.V.

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.

Hand Sanitizer Gel

Drug Facts

Active ingredient[s]

Alcohol 80% v/v

Purpose

Antiseptic

Use[s]

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product

keep out eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor

if irritation or rash 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 this product to avoid swallowing.

Other information

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

Inactive ingredients:

Purified water, Carbomer, Fragrance, AMP, Blue No. 1 CI. 42090

Package Labeling:

zermat®

Gel

ALCOHOL ANTISEPTIC 80%
TOPICAL PRODUCT
HAND SANITIZER
NON-STERILE PRODUCT

ALCOHOL ANTISÉPTICO 80%
PRODUCTO TÓPICO
DESINFECTANTE DE MANOS
PRODUCTO NO ESTÉRIL

CONT. NET. 195 ML

30

Drug Facts	
Active ingredient(s)	Purpose
Alcohol 80% v/v.....	Antiseptic
Use(s)	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings	
For external use only. Flammable. Keep away from heat or flame.	
Do not use	
• in 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 eyes thoroughly with water.	
Stop use and ask a doctor if irritation or rash 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 this product to avoid swallowing.	
Other information	
• Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F)	
Inactive ingredients: Purified water, Carbomer, Fragrance, AMP, Blue No. 1 CI. 42090.	

Información	
Ingrediente Activo	Propósito
Alcohol 80% v/v.....	Antiséptico
Uso	
Desinfectante de manos para ayudar a reducir las bacterias que potencialmente pueden causar enfermedades. Para usar cuando no hay agua y jabón disponibles.	
Advertencias	
Sólo para uso externo. Inflamable. Mantener alejado del calor o las llamas.	
No utilice	
• en niños menores de 2 meses de edad • en heridas abiertas de la piel	
Cuando use este producto, manténgalo fuera de los ojos, oídos y boca. En caso de contacto con los ojos, enjuague bien los ojos con agua.	
Suspenda su uso y consulte a un médico si se produce irritación o sarpullido. Estos pueden ser signos de una afección grave.	
Mantener fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o comuníquese con un Centro de Control de Envenenamiento de inmediato.	
Instrucciones	
• Coloque suficiente producto en las manos para cubrir todas las superficies. Frotar las manos juntas hasta que se sequen. • Supervise a los niños menores de 6 años cuando use este producto para evitar que se lo traguen.	
Otra información	
• Almacenar entre 15-30°C (59-86°F) • Evite el congelamiento y el calor excesivo por encima de 40°C (104°F)	
Ingredientes inactivos: Agua purificada, Carbómero, Fragancia, AMP, Azul No. 1 CI. 42090.	

HECHO EN MÉXICO / MADE IN MEXICO
Hecho en México por:/ Made in Mexico by:
Zermat Internacional, S.A. de C.V.
Lázaro Cárdenas No. 47, Col. San Jerónimo Tepetlaco, Tlalnepanla, Estado de México, México, C.P. 54090
Distributed by: / Distribuido por: Zermat USA Inc.
3540 W T C Jester Blvd, Houston, TX 77018.

Lote. / Lot No.
Cad. / Exp. Date.

74151

zermat®
INTERNACIONAL
®MARCA REGISTRADA

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:15828-196
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.8 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
ADENOSINE PHOSPHATE (UNII: 415SHH325A)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15828-196-01	195 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/24/2020	

Labeler - Zermat Internacional S.A. de C.V. (812820712)

Revised: 4/2020

Zermat Internacional S.A. de C.V.