

**COVIDEX- vernel kozmetik spray**  
**VERNEL KOZMETIK SANAYI VE TICARET ANONIM SIRKETI**

*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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This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

**Active Ingredient(s)**

Alcohol 75% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

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.

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

**Inactive ingredients**

glycerin,carbomer 940,trolamine, aloe vera leaf, fragrance lemon, purified water USP

**Package Label - Principal Display Panel**



*Spray*  
**SANITIZER**  
ALCOHOL BASED FORMULA

**Instructions:** Just put some spray on the palms of your hands and rub in for about 15-30 seconds. Wash your hands if you are sensitive to any substance in the product content. **Hazard warnings:** Flammable liquid, Causes serious eye irritation. **Safety instructions:** Prevention: Keep away from heat / sparks / open flames. Do not smoke. Keep container closed. **IF IN EYES:** Rinse gently with water for a few minutes. Remove contact lenses if possible. Continue to rinse. If eye irritation persists: Get medical advice / attention. Do not use for dry chemical, alcohol or chemical resistant foam to extinguish. **Storage:** Store in a well-ventilated place in a cool place. **Disposal:** Dispose of the contents / container to an approved waste disposal unit.

**Instrucciones:** Sólo aplique un poco de rociar en las palmas de las manos y frótele durante unos 15-30 segundos. Lávese las manos si es sensible a cualquier sustancia en el contenido del producto. **Advertencia:** Líquido inflamable. Causa irritación ocular grave. **Instrucciones de seguridad:** Mantener alejado del calor / chispas / llamas abiertas / superficies calientes. No fumar. No encender cigarrillos. **SI EN LOS OJOS:** Enjuague suavemente con agua durante unos minutos. Si la irritación persiste: Continuar enjuagando. Si la irritación ocular persiste: obtener consejo médico. **En caso de incendio:** Utilice polvo químico seco, alcohol o espuma resistente a productos químicos. **Almacenamiento:** Almacenar en un lugar bien ventilado. **Eliminación:** Eliminar el contenido / contenedor en una instalación de eliminación de residuos aprobada.

**Instructions:** Il suffit de mettre un peu de vaporisateur sur la paume de vos mains et de frotter pendant environ 15-30 secondes. **Avertissement:** Vérifiez avant utilisation si vous êtes sensible à une substance dans le contenu. **Précautions de danger:** Liquide et vapeurs inflammables. Provoque une sévère irritation des yeux. **Prévention:** Tenir à l'écart de la chaleur/des étincelles/des flammes nues / des surfaces chaudes. Ne pas fumer. Garder le récipient fermé. **EN CAS DE CONTACT AVEC LES YEUX:** rincer avec abondance pendant quelques minutes. Retirez si possible les lentilles de contact. Continuez à rincer. Si l'irritation persiste: consultez un médecin. **En cas d'incendie:** utiliser un produit chimique approprié. **Stockage:** stocker dans un endroit bien ventilé. **Élimination:** éliminer le contenu / récipient dans une installation d'élimination des déchets approuvée.

INGREDIENTS: CAS NO % v/v  
64-17-5 80

**INACTIVE INGREDIENTS:** Aqua, Glycerin, Carborner, Triethanolamine, Fragrance, Aloe Barbadensis Extract

**Vernel Kozmetik San. ve Tic. A.Ş.**  
Ataköy Mah. Akademi Sok. No: 10  
34750 Beşiktaş / İstanbul  
Tic. Sic. No: 272027  
WWW.VERNEL.COM



4,22 oz  
125 ml e

Pro. Date : 06.2020  
Exp. Date : 06.2022  
Batch No : H20008







**COVIDEX**

*Spray*

**SANITIZER**

ALCOHOL BASED FORMULA

SURFACE SANITIZING



AIR SANITIZING

80% alcohol



Glycerin  
+  
Aloe Vera

*effective*

**AGAINST VIRUSES & BACTERIAS**

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## COVIDEX

vernel kozmetik spray

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79652-004
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	1.18 mL in 100 mL
WATER (UNII: 059QF0KO0R)	24.718 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.47 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.24 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.12 mL in 100 mL
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	0.83 mL in 100 mL

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:79652-004-02	400 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
2	NDC:79652-004-01	125 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	

**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	03/30/2020	

**Labeler** - VERNEL KOZMETIK SANAYI VE TICARET ANONIM SIRKETI (519821634)**Registrant** - VERNEL KOZMETIK SANAYI VE TICARET ANONIM SIRKETI (519821634)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
VERNEL KOZMETIK SANAYI VE TICARET ANONIM SIRKETI		519821634	manufacture(79652-004)