

LEMON SANITIZING COLOGNE- alcohol spray
L3VEL3 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.

Lemon Sanitizing Cologne

Purpose

Sanitizing Cologne

Description

Refreshing and energizing, the LEVEL3 Lemon Cologne delivers a fresh and aromatic citrus fragrance. The scent combines lemon and a sweet smell of vanilla, producing an elegant and revitalizing aroma that is perfect for any occasion.

Directions:

Apply to clean and dry skin. Pour a small amount of cologne on your palm or fingers and dab gently on the desired areas.

Warnings

For external use only. Flammable. Do not use near heat or open flame. Avoid Contact with Eyes. In case of contact with eyes, rinse with plenty of water. Keep out of the reach of children. Keep in a cool place protected from direct sunlight.

Keep out of the reach of children.

Active Ingredient(s)

Alcohol

Inactive ingredients

Aqua, Parfum, Coumarin, Limonene, Hydroxycitronellal, Alpha-Isomethyl Ionone, Linalool

Package Label - Principal Display Panel



LEMON SANITIZING COLOGNE

SPRAY DÉSINFECTANT AU CITRON
SPRAY DÉSINFECTANTE DE LIMÓN

ANTISEPTIC
ANTISEPTIQUE
ANTISÉPTICO

REFRESHING
RAFRAÎCHISSANT
REFRESCANTE

80% ALCOHOL
80% D'ALCOOL
80% DE ALCOHOL

8.45 FL.OZ / 250 ML

EN: DESCRIPTION: Refreshing and energizing, the LEVEL3 Lemon Sanitizing Cologne delivers a fresh and aromatic citrus fragrance. The scent combines lemon and a sweet smell of vanilla, producing an elegant and revitalizing aroma that is perfect for any occasion. **HOW TO USE:** Apply to clean and dry skin. Pour a small amount of cologne on your palm or fingers and dab gently on the desired areas. **WARNINGS:** For external use only. Flammable. Do not use near heat or open flame. Avoid contact eyes. Rinse with plenty of water in case of contact. Keep out of reach of children. Keep in a cool place protected from direct sunlight.

FR: DESCRIPTION: Rafraîchissante et énergisante, la LEVEL3 Lemon Sanitizing Cologne délivre un parfum d'agrumes frais et aromatique. Le parfum combine le citron et une douce odeur de vanille, produisant un arôme élégant et revitalisant qui est parfait pour toute occasion. **MODE D'EMPLOI:** Appliquez sur une peau propre et sèche. Versez une petite quantité d'eau de Cologne sur votre paume ou vos doigts et tamponnez doucement les zones souhaitées. **AVERTISSEMENTS:** Pour usage externe uniquement. Inflammable. Ne pas utiliser à proximité de la chaleur ou d'une flamme nue. Évitez les yeux de contact. Rincer abondamment à l'eau en cas de contact. Tenir hors de portée des enfants. Conserver dans un endroit frais à l'abri de la lumière directe du soleil.

SP: DESCRIPCIÓN: Refrescante y energizante, la LEVEL3 Lemon Sanitizing Cologne proporciona una fragancia cítrica fresca y aromática. El aroma combina el limón y un dulce olor a vainilla, produciendo un elegante y revitalizante aroma que es perfecto para cualquier ocasión. **INSTRUCCIONES:** Aplicar sobre la piel limpia y seca. Vierte una pequeña cantidad de colonia en la palma de la mano o en los dedos y frota suavemente en las áreas deseadas. **ADVERTENCIAS:** Solo para uso externo. Inflammable. No lo use cerca del calor o llamas abiertas. Evitar el contacto con los ojos. Enjuague con abundante agua en caso de contacto. Mantener fuera del alcance de los niños. Mantener en un lugar fresco protegido de la luz solar directa.

INGREDIENTS: Alcohol Denat., Aqua, Parfum, Coumarin, Limonene, Hydroxycitronellal, Alpha-Isomethyl Ionone, Linalool.

LEVEL3

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MADE IN TURKEY
FABRIQUÉ EN TURQUIE
HECHO EN PAVO
ITEM# 100120

8.45 FL.OZ / 250 ML



250 mL NDC: 80848-003-01

LEMON SANITIZING COLOGNE

alcohol spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:80848-003 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M) | ALCOHOL | 80 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|--------------------|
| LINALOOL, (+/-)- (UNII: D81QY6I88E) | 0.016 mL in 100 mL |
| HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR) | 0.032 mL in 100 mL |
| ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B) | 0.025 mL in 100 mL |
| COUMARIN (UNII: A4VZ22K1WT) | 0.045 mL in 100 mL |
| LIMONENE, (+/-)- (UNII: 9MC3I34447) | 0.039 mL in 100 mL |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:80848-003-01 | 250 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 10/15/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 10/15/2020 | |

Labeler - L3VEL3 LLC (128877852)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|------------------------|
| KOZMOTEK PAZARLAMA KOZMETIK ITHALAT IHRACAT SANAYI VE TICARET LIMITED SIRKETI | | 505246218 | manufacture(80848-003) |

Revised: 10/2020

L3VEL3 LLC