

BUBISON GOLD GEL (ETHANOL) COMPLETE HAND SANITIZER- alcohol gel
Seoul cosmetics co 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.

ethanol

Purifiedwater, butyleneglycol, carbomer, licoriceextract, glycerin, aloevera gel, greenteaextract, sodiumhyaluronate (2), fragrance, triethanolamine

Hand wash for disinfection and bacteria removal

■ if following abnormal symptoms persist, discontinue use

Irritation around the eyes, ears, mucous membranes, including the mouth, under the skin irritation and rashes

■ Stop immediately and consult a doctor if you experience

1) Hypersensitivity symptoms such as erythema, itching and dermatitis.

2) Skin Irritation

3) Following Instructions when using medication

(1) For external use only (Do not use internally)

(2) Avoid getting into the eyes (if contact occurs, wash well with clean water)

■ Be careful not to inhale or use excessively for a long time (ingesting ethanol repeatedly causes irritation to mucous membranes and headaches or other symptoms may appear. When used repeatedly in the same area, skin irritation may occur.

■ Do not use the product for a long time in the same area as swelling, inflammation or sickness may occur due to absorption through the skin.

It is not recommended to use this one areas that have been medically treated with a cast or bandage.

■ Do not use in combination with soap or antibacterial cleansing agents.

• Keep Out of Reach of Children.

■ Pour a small amount into hands, spread evenly and rub into the skin

for topical use only

접착면

Bubison Gold Gel (Ethanol) Complete Hand Sanitizer / 2mL
A safe quasi-drug grade hand sanitizer with 62% of ethanol content, which helps effective anti-bacterial activity. It allows a simple and handy use with no water required and leaves refreshing feeling after use.

Drug Facts	
<i>Active Ingredients</i> Ethanol (Synthetic Alcohol) 62%	<i>Purpose</i> Disinfecting Agent
<i>Uses</i> ■ Hand wash for disinfection and bacteria removal	
<i>Warnings</i>	
<i>For external use only.</i>	
<ul style="list-style-type: none"> Do not apply on the following body parts: skin around eyes and ears, oral skin, large area of skin and damaged skin. (May cause irritation.) Following patients should be administered with caution before use. The product contains propylene glycol, which may cause irritation or allergic reactions depending on the patient. Immediately stop using the product and consult a doctor, dentist or pharmacist in following cases. <ul style="list-style-type: none"> 1) Hypersensitivity symptoms, such as rash or itchiness. 2) Skin irritation symptoms. Other precautions <ul style="list-style-type: none"> 1) Use the product only for external use (do not eat). 2) Be careful not to get the product in eyes and if so, thoroughly rinse out with clean water and consult a doctor or pharmacist. 3) Be careful not to inhale the vapor from the product when using it on large area of skin or for a long time. (Excessive intake of ethanol vapor may cause irritation on mucous membrane, headache, etc.) 4) If used repeatedly on a same area, the applied skin may become rough due to degreasing of skin surface. 5) Do not use with sealed bandages, cast bandages, packs, etc., for it may cause irritation on skin. 	
	

Drug Facts (continued)	
<ul style="list-style-type: none"> 6) Do not use the product on anal or vaginal skin as it may cause irritation or chemical burns. 7) Do not use for any other purposes than directed. 	
<ul style="list-style-type: none"> ■ Storage precautions <ul style="list-style-type: none"> 1) Avoid shading and keep away from heat or fire. 2) Keep out of reach of children. If a child drinks the product, go to a hospital immediately. 3) After use, make sure to completely close the cap to avoid evaporation or contamination of the product. 4) Taking out the product from the original container and transferring into another may cause accidents due to misuse or deterioration of the product quality. 	
<i>Directions</i> ■ Take an appropriate amount on hand and rub well to dry.	
<i>Other Information</i> ■ Store in sealed container. Keep in room temperature (1-30°C)	
<i>Inactive Ingredients</i> Purified water, butylene glycol, carbomer, licorice extract, glycerin, aloe vera gel, green tea extract, sodium hyaluronate (2), fragrance, triethanolamine	
<i>Questions?</i> 1800-7222	
<p>According to the Consumer Dispute Resolution Standards announced by the Fair Trade Commission, the purchased product may be exchanged or refunded under circumstances where the product has caused a trouble. Expiry period : 36 months from the production Product number and expiry period : refer to the bottom of the container Distributor : CJ-E Inc. 3F, 15 Hwanggangdae-ro 46-gil (Hwangang-ro 2-ga), Yongsan-gu, Seoul Producer: Seoul Cosmetics Inc. 12, Namdongdong-ro 63-beongil, Namdong-gu, Incheon MADE IN KOREA</p>	

Bubison Gold Gel (Ethanol) Complete Hand Sanitizer / 300 mL

Drug Facts	
<i>Active Ingredients</i> Ethanol (Synthetic Alcohol) 62%	<i>Purpose</i> Disinfecting Agent
<i>Uses</i> ■ Hand wash for disinfection and bacteria removal	
<i>Warnings</i>	
<i>For external use only.</i> <i>When using this product</i>	
<ul style="list-style-type: none"> Do not apply on the following body parts: skin around eyes and ears, oral skin, large area of skin and damaged skin. (May cause irritation.) Following patients should be administered with caution before use. The product contains propylene glycol, which may cause irritation or allergic reactions depending on the patient. Immediately stop using the product and consult a doctor, dentist or pharmacist in following cases. <ul style="list-style-type: none"> 1) Hypersensitivity symptoms, such as rash or itchiness. 2) Skin irritation symptoms. Other precautions <ul style="list-style-type: none"> 1) Use the product only for external use (do not eat). 2) Be careful not to get the product in eyes and if so, thoroughly rinse out with clean water and consult a doctor or pharmacist. 3) Be careful not to inhale the vapor from the product when using it on large area of skin or for a long time. (Excessive intake of ethanol vapor may cause irritation on mucous membrane, headache, etc.) 4) If used repeatedly on a same area, the applied skin may become rough due to degreasing of skin surface. 5) Do not use with sealed bandages, cast bandages, packs, etc., for it may cause irritation on skin. 6) Do not use the product on anal or vaginal skin as it may cause irritation or chemical burns. 7) Do not use for any other purposes than directed. Storage precautions <ul style="list-style-type: none"> 1) Avoid shading and keep away from heat or fire. 2) Keep out of reach of children. If a child drinks the product, go to a hospital immediately. 3) After use, make sure to completely close the cap to avoid evaporation or contamination of the product. 4) Taking out the product from the original container and transferring into another may cause accidents due to misuse or deterioration of the product quality. 	
<i>Directions</i> ■ Take an appropriate amount on hand and rub well to dry.	
<i>Other Information</i> ■ Store in sealed container. Keep in room temperature (1-30°C)	
<i>Inactive Ingredients</i> Purified water, butylene glycol, carbomer, licorice extract, glycerin, aloe vera gel, green tea extract, sodium hyaluronate (2), fragrance, triethanolamine	
<i>Questions?</i> 1800-7222	
<p>According to the Consumer Dispute Resolution Standards announced by the Fair Trade Commission, the purchased product may be exchanged or refunded under circumstances where the product has caused a trouble. Expiry period : 36 months from the production Product number and expiry period : refer to the bottom of the container Distributor : CJ-E Inc. 3F, 15 Hwanggangdae-ro 46-gil (Hwangang-ro 2-ga), Yongsan-gu, Seoul Producer: Seoul Cosmetics Inc. 12, Namdongdong-ro 63-beongil, Namdong-gu, Incheon MADE IN KOREA</p>	
	

Bubison Gold Gel (Ethanol) Complete Hand Sanitizer / 50 mL
A safe quasi-drug grade hand sanitizer with 62% of ethanol content, which helps effective anti-bacterial activity. It allows a simple and handy use with no water required and leaves refreshing feeling after use.

Drug Facts	
<i>Active Ingredients</i> Ethanol (Synthetic Alcohol) 62%	<i>Purpose</i> Disinfecting Agent
<i>Uses</i> ■ Hand wash for disinfection and bacteria removal	
<i>Warnings</i>	
<i>For external use only.</i>	
<ul style="list-style-type: none"> Do not apply on the following body parts: skin around eyes and ears, oral skin, large area of skin and damaged skin. (May cause irritation.) Following patients should be administered with caution before use. The product contains propylene glycol, which may cause irritation or allergic reactions depending on the patient. Immediately stop using the product and consult a doctor, dentist or pharmacist in following cases. <ul style="list-style-type: none"> 1) Hypersensitivity symptoms, such as rash or itchiness. 2) Skin irritation symptoms. Other precautions <ul style="list-style-type: none"> 1) Use the product only for external use (do not eat). 2) Be careful not to get the product in eyes and if so, thoroughly rinse out with clean water and consult a doctor or pharmacist. 	
	

Drug Facts (continued)	
<ul style="list-style-type: none"> 3) Be careful not to inhale the vapor from the product when using it on large area of skin or for a long time. (Excessive intake of ethanol vapor may cause irritation on mucous membrane, headache, etc.) 4) If used repeatedly on a same area, the applied skin may become rough due to degreasing of skin surface. 5) Do not use with sealed bandages, cast bandages, packs, etc., for it may cause irritation on skin. 6) Do not use the product on anal or vaginal skin as it may cause irritation or chemical burns. 7) Do not use for any other purposes than directed. 	
<ul style="list-style-type: none"> ■ Storage precautions <ul style="list-style-type: none"> 1) Avoid shading and keep away from heat or fire. 2) Keep out of reach of children. If a child drinks the product, go to a hospital immediately. 3) After use, make sure to completely close the cap to avoid evaporation or contamination of the product. 4) Taking out the product from the original container and transferring into another may cause accidents due to misuse or deterioration of the product quality. 	
<i>Directions</i> ■ Take an appropriate amount on hand and rub well to dry.	
<i>Other Information</i> ■ Store in sealed container. Keep in room temperature (1-30°C)	
<i>Inactive Ingredients</i> Purified water, butylene glycol, carbomer, licorice extract, glycerin, aloe vera gel, green tea extract, sodium hyaluronate (2), fragrance, triethanolamine	
<i>Questions?</i> 1800-7222	
<p>According to the Consumer Dispute Resolution Standards announced by the Fair Trade Commission, the purchased product may be exchanged or refunded under circumstances where the product has caused a trouble. Expiry period : 36 months from the production Product number and expiry period : refer to the bottom of the container</p>	

BUBISON GOLD GEL (ETHANOL) COMPLETE HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59405-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TROLAMINE (UNII: 9O3K93S3TK)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
WATER (UNII: 059QF0KO0R)	
LICORICE (UNII: 61ZBX54883)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59405-0001-3	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/04/2020	
2	NDC:59405-0001-2	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/04/2020	
3	NDC:59405-0001-1	2 mL in 1 POUCH; Type 0: Not a Combination Product	04/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/04/2020	

Labeler - Seoul cosmetics co ltd (688397660)

Registrant - Seoul cosmetics co ltd (688397660)

Establishment

Name	Address	ID/FEI	Business Operations
Seoul cosmetics co ltd		688397660	manufacture(59405-0001)

Revised: 4/2020

Seoul cosmetics co ltd