

**DAY HYDRATOR SPF-15- octinoxate and octisalate and oxybenzone lotion**  
**220 Laboratories Inc.**

*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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**DAY HYDRATOR SPF-15 ARTWORK**

**ACTIVE INGREDIENTS:**

Ethylhexyl Methoxycinnamate - 7.5%

Ethylhexyl Salicylate - 5.0%

Benzophenone-3 - 3.0%

**DIRECTIONS:** In the morning, gently apply a small amount of moisturizer onto clean face and neck for daily hydration and skin protection.

**CAUTION:** Discontinue use if redness or rash occurs. Seek medical attention if irritation persists.

**WARNING:** For external use only.

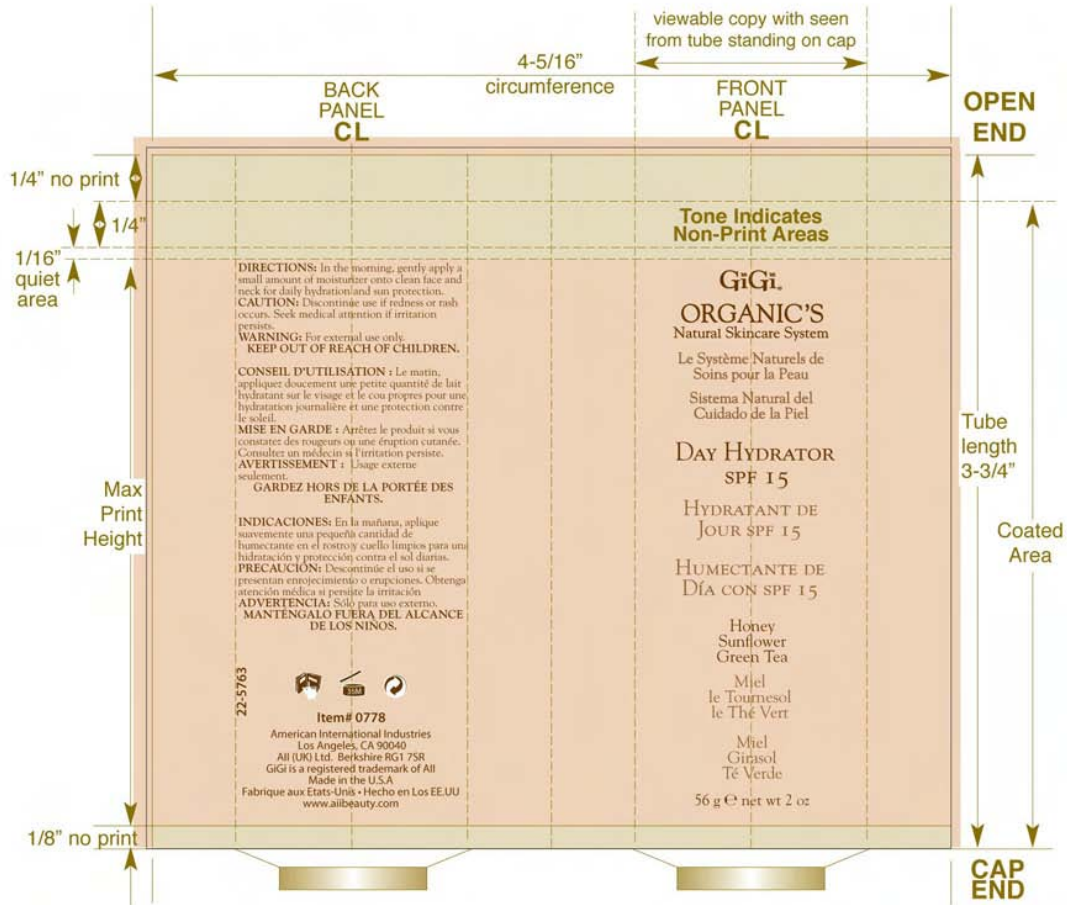
**KEEP OUT OF REACH OF CHILDREN.**

GiGi ORGANICS  
Natural Skincare System

**DAY HYDRATOR**  
**SPF 15**

Honey  
Sunflower  
Green Tea

1 3/8" x 3 3/4"





840008  
**GiGi.**  
**ORGANICS**  
 Le Système Naturels  
 de Soins pour la Peau  
**ORGANICS**  
 Sistema Natural del  
 Cuidado de la Piel



**HYDRATANT DE  
 JOUR SPF 15**  
**HUMECTANTE DE  
 DÍA CON SPF 15**

Miel  
 le Tournesol  
 le Thé Vert

Miel  
 Citrusol  
 Té Verde

Sans Parabènes • Sans Fragrances Artificielles  
 Sin Parabenos • Sin Fragancias Artificiales

56 g e net wt 2 oz

**DIRECTIONS:** In the morning, gently apply a small amount of moisturizer onto clean face and neck for daily hydration and sun protection.  
**CAUTION:** Discontinue use if redness or rash occurs. Seek medical attention if irritation persists.  
**WARNING:** For external use only. **KEEP OUT OF REACH OF CHILDREN.**

**CONSEIL D'UTILISATION :** Le matin, appliquez doucement une petite quantité de lait hydratant sur le visage et le cou propres pour une hydratation journalière et une protection contre le soleil.  
**MISE EN GARDE :** Arrêtez le produit si vous constatez des rougeurs ou une éruption cutanée. Consultez un médecin si l'irritation persiste.

**AVERTISSEMENT :** Usage externe seulement.  
**GARDEZ HORS DE LA PORTÉE DES ENFANTS.**

**INDICACIONES:** En la mañana, aplique suavemente una pequeña cantidad de humectante en el rostro y cuello limpios para una hidratación y protección contra el sol diarias.  
**PRECAUCIÓN:** Descontinúe el uso si se presentan enrojecimiento o erupciones. Obtenga atención médica si persiste la irritación.  
**ADVERTENCIA:** Solo para uso externo. **MANTÉNGALO FUERA DEL ALCANCE DE LOS NIÑOS.**

21-5746



**GiGi.**  
**ORGANICS**  
 Natural  
 Skincare System



**DAY  
 HYDRATOR  
 SPF 15**

Honey  
 Sunflower  
 Green Tea

No Parabens  
 No Artificial Fragrances

56 g e net wt 2 oz

**ACTIVE INGREDIENTS:**  
 Ethylhexyl Methoxycinnamate 7.5%  
 Ethylhexyl Salicylate 5.0%  
 Benzophenone-3 3.0%

**INACTIVE INGREDIENTS:** Water (Aqua, Eau), Ethylhexyl Palmitate, Propylene Glycol, Glycerol Stearate, PEG-100 Stearate, Cetearyl Alcohol, Stearic Acid, Dimethicone, \*Calendula Officinalis Flower Extract, \*Bellis Perennis (Daisy) Flower Extract, \*Jasminum Officinale (Jasmine) Extract, \*Lavandula Angustifolia (Lavender) Flower Extract, \*Rosa Canina Flower Extract, \*Hibiscus Rosa Sinensis Extract, Camellia Sinensis Leaf Extract, Helianthus Annuus (Sunflower) Extract, Honey Extract (Mel, Extrait de miel), Citrus Aurantium Dulcis (Orange) Oil, Allantoin, Panthenol, Burylene Glycol, Myristyl Myristate, Hydroxyethylcellulose, Acrylates/C10-30 Alkyl Acrylates Copolymer, Triethanolamine, Tetrasodium EDTA, Caprylyl Glycol, Phenoxyethanol, Hexylene Glycol  
 \*Certified Organic Extracts

**INGREDIENTES ACTIVOS:**  
 Ethylhexil metoxicinamato 7.5%  
 Ethylhexil salicilato 5.0%  
 Benzotenoa-3 3.0%

**INGREDIENTES INACTIVOS:**  
 Agua, Ethylhexil Palmirato, Propileno Glicol, Estearato Glicélico, Peg-100 Estearato, Alcohol Cetílico, Ácido Estéarico, Dimeticona, \*extracto De Flores De Calendula Officinalis, \*extracto De Flores De Bellis Perennis (Margarita), \*Extracto De Jasminum Officinale (Jazmin), \*Extracto De Flores De Lavandula Angustifolia (Lavanda), \*Extracto De Flores De Rosa Canina, \*Extracto De Hibiscus Rosa Sinensis, Extracto De Hojas De Camellia Sinensis, Extracto De Helianthus Annuus (Girasol), Extracto De Miel (Mel [Hde2], Extrait De Miel) Aceite De Citrus Aurantium Dulcis (Naranja), Alantoina, Pantenol, Glicol Buryleno, Miristil Miristato, Hidroxietilcelulosa, Acrilatos/Polímero Cruzado De Alquil Acrilato C10-30, Trietanolamina, Tetrasodio Edta, Glicol Caprílico, Fenoxietanol, Glicol Hexileno  
 \*Extractos orgánicos certificados

Item# 0778

American International Industries  
 Los Angeles, CA 90040  
 All (UK) Ltd. Berkshire RG1 7SR  
 GiGi is a registered trademark of All  
 Made in the U.S.A.  
 Fabrique aux États-Unis - Hecho en Los EEUU  
 www.allbeauty.com



octinoxate and octisalate and oxybenzone lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57367-027
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 g
<b>OXYBENZONE</b> (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	30 mg in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128MIS)	
<b>POLYOXYL 100 STEARATE</b> (UNII: YD01N1999R)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>MYRISTYL MYRISTATE</b> (UNII: 4042ZC00DY)	
<b>HYDROXYETHYL CELLULOSE (2000 CPS AT 1%)</b> (UNII: S38J6RZN16)	
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>MYRISTYL LAURATE</b> (UNII: 58U0NZN2BT)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>HELIANTHUS ANNUUS</b> (UNII: BKJ0J3D1BP)	
<b>ORANGE OIL</b> (UNII: AKN3KSD11B)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>PANTHENOL</b> (UNII: WV9CM0O67Z)	
<b>HONEY</b> (UNII: Y9H1V576FH)	
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	
<b>BELLIS PERENNIS</b> (UNII: 2HU33I03UY)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>HIBISCUS SABDARIFFA CALYX</b> (UNII: 584J2XT260)	
<b>JASMINE</b> (UNII: 0Q8K841432)	
<b>LAVENDER</b> (UNII: 9YT4B71U8P)	
<b>ROSA CANINA FRUIT</b> (UNII: 3TNW8D08V3)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57367-027-19	1 in 1 CARTON		
1	NDC:57367-027-18	56 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/01/2006	

**Labeler** - 220 Laboratories Inc. (783247950)

**Registrant** - 220 Laboratories Inc. (783247950)

Establishment			
Name	Address	ID/FEI	Business Operations
220 Laboratories Inc.		783247950	manufacture

Revised: 5/2010

220 Laboratories Inc.