

**VIALPROTECTION AGE DEFYING PROTECTIVE SPF 50- homosalate, octisalate, avobenzone oxybenzone lotion  
DARPHIN DIST.**

*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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ACTIVE INGREDIENTS: HOMOSALATE 5.00%  OCTISALATE 5.00%  AVOBENZONE 3.00%  
 OXYBENZONE 3.00%

INGREDIENTS: WATER\AQUA\EAU  BUTYLOCTYL SALICYLATE  METHYL TRIMETHICONE  NEOPENTYL GLYCOL DIHEPTANOATE  POLYESTER-8  ALEURITES MOLUCCANA (KUKUI) SEED OIL  LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE  PEG-100 STEARATE  BUTYLENE GLYCOL  GLYCERYL STEARATE  DIPENTAERYTHRITYL TRI-POLYHYDROXYSTEARATE  MORUS NIGRA (MULBERRY) ROOT EXTRACT  SCUTELLARIA BAICALENSIS EXTRACT  CURCUMA LONGA (TURMERIC) ROOT EXTRACT  WHEY PROTEIN\LACTIS PROTEIN\PROTEINE DU PETIT-LAIT  LEONTOPODIUM ALPINUM FLOWER EXTRACT  THERMUS THERMOPHILLUS FERMENT  VITIS VINIFERA (GRAPE) FRUIT EXTRACT  LAMINARIA OCHROLEUCA EXTRACT  PLANKTON EXTRACT  CAFFEINE  GLYCERIN  CAPRYLIC/CAPRIC TRIGLYCERIDE  POTASSIUM CETYL PHOSPHATE  YEAST EXTRACT\FAEX\EXTRAIT DE LEVURE  CETYL ALCOHOL  C30-38 OLEFIN/ISOPROPYL MALEATE/MA COPOLYMER  VP/EICOSENE COPOLYMER  ETHYLHEXYLGLYCERIN  PALMITIC ACID  CAPRYLYL GLYCOL  DEHYDROXANTHAN GUM  ACETYL GLUCOSAMINE  AMMONIUM ACRYLOYLDIMETHYLAURATE/VP COPOLYMER  STEARIC ACID  LECITHIN  FRAGRANCE (PARFUM)  LIMONENE  GERANIOL  CITRONELLOL  ALPHA-ISOMETHYL IONONE  LINALOOL  BUTYLPHENYL METHYLPROPIONAL  HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXALDEHYDE  DISODIUM EDTA  PHENOXYETHANOL  SODIUM DEHYDROACETATE  MICA

WARNING: FOR EXTERNAL USE ONLY. KEEP OUT OF EYES. RINSE WITH WATER TO REMOVE.STOP USE AND ASK A DOCTOR STOP USE IF IRRITATION OR IRRITATION DEVELOPS AND LASTS.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP RIGHT AWAY  
PRINCIPAL DISPLAY PANEL

DARPHIN

VITALPROTECTION

AGE DEFYING

PROTECTIVE LOTION

SPF 50

1.6 FL OZ. LIQ/50 ML

DARPHIN DISTR.

PARIS, FRANCE

<p><b>DARPHIN</b> PARIS</p> <p><b>VITALPROTECTION</b></p> <p>FLUIDE PROTECTEUR ANTI-ÂGE AGE-DEFYING PROTECTIVE LOTION</p> <p><b>50</b> SPF</p> <p>D'ARÔMES ET DE PLANTES</p> <p>e 50mL 1.6 FL.OZ.LIQ.</p>	<p><b>ACTIVE INGREDIENTS:</b> Octisalate 5.0%, Homosalate 5.0%, Oxybenzone 3.0%, Avobenzone 3.0%.</p> <p><b>INGREDIENTS:</b> WATER/AQUA/EAU, BUTYL-OCTYL SALICYLATE, METHYL TRIMETHICONE, NEOPENTYL GLYCOL DIHEPTANOATE, POLYESTER-8, ALEURITES MOLUCCANA (KUKU) SEED OIL, LAURYL PEG-9 POLY-DIMETHYLSILOXYETHYL DIMETHICONE, PEG-100 STEARATE, BUTYLENE GLYCOL, GLYCERYL STEARATE, DIPENTAERYTHRITYL TRI-POLYHYDROXYSTEARATE, MORUS NIGRA (MULBERRY) ROOT EXTRACT, SCUTELLARIA BAICALENSIS EXTRACT, CURCUMA LONGA (TURMERIC) ROOT EXTRACT, WHEY PROTEIN/LACTIS PROTEIN/PROTEINE DU PETIT-LAIT, LEONTOPODIUM ALPINUM FLOWER EXTRACT, THERMUS THERMOPHILLUS FERMENT, VITIS VINIFERA (GRAPE) FRUIT EXTRACT, LAMINARIA OCHROLEUCA EXTRACT, PLANKTON EXTRACT, CAFFEINE, GLYCERIN, CAPRYLIC/CAPRIC TRIGLYCERIDE, POTASSIUM CETYL PHOSPHATE, YEAST EXTRACT/FAEX/EXTRAIT DE LEVURE, CETYL ALCOHOL, C30-38 OLEFIN/ISOPROPYL MALEATE/MA COPOLYMER, VP/EICOSENE COPOLYMER, ETHYLHEXYLGLYCERIN, PALMITIC ACID, CAPRYLYL GLYCOL, DEHYDROXANTHAN GUM, ACETYL GLUCOSAMINE, AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER, STEARIC ACID, LECITHIN, FRAGRANCE (PARFUM), LIMONENE, GERANIOL, CITRONELLOL, ALPHA-ISOMETHYL IONONE, LINALOOL, BUTYLPHENYL METHYLPROPIONAL, HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYLALDEHYDE, DISODIUM EDTA, PHENOXYETHANOL, SODIUM DEHYDROACETATE, MICA &lt;ILN35463&gt;.</p>	<p><b>DARPHIN</b> PARIS</p> <p><b>VITALPROTECTION</b></p> <p>FLUIDE PROTECTEUR ANTI-ÂGE AGE-DEFYING PROTECTIVE LOTION</p> <p><b>50</b> SPF</p> <p>D'ARÔMES ET DE PLANTES</p> <p>e 50mL 1.6 FL.OZ.LIQ.</p>	<p><b>FLUIDE PROTECTEUR ANTI-ÂGE FPS 50</b> Ce fluide délicat procure une protection vitale contre les agressions solaires et environnementales. Sa formule ultra-légère et hydratante enrichie en Venuceane™ et extrait d'Edelweiss, marie des filtres solaires avec des anti-oxydants puissants pour aider à protéger la peau des rayons UV et des agressions extérieures responsables du vieillissement cutané prématuré. Idéal comme base de maquillage. Après les soins quotidiens, appliquer le matin sur le visage et le cou. Renouveler l'application aussi souvent que nécessaire. Testé sous contrôle dermatologique.</p> <p><b>ATTENTION :</b> Usage externe uniquement. Éviter le contact avec les yeux. En cas de contact avec les yeux, rincer abondamment à l'eau. Cesser toute utilisation et demander conseil à un médecin en cas d'irritation ou d'irruption cutanée. Tenir hors de portée des enfants. En cas d'ingestion, appeler immédiatement un médecin.</p> <p><b>AGE-DEFYING PROTECTIVE LOTION SPF 50</b> Delightful fluid provides vital sun and environmental protection. Ultra-light and hydrating formula with Venuceane™ and Edelweiss extract combines sun filters and powerful anti-oxidants, to help protect against UVA and UVB rays, and guard against external aggressions known to cause premature skin aging. Ideal as an under-make-up base. In the morning, after daily skincare, apply to face and neck. Reapply as often as needed. Dermatologist tested.</p> <p><b>WARNING:</b> For external use only. Keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash or irritation develops and lasts. Keep out of reach of children. If swallowed, get medical help right away.</p> <p> <b>DARPHIN</b>  LABORATOIRES DARPHIN, Dist. Place Vendôme - 356, rue St-Honoré 75001 Paris - Made In France REF. D3Y8-01</p>
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**VIALPROTECTION AGE DEFYING PROTECTIVE SPF 50**

homosalate, octisalate, avobenzone oxybenzone lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:16555-006
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
HOMO SALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5.0 mL in 100 mL

<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5.0 mL in 100 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3.0 mL in 100 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	3.0 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	
<b>METHYL TRIMETHICONE</b> (UNII: S73ZQ10GXM)	
<b>NEOPENTYL GLYCOL DIHEPTANOATE</b> (UNII: 5LKW3C543X)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>KUKUI NUT OIL</b> (UNII: TP11QR7B8R)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>MORUS AUSTRALIS ROOT</b> (UNII: 1VL55O45RF)	
<b>SCUTELLARIA BAICALENSIS ROOT</b> (UNII: 7J95K7ID2S)	
<b>TURMERIC</b> (UNII: 856YO1Z64F)	
<b>WHEY</b> (UNII: 8617Z5FMF6)	
<b>LEONTOPODIUM ALPINUM FLOWER</b> (UNII: MWN6IZU3XM)	
<b>WINE GRAPE</b> (UNII: 3GOV20705G)	
<b>CAFFEINE</b> (UNII: 3G6A5W338E)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>POTASSIUM CETYL PHOSPHATE</b> (UNII: 03KCY6P7UT)	
<b>YEAST</b> (UNII: 3NY3SM6B8U)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>PALMITIC ACID</b> (UNII: 2V16EO95HI)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>N-ACETYLGLUCOSAMINE</b> (UNII: V956696549)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>SODIUM DEHYDROACETATE</b> (UNII: 8W46YN971G)	
<b>MICA</b> (UNII: V8A1AW0880)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16555-006-01	1 in 1 CARTON		
1	NDC:16555-006-02	50 mL in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/01/2009	

**Labeler** - DARPHIN DIST. (105157494)

**Establishment**

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		205952385	manufacture

**Establishment**

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	manufacture

**Establishment**

Name	Address	ID/FEI	Business Operations
Len-Ron Manufacturing Division of Aramis Inc.		809771152	manufacture

**Establishment**

Name	Address	ID/FEI	Business Operations
Aramis Inc.		042918826	manufacture

**Establishment**

Name	Address	ID/FEI	Business Operations
Northtec Bristol		949264774	manufacture, relabel, repack

**Establishment**

Name	Address	ID/FEI	Business Operations
Northtec Keystone		618107429	manufacture, relabel, repack

**Establishment**

Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2		828534516	manufacture, relabel, repack

**Establishment**

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics, Ltd.		255175580	manufacture

**Establishment**

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics, Ltd		253616536	manufacture

**Establishment**

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics Distribution Center		208579636	repack, relabel

**Establishment**

Name	Address	ID/FEI	Business Operations
Estee Lauder Kabushiki Kaisha		712808195	relabel, repack

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Whitman Laboratories Ltd.		216866277	manufacture

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Aveda Corporation		071352058	manufacture

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
BIOSM LABORATORIES		288479491	manufacture

Revised: 8/2010

DARPHIN DIST.