

**VITAMIN E DAY SPF 15- octisalate, avobenzone cream**  
**JO MALONE 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.*

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ACTIVE INGREDIENTS: OCTISALATE 5.00% [] AVOBENZONE 3.00%

INGREDIENTS: WATER [] DIMETHICONE [] BUTYLOCTYL SALICYLATE [] BUTYLENE GLYCOL [] POLYESTER-8 [] CETYL RICINOLEATE [] STEARETH-21 [] STEARETH-2 [] DI-C12-15 ALKYL FUMARATE [] CAPRYLIC/CAPRIC/MYRISTIC/STEARIC TRIGLYCERIDE [] POLYSILICONE-11 [] GENTIANA LUTEA (GENTIAN) ROOT EXTRACT [] POLYGONUM CUSPIDATUM ROOT EXTRACT [] HORDEUM VULGARE (BARLEY) EXTRACT\EXTRAIT D'ORGE [] TRITICUM VULGARE (WHEAT) GERM EXTRACT [] LAMINARIA OCHROLEUCA EXTRACT [] HYDROLYZED RICE EXTRACT [] FUMARIA OFFICINALIS FLOWER/LEAF/STEM EXTRACT [] CITRUS MEDICA LIMONUM (LEMON) FRUIT EXTRACT [] HYDROLYZED RICE BRAN EXTRACT [] ROSMARINUS OFFICINALIS (ROSEMARY) LEAF EXTRACT [] VITIS VINIFERA (GRAPE) SEED EXTRACT [] ARTEMIA EXTRACT [] THERMUS THERMOPHILLUS FERMENT [] STEARYL ALCOHOL [] PENTYLENE GLYCOL [] POLYQUATERNIUM-51 [] LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE [] BEHENYL ALCOHOL [] TRIACONTANYL PVP [] GLYCERIN [] LECITHIN [] C12-15 ALKYL BENZOATE [] LINOLEIC ACID [] CAFFEINE [] CHOLESTEROL [] SQUALANE [] SODIUM PCA [] ACRYLIC ACID/VP CROSSPOLYMER [] UREA [] 1,2-HEXANEDIOL [] CAPRYLIC/CAPRIC TRIGLYCERIDE [] DIPROPYLENE GLYCOL DIBENZOATE [] TOCOPHERYL ACETATE [] TETRAHEXYLDECYL ASCORBATE [] SODIUM HYALURONATE [] PPG-15 STEARYL ETHER BENZOATE [] GLYCYRRHETINIC ACID [] TREHALOSE [] HYDROGENATED LECITHIN [] FUMARIC ACID [] PALMITOYL HYDROXYPROPYLTRIMONIUM AMYLOPECTIN/GLYCERIN CROSSPOLYMER [] CYCLODEXTRIN [] NORDIHYDROGUAIARETIC ACID [] ASCORBYL TOCOPHERYL MALEATE [] CAPRYLYL GLYCOL [] ERGOTHIONEINE [] SODIUM CHLORIDE [] FRAGRANCE (PARFUM) [] SODIUM HYDROXIDE [] CITRIC ACID [] ETHYLBISIMINOMETHYLGUAIACOL MANGANESE CHLORIDE [] DISODIUM EDTA [] PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE [] SODIUM DEHYDROACETATE [] PHENOXYETHANOL

WARNING: KEEP OUT OF EYES. STOP USE IF IRRITATION OCCURS. KEEP OUT OF REACH OF CHILDREN.

PRINCIPAL DISPLAY PANEL:

JO MALONE

VITAMIN E DAY CREAM

NET WT. 1.7 OZ/50ML

DISTR JO MALONE LTD

LONDON, ENGLAND W1K 3BQ

JO MALONE  
LONDON



VITAMIN E MOISTURISING DAY CRÈME SPF 15  
CRÈME HYDRATANTE À LA VITAMINE E SPF 15

VITAMIN E FEUCHTIGKEITSSPENDENDE TAGESCREME MIT SPF 15  
CREMA HIDRATANTE DE DIA CON VITAMINA E SPF 15  
CREMA IDRATANTE DA GIORNO ALLA VITAMINA E CON SPF 15

NET WT./POIDS NET 1.7 OZ./50 ML. ±1



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MADE IN ENGLAND L2HW



ACTIVE INGREDIENTS:

OCTISALATE 5.00%, A/OBENZONE 3.00%

INGREDIENTS: WATER/AQUA/EAU, DIMETHICONE,  
BUTYLOCTYL SALICYLATE, BUTYLENE GLYCOL, POLYESTER-8,  
CETYL RICINOLEATE, STEARETH-21, STEARETH-2, DI-C12-15 ALKYL  
FUMARATE, CAPRYLIC/CAPRIC/MYRISTIC/STEARIC TRIGLYCERIDE,  
POLYSILICONE-11, GENTIANA LUTEA (GENTIAN) ROOT EXTRACT, POLYGONUM  
CUSPIDATUM ROOT EXTRACT, HORDEUM VULGARE (BARLEY) EXTRACT/EXTRAIT  
D'ORSE, TRITICUM VULGARE (WHEAT) GERM EXTRACT, LAMINARIA OCHROLEUCA  
EXTRACT, HYDROLYZED RICE EXTRACT, FUMARIA OFFICINALIS FLOWER/LEAF/STEM  
EXTRACT, CITRUS MEDICA LIMONUM (LEMON) FRUIT EXTRACT, HYDROLYZED RICE  
BRAN EXTRACT, ROSMARINUS OFFICINALIS (ROSEMARY) LEAF EXTRACT, VITIS VINIFERA  
(GRAP) SEED EXTRACT, ARTEMIA EXTRACT, THERMUS THERMOPHILLUS FERMENT,  
STEARYL ALCOHOL, PENTYLENE GLYCOL, POLYQUATERNIUM-15, LAURYL BEG-9

POLYDIMETHYLSILOXYETHYL DIMETHICONE, BEHENYL ALCOHOL, TRIACONTANYL PVB, GLYCERIN, LECITHIN, C12-15 ALKYL BENZOATE, LINOLEIC ACID, CAFFEINE, CHOLESTEROL, SQUALANE, SODIUM PCA, ACRYLIC ACID/VP CROSSPOLYMER, UREA, 1,2-HEXANEDIOL, CAPRYLIC/CAPRIC TRIGLYCERIDE, DIPROPYLENE GLYCOL DIBENZOATE, TOCOPHERYL ACETATE, TETRAHEXYLDECYL ASCORBATE, SODIUM HYALURONATE, PPG-15 STEARYL ETHER BENZOATE, GLYCYRRHETIC ACID, TREHALOSE, HYDROGENATED LECITHIN, FUMARIC ACID, PALMITOYL HYDROXYPROPYLTRIMONIUM AMYLOPECTIN GLYCERIN CROSSPOLYMER, CYCLODEXTRIN, NORDIHYDROGUAIARETIC ACID, ASCORBYL TOCOPHERYL MALEATE, CAPRYLYL GLYCOL, ERGOTHIONEINE, SODIUM CHLORIDE, FRAGRANCE (PARFUM), SODIUM HYDROXIDE, CITRIC ACID, ETHYLBISIMINOMETHYLGUAIACOL MANGANESE CHLORIDE, DISODIUM EDTA, PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCCINAMATE, SODIUM DEHYDROACETATE, PHENOXYETHANOL <L137878>



**THIS NOURISHING  
MOISTURISER HELPS PREVENT LINES  
AND WRINKLES BY DEFENDING SKIN FROM  
THE HARMFUL EFFECTS OF THE ENVIRONMENT,  
INCLUDING UVA/UVB RAYS.**

**WARNING:  
KEEP OUT OF EYES. STOP USE IF IRRITATION OCCURS.  
KEEP OUT OF REACH OF CHILDREN.**

**CE SOIN NOURRISSANT AIDE À PRÉVENIR L'APPARITION DES  
RIDES ET RIDULES TOUT EN AIDANT LA PEAU À LUTTER CONTRE  
LES AGRESSIONS EXTÉRIEURES, LES UVA ET UVB.**

**ATTENTION:  
ÉVITER TOUT CONTACT AVEC LES YEUX. SUSPENDRE  
L'UTILISATION EN CAS D'IRRITATION. TENIR HORS DE PORTÉE  
DES ENFANTS.**

**DIE INTENSIVE FEUCHTIGKEITSPFLEGE HILFT, DER  
ENTSTEHUNG VON LINIEN UND FALTEN VORZUBEUGEN,  
INDEM SIE DIE HAUT VOR SCHÄDIGENDEN  
UMWELTEINFLÜSSEN UND UVA/UVB-STRAHLEN  
SCHÜTZT.**

## VITAMIN E DAY SPF 15

octisalate, avobenzone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62874-005
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5.0 mL in 100 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3.0 mL in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>POLYESTER-10</b> (UNII: 212N9O2MMZ)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>GENTIANA LUTEA ROOT</b> (UNII: S72O3284MS)	
<b>BARLEY</b> (UNII: 5PWM7YL17R)	
<b>WHEAT GERM</b> (UNII: YR3G369F5A)	
<b>LAMINARIA OCHROLEUCA</b> (UNII: 4R2124HE76)	
<b>FUMARIA OFFICINALIS FLOWERING TOP</b> (UNII: VH659J61ZL)	
<b>LEMON</b> (UNII: 24RS0A988O)	
<b>RICE BRAN</b> (UNII: R60QEP13IC)	
<b>ROSEMARY</b> (UNII: IJ67X351P9)	
<b>VITIS VINIFERA SEED</b> (UNII: C34U15ICXA)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>DOCOSANOL</b> (UNII: 9G1OE216XY)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>LINOLEIC ACID</b> (UNII: 9KJL21T0QJ)	
<b>CAFFEINE</b> (UNII: 3G6A5W338E)	
<b>CHOLESTEROL</b> (UNII: 97C5T2UQ7J)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>SODIUM PYRROLIDONE CARBOXYLATE</b> (UNII: 469OTG57A2)	
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)	
<b>.ALPHA.-TOCOPHEROL ACETATE, D-</b> (UNII: A7E6112E4N)	
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>ENOXOLONE</b> (UNII: P540XA09DR)	
<b>TREHALOSE</b> (UNII: B8WCK70T7I)	
<b>HYDROGENATED SOYBEAN LECITHIN</b> (UNII: H1109Z9J4N)	
<b>MASOPROCOL</b> (UNII: 7B08G1BYQU)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>ERGOTHIONEINE</b> (UNII: BDZ3DQM98W)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE)</b> (UNII: 255PIF62MS)	
<b>SODIUM DEHYDROACETATE</b> (UNII: 8W46YN971G)	

PHENOXYETHANOL (UNII: HIE492ZZ3T)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62874-005-01	50 mL in 1 JAR		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/01/2011	

### Labeler - JO MALONE LTD (347366049)

#### 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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	manufacture