

**SUN PROTECTION- lanolin, avobenzone, octinoxate ointment
MAKRA KOZMETIKA D.O.O.**

Sun Protection

Drug Facts

Active ingredients

Lanolin 24.91%

Avobenzone 2.5%

Octinoxate 7%

Purposes

Skin Protectant

Sunscreen

Sunscreen

Uses

- temporarily protects minor:
 - temporarily protects chapped or cracked skin
 - helps protect from the drying effects of wind and cold weather
 - helps prevent sunburn
 - if used as directed with other sun protection measures (see), decreases the risk of skin cancer and early skin aging caused by the sun **Directions**
- cuts
- scrapes
- burns

Warnings

For external use only.

Do not use

- on damaged skin
- on deep or puncture wounds
- on animal bites
- on serious burns

When using this product

- keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

- rash occurs
- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

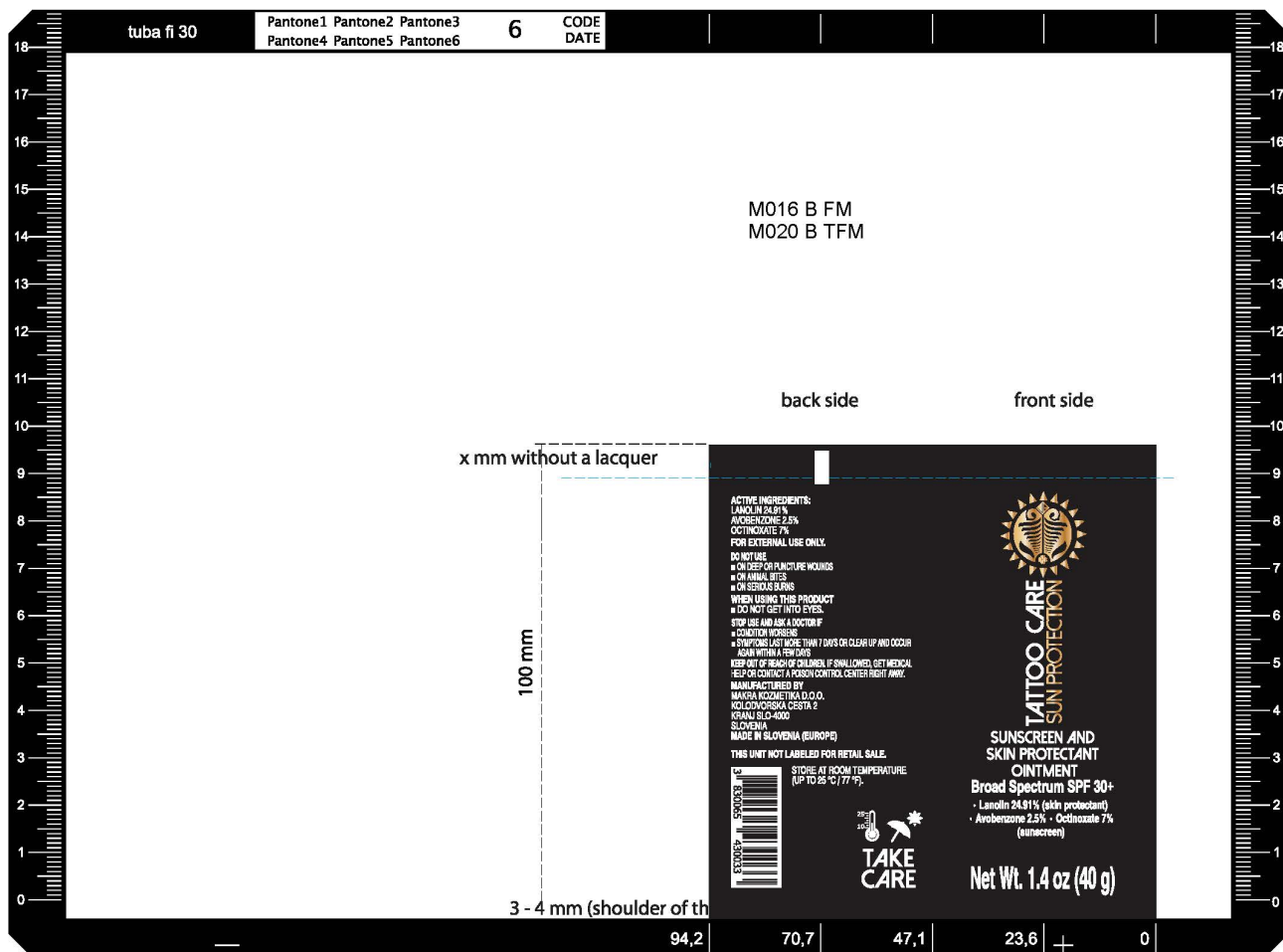
Directions

- apply generously 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: **Sun Protection Measures.**
- children under 6 months of age: ask a doctor
- limit time in the sun, especially from 10 a.m.-2 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses

Inactive ingredients

Water, petrolatum, chocolate (Theobroma cacao) butter, calendula (Calendula officinalis) flower extract, almond (Prunus dulcis) oil, cetearyl alcohol, jojoba (simmondsia chinensis) seed oil, sodium benzoate, potassium sorbate, bisbolol, allantoin, tocopheryl acetate, sodium cetearyl sulfate, coumarin, sodium lauryl sulfate, linalool, citric acid, fragrance, cinnamyl alcohol, benzyl salicylate, geraniol.

Tattoo Care Sun Protection Sunscreen and Skin Protectant Ointment SPF 30+, 1.4 oz (40g) 82806-200-01



SUN PROTECTION

lanolin, avobenzone, octinoxate ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82806-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)	LANOLIN	249.1 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	25 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	70 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	
COCOA BUTTER (UNII: 512OYT1CRR)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	

ALMOND OIL (UNII: 66YXD4DKO9)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
JOJOBA OIL (UNII: 724GKU717M)
SODIUM BENZOATE (UNII: OJ245FE5EU)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
LEVOMENOL (UNII: 24WE03BX2T)
ALLANTOIN (UNII: 344S277G0Z)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)
COUMARIN (UNII: A4VZ22K1WT)
SODIUM LAURYL SULFATE (UNII: 368GB5141J)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
CINNAMYL ALCOHOL (UNII: SS8YOP444F)
BENZYL SALICYLATE (UNII: WAO5MKNK9TU)
GERANIOL (UNII: L837108USY)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82806-002-01	1 in 1 CARTON	09/01/2022	
1		40 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	09/01/2022	

Labeler - MAKRA KOZMETIKA D.O.O. (537064093)

Registrant - MAKRA KOZMETIKA D.O.O. (537064093)

Establishment

Name	Address	ID/FEI	Business Operations
MAKRA KOZMETIKA D.O.O.		537064093	manufacture(82806-002)

Revised: 12/2023

MAKRA KOZMETIKA D.O.O.