# WKND UNDERWATER SUN SCREEN 50ML- octinoxate, octisalate, titanium dioxide cream SURFCODE

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 INGREDIENT

Active Ingredient: ETHYLHEXYL METHOXYCINNAMATE 7.50%, ETHYLHEXYL SALICYLATE 5.00%, TITANIUM DIOXIDE 3.5%

### INACTIVE INGREDIENT

**Inactive Ingredients:** 

Water, Cyclopentasiloxane, C12-15 Alkyl Benzoate, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Butylene Glycol, PEG-9 Polydimethylsiloxyethyl Dimethicone, Sorbitan Olivate, Isoamyl p-Methoxycinnamate, Niacinamide, Cetyl PEG/PPG-10/1 Dimethicone, Silica, Glycerin, Sodium Chloride, Disteardimonium Hectorite, Polyglutamic Acid, Dimethicone Crosspolymer, Aluminum Stearate, Polyhydroxystearic Acid, Alumina, Dimethicone, Dimethiconol, Zanthoxylum Piperitum Fruit Extract, Pulsatilla Koreana Extract, Usnea Barbata (Lichen) Extract, 1,2-Hexanediol, Caprylyl Glycol, Dipotassium Glycyrrhizate, Salicornia Herbacea Extract, Phragmites Communis Extract, Adenosine, CI 77492, CI 77491

### **PURPOSE**

Purpose: Sunscreen

### **WARNINGS**

Warnings:

### FOR EXTERNAL USE ONLY

- Do not use on damaged or broken skin
- When using this product, Keep out of eyes. Rinse with water to remove.
- Stop use and ask a doctor if rash occurs.
- Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

### DESCRIPTION

Direction: - Apply liberally and uniformly to all exposed areas 15-20 minutes before sun exposure. Reapply often (every 2 hours) and after swimming, excessive perspiration and washing to ensure maximum sun protection.

Uses: - Helps prevent sunburn - Higher SPF gives more sunburn protection - Retains SPF after 80 minutes of activity in the water or sweating

### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

# Wknd

### Drug Facts

### Active ingredients :

Ethylhexyl Methoxycinnamate 7.5% Ethylhexyl Salicylate 5.0% Titanium Dioxide 3.5%

### Purpose:

### Uses:

- Helps prevent sunburn
   Higher SPF gives more sunburn protection
   Retains SPF after 80 minutes of activity in the water or sweating

### Warnings: FOR EXTERNAL USE ONLY

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Keep out of eyes. Rinse with water
to remove.

Stop use and ask a doctor if rash occurs.

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help or contact a Poison Control Center
right away.

### Directions:

Apply liberally and uniformly to all exposed areas 15-20 minutes before sun exposure. Reapply often (every 2 hours) and after swimming, excessive perspiration and washing to ensure maximum sun protection.

### Inactive ingredients :

Inactive ingredients:
Water. Cyclopentasiloxane, C12-15 Alkyl
Benzoate, Bis-Ethylhexyloxyphenol
Methoxyphenyl Triazine, Butylene Glycol,
PEG-9 Polydimethylsiloxyethyl Dimethicone,
Sorbitan Olivate, Isoamyl
p-Methoxycinnamate, Niacinamide, Cetyl
PEG/PPG-10/1 Dimethicone, Silica,
Glycerin, Sodium Chloride,
Disteardimonium Hectorite, Polyglutamic
Acid, Dimethicone Crosspolymer, Aluminum
Stearate, Polyhydroxystearic Acid, Alumina,
Dimethicone, Dimethiconol, Zanthoxylum
Piperitum Fruit Extract, Pulsatilia Koreana
Extract, Usnea Barbata (Lichen) Extract,
1,2-Hexanediol, Caprylyl Glycol,
Dipotassium Glycyrhizate, Salicornia
Herbacea Extract, Pragmitles Communis
Extract, Adenosine, Cl 77492, Cl 77491
Manufacturer for SURFCODE

Manufacturer for SURFCODE 52 Jayugongwonnam-ro, Jung-gu, Incheon, 22315, Korea

Manufactured for NATUZEN 289 Namdongdong-ro, Namdong-gu, Incheon, 21639, Korea

SPF50+ PA+++ / 50ml 1.69oz **UNDERWATER SUNSCREEN** 



### WKND UNDERWATER SUN SCREEN 50ML

octinoxate, octisalate, titanium dioxide cream

Product Type HUMAN OTC DRUG	Item Code (Source)	NDC:71192-050
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Route of Administration TOPICAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W) OCTISALATE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP) TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP) TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)

Inactive Ingredients	
Ingredient Name	Strength
Butylene Glycol (UNII: 3XUS85K0RA)	
Sorbitan Olivate (UNII: MDL271E3GR)	

	Packaging					
1	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	NDC:71192-050- 02	1 in 1 CARTON	07/01/2018			
	NDC:71192-050-01	50 mL in 1 CONTAINER; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	07/01/2018		

### **Labeler -** SURFCODE (693717579)

## Registrant - SURFCODE (693717579)

Establishment			
Name	Address	ID/FEI	Business Operations
Natuzen Co.,Ltd.		688201272	manufacture(71192-050)

Revised: 12/2019 SURFCODE