## MEIJER BABY TEAR FREE SPF 50 CS - avobenzone, homosalate, octisalate, octocrylene s pray Meijer Distribution, 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.

-----

## **Drug Facts**

## Active ingredients

Avobenzone 3.0%, Homosalate 10.0%, Octisalate 5.0%, Octocrylene 6.0%

## **Purpose**

Sunscreen

#### Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

## Warnings

## For external use only

**Flammable:** Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F. Do not use in the presence of a flame or spark. Keep away from sources of ignition-No smoking.

#### Do not use

on damaged or broken skin

## When using this product

- Keep away from face to avoid breathing it
- 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.

- Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.
- May stain some fabrics

#### Directions

- hold container 4-6 inches from the skin to apply
- spray liberally and spread evenly by hand 15 minutes before sun exposure

- **Do not spray directly on face**. Spray on hands then apply to face.
- do not apply in windy conditions
- use in well-ventilated area
- reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- **Sun Protection Measures.** 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 of 15 or higher and other sun protection measures including:
- limit time in the sun, especially from 10 a.m. to 2 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses
- children under 6 months of age: Ask a doctor

## **Inactive ingredients**

Isobutane, Water, Isohexadecane, Ethylhexyl Benzoate, Cetyl PEG/PPG-10/1 Dimethicone, Dibutyl Adipate, Lauryl PEG-8 Dimethicone, Ethylhexyl Methoxycrylene, Sodium Chloride, PEG-8, Caprylyl Glycol, Glycerin, Sodium Citrate, PEG-8 Dimethicone, Aloe Barbadensis Leaf Juice, Octyldodecanol, Retinyl Palmitate, Silica, Tocopheryl Acetate, Ascorbic Acid, Sodium Propoxyhydroxypropyl Thiosulfate Silica, Phenoxyethanol, Methylparaben, Butylparaben, Ethylparaben, Isobutylparaben, Propylparaben.

#### Other information

protect this product from excessive heat and direct sun

## Questions or comments?

Call 1-800-697-9868 Mon-Fri

## **Principle Display Label**

NDC: 41250-921-55

meijer

tear free

baby Sunscreen

continuous spray

pediatrician tested

UVA/UVB protection

50+

Broad Spectrum SPF 50+

Water Resistant

(80 minutes)

Net Wt 6 OZ. (170 g)

# meijer



pediatrician tested UVA/UVB protection

**Broad Spectrum** SPF 50+

Water Resistant (80 Minutes)

NET WT 6 OZ. (170 g)

## **Drug Facts**

## Active ingredients

Avobenzone 3.0%, Homosalate 10.0%, Octisalate 5.0% Octocrylene 6.0%

Purpose

Uses • helps prevent sunburn • if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings For external use only

Flammable: Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F. Do not use in the presence of a flame or spark. Keep away from sources of ignition-No smoking. Do not use on damaged or broken skin

When using this product . Keep away from face to avoid breathing it

Keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Keep out of the reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal. May stain some fabrics.

**Directions** • hold container 4-6 inches from the skin to apply . spray liberally and spread evenly by hand 15 minutes before sun exposure . Do not spray directly on face. Spray on hands then apply to face. . do not apply in windy conditions . use in well-ventilated area . reapply: . after 80 minutes of swimming or sweating . immediately

after towel drying • at least every 2 hours

Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a subscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including: . limit time in the sun, especially from 10 a.m. - 2 p.m. • wear long-sleeved shirts, pants, hats and sunglasses . children under 6 months of age: Ask a doctor

Inactive ingredients Isobutarie, Water, Isohexadecane, Ethylhex Benzoate, Cetyl PEG/PPG-10/1 Dimethicone, Dibutyl Adipate, Lauryl PEG-1 Dimethicone, Ethylhexyl Methoxycrylene, Sodium Chloride, PEG-8, Phenoxyethanol, Caprylyl Glycol, Glycerin, Sodium Citrate, Methylparaben Butylparaben, Ethylparaben, Isobutylparaben, Propylparaben, PEG-8 Dimethicone, Aloe Barbadensis Leaf Juice, Octyldodecanol, Retinyl Palmitate, Silica, Tocopheryl Acetate, Ascorbic Acid, Sodium Propoxyhydroxypropyl Thiosulfate Silica.

Other information protect this product from excessive heat and direct su Questions or comments? Call 1-800-697-9868 Mon-Fri

## MEIJER BABY TEAR FREE SPF 50 CS

avobenzone, homosalate, octisalate, octocrylene spray

#### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-921

**Route of Administration** TOPICAL

#### Active Ingredient/Active Moiety

· · · · · · · · · · · · · · · · · · ·		
Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	6 g in 100 g

#### **Inactive Ingredients**

Ingredi	ent Name	Strength

ISOBUTANE (UNII: BXR49TP611)	
WATER (UNII: 059QF0KO0R)	
ISOHEXADECANE (UNII: 918 X10 UF1E)	
2-ETHYLHEXYL BENZOATE (UNII: R63ZWW1A13)	
DIBUTYL ADIPATE (UNII: F4K100DXP3)	
ETHYLHEXYL METHO XYCRYLENE (UNII: S3KFG6Q5X8)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438U)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
PEG-8 DIMETHICONE (UNII: GIA7T764OD)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
.ALPHATO COPHERO L ACETATE (UNII: 9E8 X80 D2L0)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM PROPOXYHYDROXYPROPYL THIOSULFATE SILICA (UNII: 208G222332)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPARABEN (UNII: A218 C7HI9 T)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

]	Packaging			
‡	# Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-921- 55	170 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/06/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/11/2016	

## **Labeler** - Meijer Distribution, Inc. (006959555)

Revised: 3/2016 Meijer Distribution, Inc.