

## **LICE COMPLETE KIT- piperonyl butoxide, pyrethrum extract Kroger Company**

*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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### **Kroger Co. Lice Complete kit Drug Facts**

#### **Active ingredients**

Piperonyl butoxide 4%

Pyrethrum extract (equivalent to 0.33% pyrethrins)

#### **Purpose**

Lice treatment

#### **Uses**

treats head, pubic (crab), and body lice

#### **Warnings**

**For external use only**

#### **Do not use**

- near eyes
- inside nose, mouth, or vagina
- on lice in eyebrows or eyelashes. See a doctor if lice are present in these areas.

#### **Ask a doctor before use if you are**

allergic to ragweed. May cause breathing difficulty or an asthmatic attack.

#### **When using this product**

- keep eyes tightly closed and protect eyes with a washcloth or towel
- scalp itching or redness may occur
- if product gets in eyes, flush with water right away

#### **Stop use and ask a doctor if**

- eye irritation occurs
- breathing difficulty occurs
- skin or scalp irritation continues or infection occurs

## **Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).

## **Directions**

- **Important: Read warnings before use**  
**Adults and children 2 years and over:**

## **Inspect**

- check each household member with a magnifying glass in bright light for lice/nits (eggs)
- look for tiny nits near scalp, beginning at back of neck and behind ears
- examine small sections of hair at a time
- unlike dandruff which moves when touched, nits stick to the hair
- if either lice or nits are found, treat with this product

## **Treat**

- shake well before using
- apply thoroughly to **DRY HAIR** or other affected area. For head lice, first apply behind ears and to back of neck.
- allow product to remain for 10 minutes, but no longer
- use warm water to form a lather, shampoo, then thoroughly rinse
- for head lice, towel dry hair and comb out tangles

## **Remove lice and their eggs (nits)**

- use a fine-tooth or special lice/nit comb. Remove any remaining nits by hand (using a throw-away glove).
- hair should remain slightly damp while removing nits
- if hair dries during combing, dampen slightly with water
- for head lice, part hair into sections. Do one section at a time starting on top of head. Longer hair may take 1 to 2 hours.
- lift a 1- to 2-inch wide strand of hair. Place comb as close to scalp as possible and comb with a firm, even motion away from scalp.
- pin back each strand of hair after combing
- clean comb often. Wipe nits away with tissue and discard in a plastic bag. Seal bag and discard to prevent lice from coming back.
- after combing, thoroughly recheck for lice/nits. Repeat combing if necessary.
- check daily for any lice/nits that you missed
- a second treatment must be done in 7 to 10 days to kill any newly hatched lice
- if infestation continues, see a doctor for other treatments

**Children under 2 years:** ask a doctor

## **Other information**

- store at 20-25°C (68-77°F)
- avoid excessive heat
- keep carton for important product information
- see Consumer Information Insert for additional information

### Inactive ingredients

benzyl alcohol, C13-C14 isoparaffin, fragrance, polyoxyethylene (1,1,3,3-tetramethyl butyl) phenyl ether, purified water, xanthan gum

### Questions or comments?

**1-800-632-6900**

### Consumer Information

#### 3-STEP PROCESS FOR LICE TREATMENT

*See carton for complete product information.*

#### Step 1 ● Treat

##### Apply Lice Killing Shampoo

See Usage Guidelines to estimate how much product you will need.

#### NOTE:

- Shake well before using.
- Use towels to protect child's eyes from treatment and prevent clothes from getting wet.
- Apply Lice Killing Shampoo thoroughly to **DRY HAIR** or other affected area.
- Wetting the hair dilutes the treatment making it less effective.
- Also, lice can hold their breath when immersed in water making it difficult for the active ingredient to penetrate the lice.



- For head lice, thoroughly massage shampoo into scalp, behind the ears and to the back of the neck. Lice can crawl up and down the shaft of the hair very quickly so it is important to apply the treatment from the roots to the ends of the hair.



- Allow product to remain on the hair (or other affected area) for 10 minutes, but no longer.



- Add warm water and massage to form a lather.
- Rinse thoroughly.



- For head lice, towel dry hair and comb out tangles.
- Proceed to Step 2.
- **A second treatment must be done in 7 to 10 days to kill any newly hatched lice.**

Usage Guidelines	Hair Length	Short (ear length or	Medium (shoulder length)	Long (past shoulder
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	shorter)		length)	
<b>Approximate Amount for 1 Adult/Child</b>	First	1 oz - 2	First	2 oz - 3
	Application:	oz	Application:	oz
	Second	1 oz - 2	Second	2 oz - 3
	Application:	oz	Application:	oz
	<b>Total:</b>	<b>2 oz - 4 oz</b>	<b>Total:</b>	<b>4 oz - 6 oz</b>
			<b>Total:</b>	<b>6 oz - 8 oz</b>

## Step 2 • Remove

### Comb out lice and eggs with lice comb or other fine-tooth comb and Lice & Egg Comb-Out Spray

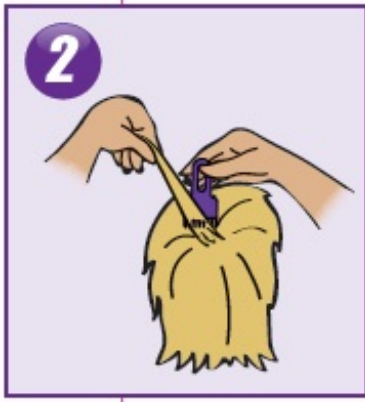
This product should be used **AFTER** Lice Killing Shampoo (Step 1). Combing is an important step to remove eggs.

#### NOTE:

- A fine-toothed comb or the special lice/nit removing comb (included) must be used to remove lice, eggs, and nits from hair.
- Before starting have on hand:
  - extra towels
  - bobby pins or hair clips
  - facial tissues or paper towels
  - regular comb for parting and detangling hair
  - throw-away gloves
- Find a distraction for your child (e.g. books, TV, game).
- Comb out damp hair with a regular wide-tooth comb to take out snarls and tangles.



Apply a small amount of Lice & Egg Comb-Out Spray and use a wide-tooth comb to remove any tangles.



Lift a 1-2" section of hair. Start as close to scalp as possible, slowly comb section all the way to ends of hair with lice comb, using additional Lice & Egg Comb-Out Spray to remove tangles as needed. Use a tissue or paper towel to wipe any lice or eggs off comb.



Pin back this section of hair. Continue to comb out one 1-2" section at a time until entire head has been combed and pinned.



Remove pins and rinse thoroughly with warm water. You may use your regular shampoo now if desired.

Combs should be disinfected for reuse by soaking in hot water (above 130°F) for 10

minutes.

### **Step 3 • Control**

#### **Treat the home with Home Lice, Bedbug & Dust Mite Spray**

Use Home Lice, Bedbug & Dust Mite Spray to kill lice and their eggs on mattresses, furniture, car interiors and other non-washable items.

**Not for use on humans.**

#### **Additional Tips for Success**

- Be sure to complete all three steps in the Lice Treatment process. This includes a second shampooing between 7-10 days after the initial treatment, but no sooner. If any eggs were not initially combed out, lice may hatch and can be killed with the second treatment. Newly hatched lice are not mature enough to lay new eggs.
- Carefully inspect infested family members daily for at least 2 weeks after the second shampooing. If you see eggs or nits, consult your doctor.
- Teach children not to share personal items, such as hats, combs and brushes and to avoid prolonged contact with a person who has lice.

Did You Know?

#### **HEAD LICE**

- Lay small white eggs (nits) on hair shaft close to scalp.
- Nits are most easily found on back of neck or behind ears.
- Disinfect hats, hair ribbons, scarves, coats, towels, and bed linens by machine washing in hot water (above 54°C (130°F)), then using hottest dryer cycle for at least 20 minutes.
- Items that cannot be washed (bedspreads, blankets, pillows, stuffed toys, etc.) should be dry-cleaned or sealed in a plastic bag for 4 weeks, then removed outdoors and shaken out very hard before using again.
- Items that cannot be washed, dry-cleaned, or stored may be sprayed with a product designed for this purpose.
- Soak all combs and brushes in hot water (above 54°C (130°F)) for at least 10 minutes.
- Vacuum all carpets, mattresses, upholstered furniture, and car seats that may have been used by affected people.

#### **PUBIC (CRAB) LICE**

- May be transmitted by sexual contact. Sexual partners should be treated simultaneously to avoid reinfestation.
- Lice are very small and look like brown or grey dots on skin.
- Usually cause intense itching and lay small white eggs (nits) on the hair shaft generally close to the skin surface.
- May be present on the short hairs of groin, thighs, trunk, and underarms, and occasionally on the beard and mustache.
- Disinfect underwear by machine washing in hot water (above 54°C (130°F)), then using hottest dryer cycle for at least 20 minutes.

#### **BODY LICE**

- Body lice and their eggs (nits) are generally found in the seams of clothing particularly in waistline and armpit area.
- Body lice feed on skin then return to clothing to lay their eggs.
- Disinfect clothing by machine washing in hot water (above 54°C (130°F)), then using hottest dryer cycle for at least 20 minutes.
- Do not seal clothing in a plastic bag because nits can remain dormant for up to 30 days.

**Save this insert for future reference**

Distributed By

Perrigo®

Allegan, MI 49010

: 6Y600 00 J1

**Keep carton for important product information.**

Lice Killing Shampoo

Drug Facts

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**Ask a doctor before use if you are** allergic to ragweed. May cause breathing difficulty or an asthmatic attack.

**When using this product**

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- if product gets in eyes, flush with water right away
- scalp itching or redness may occur

**Stop use and ask a doctor if**



- breathing difficulty occurs
- eye irritation occurs
- skin or scalp irritation continues or infection occurs

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## **Directions**

- **Important: Read warnings before use**

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- use a fine-tooth or special lice/nit comb. Remove any remaining nits by hand (using a throw-away glove).
- hair should remain slightly damp while removing nits
- if hair dries during combing, dampen slightly with water
- for head lice, part hair into sections. Do one section at a time starting on top of head. Longer hair may take 1 to 2 hours.
- lift a 1- to 2-inch wide strand of hair. Place comb as close to scalp as possible and comb with a firm, even motion away from scalp.
- pin back each strand of hair after combing
- clean comb often. Wipe nits away with tissue and discard in a plastic bag. Seal bag and discard to prevent lice from coming back.
- after combing, thoroughly recheck for lice/nits. Repeat combing if necessary.
- check daily for any lice/nits that you missed
- a second treatment must be done in 7 to 10 days to kill any newly hatched lice
- if infestation continues, see a doctor for other treatments

**Children under 2 years:** ask a doctor

## **Other information**

- store at 20-25°C (68-77°F). Avoid excessive heat.

**Inactive ingredients** benzyl alcohol, C13-C14 isoparaffin, fragrance, polyoxyethylene (1,1,3,3-tetramethyl butyl) phenyl ether, purified water, xanthan gum

**Questions? 800-719-9260**

## Lice & Egg Comb-Out Spray

### Product Information

**Use** detangles hair in order to make lice and egg comb-out easier

### Warnings

**For external use only. Keep out of reach of children. Avoid contact with eyes.**

### Directions for use

- use AFTER shampooing with a lice killing shampoo
- towel dry hair. Apply a small amount of this product and use a wide-toothed comb to remove any tangles.
- comb out the dead lice, eggs and nits, one small section at a time, with the enclosed lice comb. **This step is very important.**
- use additional product to remove tangles, if needed, during the comb-out process
- after you have combed entire head, rinse hair thoroughly with warm water. Disinfect combs with hot water (130°F).

**Ingredients** purified water, polysorbate 20, glycerin, propylene glycol, phenoxyethanol, amodimethicone, fragrance, DL-panthenol, trideceth-12, cetrimonium chloride, methylchloroisothiazolinone, methylisothiazolinone

### Home Lice, Bedbug & Dust Mite Spray

**Not for use on humans.**

#### ACTIVE INGREDIENT:

†Permethrin.....0.50%

††**OTHER INGREDIENTS:**.....99.50%

100.00%

†Cis/trans ratio: Max. 55% (+/-) cis and Min. 45% (+/-) trans.

††Contains petroleum distillate.

### FIRST AID

#### If on skin or clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

#### If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

**If swallowed:**

- Immediately call a poison control center or doctor.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give any liquid to the person.
- Do not give anything by mouth to an unconscious person.

**If inhaled:**

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.

**HOT LINE NUMBER**

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-222-1222.

**NOTE TO PHYSICIAN**

Contains petroleum distillate – vomiting may cause aspiration pneumonia.

**PRECAUTIONARY STATEMENTS****Hazards To Humans & Domestic Animals**

**CAUTION:** Harmful if absorbed through skin. Avoid inhalation of spray mist. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco or the toilet. Remove and wash contaminated clothing before reuse.

**PHYSICAL OR CHEMICAL HAZARDS**

Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F (54°C) may cause bursting.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**Use Restrictions:**

- Do not allow adults, children, or pets to enter until vapors, mists and aerosols have dispersed, and the treated area has been thoroughly ventilated.
- Do not allow adults, children, or pets to enter the treated area until sprays have dried.
- In the home, cover all food processing surfaces and utensils during treatment and thoroughly wash before use. Cover or remove exposed food.
- Remove pets, birds and cover any water inhabited by fish (such as aquariums and ornamental fish ponds) before application. Turn off aquarium filtering systems before spraying and wait approximately 15 minutes after application before turning the filter back on.

- **This product is not for use on humans.** If lice infestations should occur on humans, use a product labeled for use on humans.
- Application is prohibited directly into sewers or drains, or to any area like a gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur. Do not allow the product to enter any drain during or after application.
- Not for broadcast use on indoor residential surfaces.

## SHAKE WELL BEFORE USING

Remove protective cap. Hold container upright with nozzle away from you. Depress valve and spray from a distance of 12 to 15 inches for baseboards, moldings and when applying to floors as a spot spray and 8 to 10 inches for clothing, furniture and bedding. Test product on an inconspicuous area before applying to check for possible staining or discoloration. Inspect again after drying. Spray to the point of dampness but not run-off. Over application may cause damage. Will not stain surfaces or fabrics where water alone causes no damage.

To kill **Lice** and **Louse eggs**: Clean home. Use this product for non-washable items only. Washables should be washed in hot water and dried in high heat. Spray only those articles and parts of bedding, including mattresses and furniture that cannot be either laundered or dry-cleaned. Do not use on sheets or pillowcases. Allow all sprayed articles to dry thoroughly before use. If lice infestation occurs on humans, use a product labeled for use on humans.

**Bedbugs**: Spray mattresses, particularly around tufts and seams. Take beds apart and spray into all joints. Treat baseboards, moldings and floors. Spray to the point of dampness but not run-off. After mattress is dry, cover with mattress cover and sheet. Do not use mattress without cover. Retreat if infestation occurs, but not more than once every two weeks.

To control **House Dust Mites (*Dermatophagoides spp.*)**: This product controls house dust mites that may cause asthma, hay fever, rhinitis, watery eyes and sneezing. One treatment lasts for up to 8 weeks. **On Upholstered Furniture** – Test fabric in an inconspicuous area to insure dyes will not bleed. Hold container upright with nozzle away from you. Depress valve and spray from a distance of 8 to 10 inches. Spray all fabric surfaces until damp. Spray to the point of dampness but not run-off. Do not use on delicate fabrics. Allow furniture to dry thoroughly before using. **On Carpets** – Apply as a spot spray to areas where dust mites are likely (including along baseboards and moldings). Hold nozzle approximately 12 to 18 inches from the carpet surface. Spray until damp. After application, brush the surface of the carpet with a broom or brush to insure deep penetration. Allow carpet to dry thoroughly before reentering the treated area. Drying time can be accelerated by using a fan. **On Mattresses** – Spray the top, bottom and sides of mattresses until damp, paying particular attention to tufts and seams. Allow to dry thoroughly before using. After mattress is dry, cover with mattress cover and sheet. Do not use mattress without cover. Vacuum entire area once dry. Since vacuuming stirs dust up in the air those with allergies should have another person vacuum or should wear a dust mask and use vacuum with a high efficiency particulate (HEPA) filter.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**Pesticide Storage:** Store in a cool, dry area away from children and pets and away

from heat, sparks and open flame. Do not transport or store below 32°F (0°C). Protect from freezing. Do not freeze.

**Pesticide Disposal and Container Handling:** Do Not Puncture or Incinerate.

**If empty:** Place in trash or offer for recycling if available.

**If partly filled:** Call your local solid waste agency or 1-800-CLEANUP (253-2687) for disposal instructions. Never place unused product down any indoor or outdoor drain.

**To the extent consistent with applicable law,** purchaser assumes all responsibility for safety and use not in accordance with directions.

See carton for EPA numbers.

### **Package/Label Principal Display Panel**

COMPARE TO RID® LICE KILLING SHAMPOO active ingredients

See side panel

Lice Complete Kit

3 STEP LICE CONTROL SYSTEM

1 Treat

Lice Killing Shampoo

2 Remove

Lice & Egg Comb-Out Spray

3 Control

Home Lice, Bedbug & Dust Mite Spray

The included comb is 100% effective in the removal of egg & lice from hair as demonstrated in laboratory testing

NET 4 FL OZ (118mL) SHAMPOO

NET 2 FL OZ (59mL) COMB-OUT SPRAY

NET WT 5 OZ (142g) SPRAY

ONE NIT COMB

KEEP OUT OF REACH OF CHILDREN

CAUTION:

See back and side panels for additional precautions

COMPARE TO RID® LICE KILLING SHAMPOO active ingredients \*\*\*See side panel

NDC 30142-453-62



# Lice Complete Kit

## 3 STEP LICE CONTROL SYSTEM

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Lice Killing Shampoo

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Lice & Egg Comb-Out Spray

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Home Lice, Bedbug & Dust Mite Spray

The included comb is 100% effective in the removal of eggs & lice from hair as demonstrated in laboratory testing



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ONE NIT COMB

KEEP OUT OF REACH OF CHILDREN

### CAUTION:

See back and side panels for additional precautions

Complete lice control for your family and home

### 1 Treat

Apply Lice Killing Shampoo according to label directions.

Repeat this step 7 to 10 days later to help prevent reinfection.

### 2 Remove

After Step 1, Comb out the eggs and nits in the hair with a fine-toothed comb or with the comb included.

Apply Egg & Nit Combing Spray on damp hair to make removal faster and easier.

### 3 Control

Use Home Lice, Bedbug & Dust Mite Spray to kill lice and their eggs on mattresses, furniture, car interiors and other non-washable items.

Wash bed linens, clothing and other items in hot water and dry in high heat.

This kit contains 3 products for complete lice control for your family and home. The 4 oz bottle of shampoo and 2 oz bottle of combing spray should be enough product to treat one person. However, amount of product needed will vary by hair length. See below for guidelines.

Lice Killing Shampoo		
Hair Length	Approximate Amount For 1 Adult/Child:	
Short (ear length or shorter)	First Application:	1 oz - 2 oz
	Second Application:	1 oz - 2 oz
	Total:	2 oz - 4 oz
Medium (shoulder length)	First Application:	2 oz - 3 oz
	Second Application:	2 oz - 3 oz
	Total:	4 oz - 6 oz
Long (past shoulder length)	First Application:	3 oz - 4 oz
	Second Application:	3 oz - 4 oz
	Total:	6 oz - 8 oz





# LICE COMPLETE KIT

piperonyl butoxide, pyrethrum extract kit

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-453
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-453-62	1 in 1 CARTON; Type 0: Not a Combination Product	09/15/2018	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	118 mL
Part 2	1 BOTTLE, PUMP	59 mL

## Part 1 of 2

## LICE KILLING

piperonyl butoxide, pyrethrum extract shampoo

## Product Information

Route of Administration	TOPICAL
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## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PIPERONYL BUTOXIDE (UNII: LWK91TU9AH) (PIPERONYL BUTOXIDE - UNII:LWK91TU9AH)	PIPERONYL BUTOXIDE	4 g in 100 mL
PYRETHRUM EXTRACT (UNII: ZUM06L90GV) (PYRETHRUM EXTRACT - UNII:ZUM06L90GV)	PYRETHRUM EXTRACT	.33 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	



### Product Characteristics

Color	YELLOW (cloudy to transparent, cream to straw)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358G		

### Part 2 of 2

### LICE AND EGG COMB OUT

other hair preparations

### Product Information

Route of Administration	TOPICAL
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### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>WATER</b> (UNII: 059QF0KO0R)	
INGR	<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
INGR	<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
INGR	<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
INGR	<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
INGR	<b>PANTHENOL</b> (UNII: VW9CM0O67Z)	
INGR	<b>TRIDECETH-12</b> (UNII: YFY3KG5Y7O)	
INGR	<b>CETRIMONIUM CHLORIDE</b> (UNII: UC9PE95IBP)	
INGR	<b>METHYLCHLOROISOTHIAZOLINONE</b> (UNII: DEL7T5QRPN)	
INGR	<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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<b>1</b>	59 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
Cosmetic			
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part358G	09/15/2018	

**Labeler -** Kroger Company (006999528)

Revised: 11/2022

Kroger Company