



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 30, 2018

Mary Jo Thierry
Wexford Labs
325 Leffingwell Avenue
Kirkwood, MO 63122

Subject: Notification per PRN 98-10 – *Adding minor label changes*
Product Name: **Wexford Disinfectant Wipes**
EPA Registration Number: 34810-37
Application Date: 04/30/2018
Decision Number: 541196

Dear Ms. Thierry:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

If you have any questions, please contact Stacey Grigsby by phone at 703.305.6440, or via email at grigsby.stacey@epa.gov.

Sincerely,

A handwritten signature in blue ink that reads "Stacey Grigsby".

Stacey Grigsby
Regulatory Risk Manager, 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

[WEXFORD DISINFECTANT WIPES]
[READY TO USE]
[GERMICIDAL DETERGENT]
[CLEANS] • [DISINFECTS] • [DEODORIZES]
[GERMICIDAL], [PSEUDOMONACIDAL], [TUBERCULOCIDAL],
[FUNGICIDAL] and [VIRUCIDAL*]

ACTIVE INGREDIENT:	
Citric Acid	0.60%
OTHER INGREDIENTS:	<u>99.40%</u>
Includes biodegradable detergents	
TOTAL	100.00%

NOTIFICATION

34810-37
The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:
05/30/2018

KEEP OUT OF REACH OF CHILDREN
[CAUTION]

[PRECAUTIONARY STATEMENTS]
[HAZARD TO HUMANS AND DOMESTIC ANIMALS]

[CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.]

[FIRST AID]

[IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing. Call a Poison Control Center or doctor for further treatment advice.]

NET CONTENTS: X lbs, X oz.

X Pre-moistened Towelettes (X)" x (X)"
(e.g. 100 Pre- moistened Towelettes 7"x 8")

Wexford Labs, Inc. 325 Leffingwell Avenue Kirkwood, Missouri 63122

Efficacy Claims

[In the presence of 5% blood serum and a] contact time of 5 minutes, is effective against:

- [GERMICIDAL:] [Bactericidal] [Bactericidal Activity]**
[Enterococcus faecalis Vancomycin Resistant [VRE] [ATCC 51575]]
[Escherichia coli O157:H7 [ATCC 43888]]
[Listeria monocytogenes [ATCC 19117]]
[Pseudomonas aeruginosa [ATCC 15442]]
[Salmonella enterica [formerly Salmonella Choleraesuis][ATCC 10708]]
[Staphylococcus aureus [ATCC 6538]]
[Staphylococcus aureus - MRSA [ATCC 33592]]
[Staphylococcus epidermis - MRSE [ATCC 51625]]

[VIRUCIDAL*:]

[In the presence of 5% blood serum and a] contact time of 5 minutes, is effective against:

[Adenovirus Type 2]

[Feline Calicivirus [surrogate for Norovirus]]

[Herpes Simplex Virus Type 1]

[Herpes Simplex Virus Type 2 [Strain G]]

[Human Immunodeficiency Virus Type 1 [Strain HTLV-IIIB] (HIV-1) (AIDS Virus)]

[Influenza A Virus [Strain Hong Kong][H3N2]]

[Pandemic 2009 H1N1 Influenza A Virus [formerly called swine flu]]

[Respiratory Syncytial Virus [RSV]]

[Rotavirus]

[Vaccinia Virus]

[In the presence of 5% blood serum and a] contact time of 10 minutes, is effective against:

[FUNGICIDAL:]

[In the presence of 5% blood serum and a] contact time of 5 minutes, is effective against:

[Trichophyton mentagrophytes [ATCC 9533]]

[In the presence of 5% blood serum and a contact time of 10 minutes, is effective against:]

[GERMICIDAL:]

[Acinetobacter baumannii [ATCC 19606]]

[VIRUCIDAL:]

[Canine Parvovirus [CPV], Hepatitis B Virus [HBV], [Poliovirus Type 1]

[TUBERCULOCIDAL: Effective against **Mycobacterium tuberculosis** [Mycobacterium bovis] [BCG] [Organon Teknika Corp.] [in 5 minutes] [at 20°C / 68°F on previously cleaned hard non-porous inanimate surfaces.]

OPTIONAL MARKETING CLAIMS:

- Bleach Free
- (Antibacterial) Kitchen Cleaner
- (Antibacterial) bathroom cleaner
- (Antibacterial) household cleaner
- Disinfects while you clean
- Clean and disinfect in one step
- Kills [99.9][9] % of (household) germs
- Suitable for cleaning and deodorizing HVAC air ducts and vents
- Quick and easy cleaning
- Botanical
- Botanical Cleaning
- Botanical ingredient[s]
- Botanically derived ingredient[s]
- Botanical active ingredient
- Botanically derived active ingredient
- [Botanically based] product]
- Natural ingredient[s]

Bold, italicized text is information for the reader and is not part of the label. [Bracketed information is optional text.] **Highlighted text is new.** Strike-through (text) means removed

- Naturally derived ingredient[s]
- Natural active ingredient
- Naturally derived active ingredient
- Effectively controls odor
- Eliminates odor-causing bacteria
- Multi-Purpose
- Multi-Purpose Cleaner
- Multi-Surface
- Dye free
- Broad Spectrum Hospital Disinfectant
- Carpet Cleaner and Deodorizer
- Bathroom Cleaner
- Non-Irritating
- Non-corrosive
- We're here to help when life happens.
- Change the way you clean with a product that's simple to use and can help clean up life's everyday messes
- Everyday Cleaner
- Inspired by nature
- Disinfecting Wipe
- Disinfectant Wipe
- One Step
- [Fights] [Effective Against] [Kills] [99.9][9] % of] Bacteria
- [Fights] [Effective Against] [Kills] [99.9][9] % of] Viruses*
- Broad Spectrum Germicide
- No haze
- [Virtually] [haze-free] [film-free] [residue-free shine [clean]
- [Low-haze] [Low-Residue] [Low-Film] [No-Film] [Clear-Drying] [Formula] [Wipe] clean[s] thoroughly
- For plastic and painted surfaces, spot test on an inconspicuous area before use.
- [This product or product name] will not harm most surfaces: including acrylic, sealed fiberglass and vinyl.
- Do not use on unpainted wood.
- Note: Not recommended for unpainted wood or natural marble or brass.
- For plastic and painted surfaces, spot test on an inconspicuous area before use.
- Do not use as a diaper wipe or for personal cleansing.
- This is not a baby wipe!
- Do not flush [in toilet].
- No Rinse required [even on][food contact surfaces][and] [children's] [toys]
- Rinse free [formula]
- No Rinse
- No Rinse Formula
- Rinse Free Formula
- No Rinse Disinfectant
- Kills cold & flu
- Kills [cold] [&] [flu] viruses*
- [Kill[s]] [Remove[s]] [Effective against] [the following] [organisms:]

- o [the virus that causes the flu] [flu virus][Influenza A2]
- o [Avian Influenza A] [(H3N2)] [virus] [(Avian Reassortant)]
- o [Human Immunodeficiency Virus type 1] [HIV-1]
- o [Pseudomonas] [Pseudomonas aeruginosa] [(ATCC 15442)]
- o [the viruses* that causes the cold] [cold virus*] [Rhinovirus type 37]
- o [Salmonella enterica] [(Salmonella choleraesuis)] [Salmonella] [(ATCC 10708)]
- o [Staph] [Staphylococcus aureus] [(ATCC 6538)]
- o [MRSA] [resistant Staph](ATCC 33592)]
- o [Hep[atitis]] B [HBV], [Duck Hepatitis B (DHBV) as surrogate]
- o [Pandemic 2009 H1N1 Influenza A Virus [formerly called swine flu]][H1N1][Influenza A]
- o [Feline Calicivirus [surrogate for Norovirus]][Norovirus]
- o [Respiratory Syncytial Virus [RSV]][RSV]
- o [Staphylococcus epidermis - MRSE [ATCC 51625]][MRSE]
- o [Rotavirus]
- No quat
- Quat[-]free
- Quat[-]eliminated
- Bleach[-]free
- Paraben[-]free
- Phenol[-]free
- Does not contain [bleach] [ammonia] [chlorine]
- Does not contain [Triclosan] [Parabens] [Quaternary Amines] [Quats]
- [Contains no] [Does not contain] [bleach,] [added dyes,] [added colors,] [perfumes,] [(volatile organic compounds)], [ammonia], [phosphates], [phosphorus], [chlorine bleach], [dyes], [synthetic fragrances,] [volatile solvents,] [known or suspected endocrine disruptors,] [glycol ethers,][chlorinated compounds,] [or] [chlorine]
- [One step cleaning -and/or- disinfecting -and/or- deodorizing]
- [Disinfect -and/or- touch-up clean] [Cleans -and/or- disinfects -and/or- deodorizes] [In one easy step]
- Kills [over] [99.9][9] % of [household germs] [kitchen germs] [bathroom germs] [germs*] [.,] [botanically] [on hard, non[-]porous surfaces]
- Tough on [dirt] [germs], easy on you.
- Clean without a [harsh] [strong] chemical[s]
- [Can be used] around kids, pets and food
- Will not damage hard, non[-]porous surfaces

<<ALLERGENS>>

- Wipe(s) away dirt [and] [germs][and][allergens†]
- Allergens[†] This product removes the following allergens: [cat dander], [cockroach debris/matter/particles], [dog dander], [dust mite debris/matter/particles], [pet dander], [pollen particles] [from timothy grass], [grass].

Fragrance Descriptors:

Apple	Lemon Ginger Reed
Apple Blossoms	Lemon Verbena
Arctic breeze	Lemon Ylang
Bramley Apple Blossom	Lemon Ylang Flower
Cherry	Lime Blossom
Citrus	Mandarin Green Tea
Citrus Burst	Mint
Citrus Fresh	Mountain Green
Citrus Splash	Ocean Breeze
Clean and Fresh	Orange
Clean Mint	Orange Fresh
Clean Sparkle	Orange Mango
Cleanmint	Orange Mango Lily
Cool Mint	Orange Zest
Cotton Breeze	Outdoor Fresh
Cotton Lily	Pacific Rose Apple
Crystal Clean	Peach
Crystal Mint	Pear
Cucumber Sage	Pine
Dye and Fragrance free	Pink Grapefruit
Floral	Ruby Red Grapefruit
Floral Woods	Scent Free
Fragrance free	Strawberry
Fresh Citrus	Sweet Pea
Fresh Lemon Scent	Sweet Pea Bloom
Fresh Meadows	Tropical
Fresh Squeezed	Unscented
Glacier Mint	Waterfall Mist
Green Tea Citrus	White Diamonds
Honey Spiced Fig	Wild Lemon Ylang
Indian Mango Orange	Wild Lime Verbena
Island Springs	Winter Fresh
Japanese Cherry Blossom	Wintergreen
Lavender Vanilla Orchid	Wintermint
Lemon Breeze	

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Product is ready to use. Preclean areas with gross filth and **visible** soil prior to disinfection.

DISPENSER DIRECTIONS: [To start feed, remove large cover. Pull up the towelette corner from the center of the towelette roll, twist it into a point and thread it through the hole in the container cover. Pull through about one inch. Replace cover. Pull out first towelette and snap off at a 90° angle. Remaining towelettes feed automatically ready for their next use. When through using, keep small center cap closed to prevent moisture loss.]

[Alternative dispenser directions on pages 9, 13, 14]

[TO CLEAN/DEODORIZE]:

[Unfold premoistened cloth and wipe area to be cleaned for 30 seconds or until clean.]

[Spot check to test for compatibility]

TO DISINFECT: Unfold premoistened cloth and wipe hard non-porous area or item to be disinfected. Wet all surfaces thoroughly. [The surface must remain wet for at least] [Leave for] [5] [10] minutes. **Contact time in accordance with organisms listed on the distributed product label.** [Wipe or] Let air dry. [No rinsing or wiping is required], [even on food contact surfaces.] ~~except on direct food contact surfaces which require a potable water rinse after treatment.~~ [Toys: Use only on hard non-porous surfaces and rinse after treatment.] **[FUNGICIDAL DIRECTIONS:** This product is effective against Trichophyton mentagrophytes (athlete’s foot fungus and a cause of ringworm) on inanimate surfaces [in locker rooms, dressing rooms, exercise facilities, and shower and bath areas]. Follow disinfection directions.]

[Rinse (toys and) food contact surfaces with potable water.]

USAGE CLAIMS

(Suitable) (Intended) for use on (in)

[AREAS OF USE:]

[Athletic Facilities]

[Bathrooms]

[Classrooms]

[Day care centers]

[Dental offices]

[Grocery Stores]

[Grooming Facilities]

[Gyms]

[Health Care Facilities]

[Hospitals]

[Institutional facilities]

[Institutions]

[Kennels]

[Kitchens]

[Laboratories or other small animal facilities]

[Locker Rooms]

[Medical Offices]

[Nurseries]

[Nursing homes]

[Schools]

[Shopping Centers]

[Spas]

[Veterinary Clinics]

[TYPES OF SURFACES/USE SITES:] (Graphic –depicting surface)

[On washable hard, nonporous surfaces of:]

[Ambulance patient care surfaces]

[Anesthesia equipment surfaces]

[Appliances]

[Baby/infant care surfaces]

[Backboards]

[Baked Enamel]

[Bathing units]

[Bathrooms]

[Bed railings]

[Beds]

[Blood pressure devices]

[Cabinets]

[Car Interiors]

[Chairs]

[Changing tables]

[Lumens]

[Patient stretchers]

[Medical equipment surfaces/devices]

[Metal]

[Microscopes]

[MRI equipment surfaces]

[Neonatal/nursery surfaces]

[Nonporous athletic mats]

[Obstetrical equipment surfaces]

[Operating room lights/tables]

[Ophthalmic equipment surfaces/devices]

[Optical wear (excluding contact lenses)]

[Oxygen hoods]

[PPE (Personal Protective Equipment)]

[Patient bed surfaces]

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[Children's toys]	[Patient transport surfaces]
[Chrome]	[Pet Habitats]
[Computer surfaces]	[Physical therapy equipment]
[Computers]	[Plastic]
[Counters]	[Play mats]
[Countertops]	[Play-care equipment]
[CPR manikins]	[Radiology equipment surfaces]
[CT equipment/surfaces]	[Refrigerators (exterior surface)]
[Curing lights]	[Respirators]
[CuVerro® antimicrobial copper]	[Respiratory care equipment surfaces]
[Dental equipment surfaces/devices]	[Sealed Granite]
[Desks]	[Shopping carts]
[Doorknobs]	[Shower floors/walls]
[Exam tables]	[Sinks]
[Exercise equipment]	[Skin care equipment/surfaces]
[Fixtures]	[Soaking containers]
[Floors]	[Stainless Steel]
[Furniture]	[Stalls]
[Garbage cans]	[Surgical equipment surfaces]
[Glass]	[Surgical microscopes]
[Glazed ceramic tile]	[Tables]
[Glazed porcelain]	[Telephones]
[Handrailings]	[Toilet Seats]
[Highchairs]	[Toilets (rims, seats and exterior surfaces)]
[Immobilization devices]	[Toys]
[Infant care equipment]	[Training tables]
[Isolettes]	[Transportation equipment surfaces]
[Keyboards]	[Trays]
[Kitchen surfaces]	[Vinyl]
[Laboratory equipment/surfaces]	[Walls]
[Light lens covers]	[Work stations]
[Lights]	[Wrestling mats]
	[X-ray equipment/surfaces]

Where medical devices are listed as applicable sites, the following will be included as required by PR 94-4

DECONTAMINATION OF CRITICAL OR SEMI-CRITICAL DEVICES PRIOR TO TERMINAL STERILIZATION/HIGH LEVEL DISINFECTION: This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or, (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

*The following special instructions ~~should~~ **must** be included on the label if the product is used as a hospital-grade disinfectant rather than retail/household.*

***[This Product] KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in all settings in which there is an expected likelihood of soiling of hard, non-porous surfaces/objects with blood or body fluids and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS **virus**).

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SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATING SURFACES/OBJECTS SOILED WITH BLOOD AND BODY FLUIDS WHICH MAY CONTAIN HIV-1 (AIDS virus).

PERSONAL PROTECTION: When handling objects soiled with blood or body fluids use disposable latex gloves, gowns, mask and eye coverings.

CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of the disinfectant.

CONTACT TIME: Leave precleaned surfaces wet for five minutes to mitigate HIV-1 virus. Use a (5) (10) minute contact time to kill all bacteria, viruses* and fungi listed on the label. *Contact time in accordance with organisms listed on the distributed product label.*

DISPOSAL OF INFECTIOUS MATERIAL: Blood and other fluids should be autoclaved and disposed of according to Federal, State and Local regulations for infectious waste disposal.

[Veterinary Practice / Animal Care / Animal Laboratory / Zoos / Pet Shop / Kennels Disinfection

Directions: For cleaning and disinfecting hard nonporous surfaces: equipment used for animal food or water, utensils, instruments, cages, kennels, stables, catteries, etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with [this product] for a period of 10 minutes. Wipe or allow to air dry. Thoroughly scrub all treated surfaces that come into contact with food, including equipment used for feeding or watering, with soap or detergent and rinse with potable water before reuse. Do not house animals or employ equipment until treatment has been absorbed, set or dried.]

STORAGE AND DISPOSAL: Do not leave containers open during storage. No special handling is required. **Towelette:** Do not reuse towelette. Dispose of used towelette in trash. **Dispenser:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available.

EPA Reg. No. 34810-37

EPA Est. No. [insert Est. No. here]

For ingredient information, go to [www.wexfordlabs.com/DfE/wipes.html]

[Made in (insert country)]

[Barcode]

SDS #: [insert SDS number here]

[Reorder #: [insert reorder number here]]

Revised: 03/15/2018

[The following graphics are optional. They will be affixed to the label/canister so that it does not interfere with any label text.]



www.epa.gov/pesticides/regulating/labels/design-dfe-pilot.html

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The graphics and language on this page are proprietary

Alternate Dispenser Instructions



[Flip open lid. To remove first wipe pull up on wipe and remove wipe through wavy dispensing opening. The next wipe will pop up automatically. Always snap lid securely between uses to retain moisture.]



*Lemi Shine (Supplemental Registrant)
Company Logo*



**THE FOLLOWING OPTIONAL LANGUAGE AND
GRAPHICS ARE AVAILABLE FOR USE BY
APPROVED SUBREGISTRANTS**

 **Great Quality. Guaranteed.**
 Return the package and the receipt
 for replacement or money back.
 1-877-505-2267 or visit us
 online at walmart.com



 **Great Quality. Great Price. Guaranteed.**
 Our guarantee is our promise that you'll be fully satisfied with the quality of every Great Value product. If for any reason you aren't happy, we'll replace it or return your money. Whichever you prefer. All you need is the package. It's that simple. Guaranteed.
 Tell us what you think... 1-877-505-2267 or online at walmart.com/greatvalue



 **Great Quality. Guaranteed.**
 Return the package for replacement or money back.
 1-877-505-2267 or visit us online at walmart.com



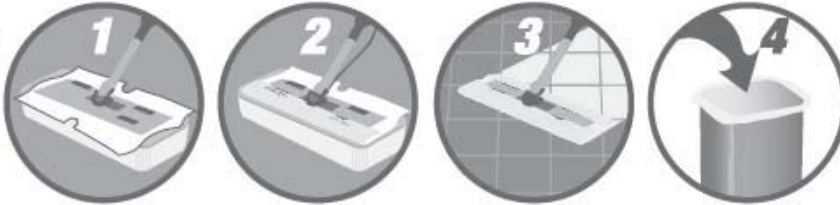
Great Value®

 **Cleans. Disinfects. Guaranteed.**
 Return the package and the receipt for replacement or money back.
 1-877-505-2267 or visit us online at walmart.com



{Optional graphics}

Use on mop head.



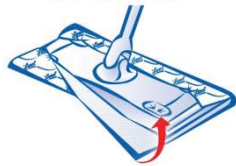
TO OPEN:

1. Cut off top of pouch with scissors.
2. Remove wipes from pouch.
3. Place wipes in plastic tub.
4. Discard empty pouch into trash.

TO USE WITH MOP:

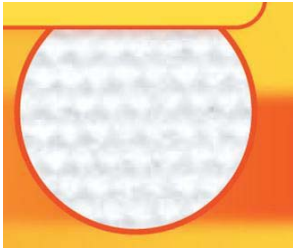
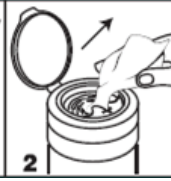
1. Unfold top wipe in tub by pulling sides of the cloth over edges of tub.
2. Place sweeper on head.
3. Wrap wipe around head of sweeper.
4. Push edges of wipe into top of sweeper head.
5. Begin wiping. No rinsing required.
6. After use, remove soiled wipe and discard in trash. Do not flush.

Tuck & Go



Note to reviewer: Representative graphic of wipe tub and/or hand pulling out wipe fabric may be added to the final printed label.

Note to reviewer: A representative graphic of a substrate may be added to the label. Only a graphic of the substrate actually in the canister can be added to the final printed label.





{Note to reviewer: the graphic to the left denotes a picture of a substrate. It will only be added to the final printed label if this substrate is actually in the canister can.}



TO OPEN PACKAGE:

- Flip open dispensing cap and remove entire lid from canister by lifting upward.
- Locate wipe at center of roll, twist corner to a point and thread through small opening in lid. **DO NOT PUSH FINGER THROUGH OPENING.**
- Replace lid and pull sheet up at an angle. Remaining wipes feed automatically.
- When finished, snap lid cap shut to retain moisture.



	We Promise to make good products at good prices for good people. Enjoy!
	Thank You Target gives 5% of its income to the community to support education, the arts, social services and volunteerism.





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