



U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division (7505P)  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460

EPA Reg. Number:

88051-3

Date of Issuance:

9/15/17

NOTICE OF PESTICIDE:

Registration  
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited  
Expires: 09/15/2019

Name of Pesticide Product:

Exidot for Cats

Name and Address of Registrant (include ZIP Code):

Mary Hunt, Agent  
Chanelle Pharmaceuticals Manufacturing Ltd.  
c/o Exponent, Inc.  
1150 Connecticut Ave., NW, Suite 1100  
Washington, D.C. 20036

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Venus Eagle, Product Manager 01  
Invertebrate & Vertebrate Branch 3, Registration Division (7505P)

Date:

9/15/17

2. This registration is time-limited and expires 09/15/2019.
3. At least three months before your intended sale/distribution date submit a mock up copy of the label. You may not sell/distribute this product until the Agency reviews and approves the mock up copy of the label. Once the mock-up label is approved, you must inform the Agency when the product is first released for shipment.
4. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. The following is a list of information that must be included in the quarterly reports for each incident:
  - EPA Registration Number
  - Product name (brand name)
  - Lot #
  - Where purchased: internet, store, veterinarian
  - Active Ingredient(s)
  - Weight range for product
  - Date on which incident occurred. (mm/dd/yyyy)
  - State in which the incident occurred. (standard 2 letter abbreviation)
  - Registrant case #
  - Species: dog, cat, other (specify)
  - Breed: (as reported by pet owner)
  - Age: months or years
  - Sex: M, F, or neutered
  - Weight: pounds
  - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
  - Body System: neurological, dermatological, GI, respiratory, ocular, other
  - Major signs noted with separate column for each sign, using standard terminology
  - Time to Onset: (hours, days)
  - Treated by veterinarian: yes or no
  - First time product used: yes or no
  - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
  - Any known precondition
  - EPA Severity Code: death, major, moderate, minor
  - Outcome: died, recovered, still treated, unknown
5. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
  - All incidents should be reported including all minor dermal and ocular irritation reports.
  - Summary table for cats showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an

- incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
  - Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
  - A summary table for cats showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
  - A summary table showing the number of cat incidents for each severity code for each pet weight range on the product label, as applicable.
  - A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range, as applicable.
  - Table showing number of incidents for each cat breed, where provided.
  - Table showing number of incidents in cats for each clinical sign.
  - Table showing number of incidents in cats for each organ system.
  - Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

6. You are required to comply with the data requirements described in the DCI or EDSP Order identified below:
  - Imidacloprid GDCI-129099-951
  - Imidacloprid EDSP-129099

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

<http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

7. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 88051-3."
8. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one-year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
9. Submit one copy of the final printed label for the record before you release the product for shipment.

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 fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 4/25/2017

If you have any questions, please contact Dee Colby by phone at 703-347-8657, or via email at [colby.deanna@epa.gov](mailto:colby.deanna@epa.gov).

Enclosure: stamped label

Exidot for Cats

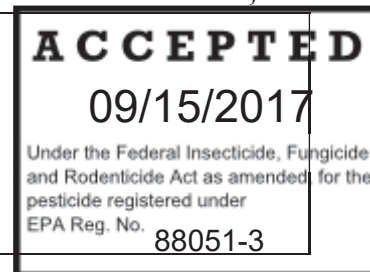
[Brackets indicate alternate language] and

EPA Reg. No. 88051-XXX

{Braces indicate location of text on container label and notes to reviewer}

**Master Label:**

- 1. Carton Label (front and back panels)**
- 2. Package Insert**
- 3. Label on Individual Pouch**
- 4. Label on Tube**
- 5. Optional Text**



**{1. Carton Label: Front Panel}**

{Note to EPA - The word “Cats” text size will be at least 75% of the height of the largest letter in the brand name.}

**Exidot for Cats**

A large, clear picture of a cat in the respective weight range for the product as packaged.

**Once-A-Month Topical Flea Treatment for Cats**  
**0.014 fl. oz. (0.4 mL)**  
**For Use Only on Cats and Kittens 8 Weeks and Older and Weighing 5 - 9 lbs**  
*OR*  
**0.027 fl. oz. (0.8 mL)**  
**For Use Only on Cats and Kittens 8 Weeks and Older and Weighing Over 9 lbs**

[Contains the active ingredient used in Advantage® [9 Topical Solution][18 Topical Solution]. This product is not manufactured or distributed by Bayer, the maker of Advantage® [9 Topical Solution][18 Topical Solution]. Advantage® is a registered trademark of Bayer.]

**ACTIVE INGREDIENT**

Imidacloprid..... 9.1%

**OTHER INGREDIENTS** ..... 90.9%

**TOTAL** ..... 100.0%

**KEEP OUT OF REACH OF CHILDREN**

**WARNING**

See back panel and insert for First Aid, Precautionary Statements, and Directions for Use.  
See insert inside carton for complete Directions for Use, Storage and Disposal.

**NET CONTENTS:** [1][2][3][4][6][18][30] Tube(s) in individually sealed pouch(es)

[0.014 fl oz (0.4 mL) [for Cats and Kittens 8 weeks and older and Weighing 5-9 lbs] or  
[0.027 fl oz (0.85 mL) [for Cats and Kittens 8 weeks and older and Weighing over 9 lbs]

**{1. Carton Label: Front or Back Panel}**

EPA Reg. No. 88051-XX

EPA Est. No.: XXXXX-XX-X

**{1. Carton Label: Back Panel}**

<b>FIRST AID</b>	
<b>If in Eyes</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Call a poison control center or doctor for treatment advice</li> </ul>
<b>If on Skin</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If Swallowed</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
Hotline Number: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Call 1-XXX-XXX-XXXX for emergency treatment information.	

**PRECAUTIONARY STATEMENTS****HAZARDS TO HUMANS - WARNING**

Causes substantial but temporary eye injury. Harmful if absorbed through skin. Harmful if swallowed. Do not get in eyes or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Avoid contact with skin

**HAZARDS TO DOMESTIC ANIMALS**

**For External Use Only.** Do NOT use on cats or kittens under eight weeks of age or weighing less than [5 lbs][9 lbs]. Do NOT use on any other animals. As with any product, consult your veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing cats. Individual sensitivities may occur after using ANY pesticide product for cats. If signs persist or become more severe, consult a veterinarian immediately.

**{Side Effects box across lower section of the back panel.}**

**Side Effects:** Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort such as hypersalivation. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects such as lethargy occur, consult your veterinarian.

Chanelle Pharmaceuticals Manufacturing Ltd

Dublin road

Loughrea

Co. Galway

Ireland

9/14/2017

Exidot for Cats [Brackets indicate alternate language] and  
EPA Reg. No. 88051-XXX {Braces indicate location of text on container label and notes to reviewer}  
See insert inside carton for complete Directions for Use.

## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. READ ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE.

### RESTRICTIONS {Back Panel}

- DO NOT use on cats or kittens under eight weeks of age or weighing less than [5 lbs][9 lbs]. DO NOT use on other animals.
- DO NOT allow your cat to ingest this product.
- DO NOT apply more than one (1) tube per treatment.
- DO NOT have contact or allow children to have contact with treated area until completely dry.
- FOR EXTERNAL USE ONLY.
- DO NOT allow children to apply the product.
- Cat is to be dry prior to application and remain dry for 24 hours after application [for product to work effectively].
- DO NOT allow cats to groom each other until product has dried in multi-cat household.

[For complete Directions for Use see insert inside carton]

### HOW TO APPLY

- REMOVE and OPEN the sealed pouch according to the instructions on package insert.
- OPEN dispenser tube according to the instructions on package insert.
- APPLY to cats or kittens according to the instruction below.
- **For cats and kittens 8 weeks and older and weighing [5-9 lbs][over 9 lbs]** To APPLY Exidot for Cats: Part the hair on the neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. *Do not get this product in your cat's eyes or allow your cat to ingest this product. The product is bitter tasting and salivation may occur for a short time if the cat licks the product immediately after treatment.* Treatment at the base of the skull will minimize the chance for the cat to lick the product. Do not allow the product to run off.
- Discard the empty tube as described in Storage and Disposal.

### {2. Package Insert}

**EXIDOT FOR CATS** {The word "Cats" text size will be at least 75% of the height of the largest letter in the brand name.}

**READ THE ENTIRE LABEL BEFORE EACH USE**

**USE ONLY ON CATS AND KITTENS 8 WEEKS AND OLDER AND WEIGHING [5-9 lbs][OVER 9 lbs]**

### Monthly Topical For the Prevention and Treatment of Flea Infestations on Cats

#### ACTIVE INGREDIENT

Imidacloprid.....	9.1%
OTHER INGREDIENTS.....	<u>90.9%</u>
TOTAL	100.0%

**KEEP OUT OF REACH OF CHILDREN****WARNING**

<b>FIRST AID</b>	
<b>If in Eyes</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Call a poison control center or doctor for treatment advice</li> </ul>
<b>If on Skin</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If Swallowed</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
Hotline Number: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Call 1-XXX-XXX-XXXX for emergency treatment information.	

**PRECAUTIONARY STATEMENTS****HAZARDS TO HUMANS - WARNING**

Causes substantial but temporary eye injury. Harmful if absorbed through skin. Harmful if swallowed. Do not get in eyes or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Avoid contact with skin.

**HAZARDS TO DOMESTIC ANIMALS**

**For External Use Only.** Do NOT use on cats or kittens under eight weeks of age or weighing less than [5 lbs][9 lbs]. Do NOT use on any other animals. As with any product, consult your veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing cats. Individual sensitivities may occur after using ANY pesticide product for cats. If signs persist or become more severe, consult a veterinarian immediately.

**{Side effects box to go immediately after Hazards to Domestic Animals section on the insert.}**

**Side Effects:** Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort such as hypersalivation. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects such as lethargy occur, consult your veterinarian.

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. READ ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.



## RESTRICTIONS

- DO NOT use on cats or kittens under eight weeks of age or weighing less than [5 lbs][9 lbs]. DO NOT use on other animals.
- DO NOT allow your cat to ingest this product.
- DO NOT apply more than one (1) tube per treatment.
- DO NOT have contact or allow children to have contact with treated area until completely dry.
- FOR EXTERNAL USE ONLY.
- DO NOT allow children to apply the product.
- Cat is to be dry prior to application and remain dry for 24 hours after application [for product to work effectively].
- DO NOT allow cats to groom each other until product has dried in multi-cat household.

## **INSTRUCTIONS**

### **HOW TO OPEN THE POUCH**

1. Remove pouch from carton.
2. Tear pouch open at the notch.
3. Remove tube from inside pouch

### **HOW TO OPEN TUBE**

Hold tube upright. Tap the narrow part of the tube to ensure the contents remain within the main body of the tube. With the tip facing away from you and your cat's face and eyes, snap back the tip.

[OR]

Hold tube upright. Tap the tube nozzle to drain any fluid in the nozzle tip back into the main body of the tube. Bend nozzle tip along the indentations to create a break. When bending, make certain to direct the breakline portion of nozzle away from you and your cat's face and eyes to avoid any incidental spray. Bend back the tip.

### **HOW TO APPLY**

- Cats should be dry prior to application and remain dry for 24 hours after application [for product to work effectively]
- REMOVE tube from pouch and OPEN tube according to the instructions above.
- To APPLY Exidot for Cats: Part the hair on the neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. *Do not get this product in your cat's eyes or allow your cat to ingest this product. The product is bitter tasting and salivation may occur for a short time if the cat licks the product immediately after treatment.* Treatment at the base of the skull will minimize the chance for the cat to lick the product. Do not allow the product to run off.
- Discard the empty tube as described in Storage and Disposal

**STORAGE AND DISPOSAL**

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

**Pesticide Storage:** Store unused tubes in the original package in a cool dry place; keep out of reach of children and animals.

**Pesticide Disposal and Container Handling:** Non-refillable container. Do not reuse or refill the container. **If Empty:** Place in trash or offer for recycling if available. **If Partly Filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

**[WARRANTY AND DISCLAIMER**

Read the entire Label, including the Precautionary Statements, First Aid, Use Directions and Warranty Disclaimer before using this Product. Use of this product constitutes acceptance of this warranty by the user or buyer. The directions for use on this product label are believed to be sufficient and must be followed carefully with every use. Elimination of all risks associated with the use of this product is impossible. Because of factors unforeseen, unintended consequences may result when using this product. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer. Chanelle Pharmaceuticals Manufacturing Ltd. makes a commitment to providing high quality products to consumers. To the extent consistent with applicable law, Chanelle Pharmaceuticals Manufacturing Ltd. makes no other express or implied warranty of merchantability or fitness for a particular purpose or any other express or implied warranty. To the extent consistent with applicable law, the exclusive remedy for losses or damages resulting from this product (including claims based on contract, negligence, strict liability, or other legal theories) shall be limited to, at Chanelle Pharmaceuticals Manufacturing Ltd.'s election, one of the following:

- (1) Refund of purchase price paid by buyer or user for product bought, or
- (2) Replacement of amount of product used.

To the extent consistent with applicable law, Chanelle Pharmaceuticals Manufacturing Ltd. shall not be liable for losses or damages resulting from handling or use of this product unless Chanelle Pharmaceuticals Manufacturing Ltd. is promptly notified of such losses or damages in writing. In no case shall Chanelle Pharmaceuticals Manufacturing Ltd. be liable for consequential or incidental damages or losses.

The terms of the Warranty Disclaimer cannot be varied by any written or verbal statements or agreements. No employee or sales agent of Chanelle Pharmaceuticals Manufacturing Ltd. or the seller is authorized to vary or exceed the terms of this Warranty Disclaimer in any manner.]

Chanelle Pharmaceuticals Manufacturing Ltd  
Dublin Road  
Loughrea  
Co. Galway  
Ireland

EPA Reg. No. 88051-XXX

EPA Est. No.:

Exidot for Cats [Brackets indicate alternate language] and  
EPA Reg. No. 88051-XXX {Braces indicate location of text on container label and notes to reviewer}

**{3. Label on Individual Pouch (contains single tube)}**

**Exidot for Cats**

Imidacloprid 9.1%

EPA Reg. No. 88051-x

Keep Out of Reach of Children

WARNING

Read The Entire Label Before Use. See insert for complete product information.

Use ONLY on 5-9 lbs Cats and Kittens 8 weeks and older

0.014 fl oz

or

Use ONLY on Cats and Kittens over 9 lbs, 8 weeks and older

0.27 fl oz

THIS UNIT IS NOT FOR RETAIL SALE

**{4. Label on Tube}**

**Exidot for Cats**

Imidacloprid 9.1%

EPA Reg. No. 88051-XXX

0.014 fl oz

or

0.27 fl oz

Lot No. 0000000

Exidot for Cats [Brackets indicate alternate language] and  
EPA Reg. No. 88051-XXX {Braces indicate location of text on container label and notes to reviewer}

**{5. Optional Text may or may not appear anywhere on Carton or Package Insert}**

[Contains imidacloprid, which effectively kills adult fleas[, which may cause Flea Allergy Dermatitis (FAD) or Flea Bite Hypersensitivity (FBH),] within 12 hours and prevents further reinfestation on cats.]

[Remains effective after bathing or after exposure to rain or sunlight.]

[Monthly treatments are recommended for control and prevention of fleas on cats.]

[Exidot for Cats contains imidacloprid]

[For use on cats and kittens 8 weeks of age and older and weighing [5-9 lbs] or [over 9 lbs]]

[A single topical application remains effective for [4 weeks][1 month]]

[Convenient, easy-to-apply topical solution]

[Convenient, easy-to-apply and fragrance-free [monthly][topical solution]]

[Once a month topical flea prevention and treatment for cats 8 weeks of age or older and [5-9 lbs] or [over 9 lbs]]

[Exidot for Cats is for the prevention and treatment of fleas on cats 8 weeks of age and older and weighing 5-9 lbs or over 9 lbs.]

[For the prevention of flea re-infestations on cats]

[For the treatment and prevention of flea infestations on cats]

[One treatment prevents further flea re-infestations on cats for up to [4 weeks][1 month][30 days]]

[Kills adult fleas on cats]

[Kills fleas on cats within 12 hours of application]

[Re-infesting fleas on cats are killed within 12 hours of application]

[Stops existing flea infestations on cats by killing adult fleas]

[Re-infesting fleas on cats are killed within 12 hours with protection against further flea infestation]

[Flea prevention and treatment for cats]

[Kills fleas on cats so they can't lay eggs]

[[Kills][Controls] fleas on cats]

[Monthly treatment [with Exidot for Cats] kills fleas which may cause flea allergic dermatitis [FAD] or flea bite hypersensitivity [FBH] on cats]

[Flea adulticide]

[Controls existing flea infestations on your cat and prevents further re-infestations]

[Controls flea problems on cats]

[Starts working through contact]

[Monthly use of Exidot for Cats kills fleas which may cause ([flea allergy dermatitis][flea bite hypersensitivity]) on cats]

[Kills fleas which may serve as intermediate hosts for tapeworms]

Exidot for Cats

[Brackets indicate alternate language] and

EPA Reg. No. 88051-XXX {Braces indicate location of text on container label and notes to reviewer}

[Remains effective after [bathing][shampooing]]

[Remains effective after exposure to rain or sunlight]

[Waterproof after 24 hours]

[Fragrance-free]