

806-14

7/12/2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON D C 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Avon Products Inc  
c/o J Michael Kelley Ph D  
toXcel  
7140 Heritage Village Plaza  
Gamesville VA 20155 3061

**JUL 12 2012**

**Subject** Label Amendments to add label language pursuant to the U S Food and Drug Administration (FDA) Final Monograph Rule for Labeling Sunscreen Products (21 CFR § 201.327) and revise alternate brand names  
Avon Skin So Soft SSS Bug Guard Plus IR3535 Insect Repellent Gentle Breeze SPF 30 Sunscreen Lotion (EPA Reg No 806 13)  
Avon Skin So Soft SSS Bug Guard Plus IR3535 Insect Repellent Cool N Fabulous SPF 30 Sunscreen Lotion (EPA Reg No 806 14)  
Avon Skin So Soft SSS Bug Guard Plus IR3535 Expedition Insect Repellent SPF 30 Sunscreen Spray Very Water Resistant Unscented (EPA Reg No 806 32)  
Avon Skin So-Soft SSS Bug Guard Plus IR3535 Expedition Insect Repellent SPF 30 Sunscreen Spray (EPA Reg No 806 33)  
Your submissions dated April 10 2012  
Decision Numbers 463803 463804 463805 and 463806

Dear Dr Kelley


The amendments referred to above submitted in connection with registration under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) section 3(c)(5) are acceptable provided that you

- 1) Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data
- 2) Submit two (2) copies of your final printed labeling before you release the products for shipment  
Final printed labeling means the label or labeling of the products when distributed or sold  
Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk screened directly onto glass or metal containers or large bags or drum labels

If these conditions are not complied with the registrations will be subject to cancellation in accordance with FIFRA section 6(e) Your release for shipment of the products bearing the amended labeling constitutes acceptance of these conditions A stamped copy of the labels are enclosed for your records

Should you have any questions you may contact Mr Colin Walsh directly at (703) 308 0298 or via email at [walsh.colin@epa.gov](mailto:walsh.colin@epa.gov)

Sincerely

  
Linda A Hollis Chief  
Biochemical Pesticides Branch  
Biopesticides and Pollution  
Prevention Division (7511P)

FRONT OF CONTAINER

[Original Brand Name]

AVON  
S  
S  
S  
SKIN SO SOFT  
BUG GUARD PLUS  
IR3535<sup>o</sup>  
INSECT REPELLENT  
SPF 30  
MOISTURIZING SUNBLOCK LOTION  
COOL N FABULOUS<sup>m</sup>

**ACCEPTED**

JUL 12 2012

Under the Federal Insecticide Fungicide and Rodenticide Act as amended for the pesticide registered under EPA Reg No 806-14

[Alternate Brand Name #1 (Notification 12/7/01) Bracketed information confined to use on Disappearing Color Lotion]

AVON  
S  
S  
S  
SKIN SO SOFT  
BUG GUARD  
PLUS  
IR3535<sup>o</sup>  
INSECT REPELLENT  
SPF 30 SUNSCREEN  
VERY WATER RESISTANT  
WITH VITAMIN E & ALOE  
[DISAPPEARING COLOR]  
COOL N FABULOUS<sup>TM</sup>

[Alternate Brand Name #2 – Bracketed information confined to use on Disappearing Color Lotion]

AVON  
SKIN SO SOFT  
S BUG  
S GUARD  
S PLUS  
IR3535<sup>o</sup>  
INSECT REPELLENT  
COOL N FABULOUS<sup>TM</sup>  
[DISAPPEARING COLOR]  
SPF 30 SUNSCREEN  
VERY WATER RESISTANT  
MOISTURIZING LOTION

[Alternate Brand Name #3 – Bracketed information confined to use on Disappearing Color Lotion]

AVON  
SKIN SO SOFT  
S BUG  
S GUARD  
S PLUS  
IR3535<sup>o</sup>  
INSECT REPELLENT  
COOL N FABULOUS<sup>TM</sup>  
[DISAPPEARING COLOR]  
SPF 30 SUNSCREEN  
WATER RESISTANT (80 MINUTES)  
MOISTURIZING LOTION

FOLLOWING IS APPLICABLE ALL FRONT LABELS [Bracketed information is optional package size]

KEEP OUT OF REACH OF CHILDREN  
CAUTION

ACTIVE INGREDIENTS  
beta alanine, n acetyl N butyl , ethyl ester\* / carboxylic acid 7 5%  
OTHER INGREDIENTS 92 5%  
TOTAL 100 0%  
\* IR3535<sup>o</sup>

4 FL OZ (118 ml) [2 5 FL OZ (75 ml)]

BACK OF CONTAINER

[Bracketed information confined to use on Disappearing Color Lotion]

**DIRECTIONS FOR USE** It is a violation of Federal law to use this product in a manner inconsistent with its labeling Apply liberally 15 minutes before sun and insect exposure An adult must apply this product to children under 10 Children under 6 months Ask a doctor For insect protection, reapply about every 2 hours or sooner if effectiveness diminishes For sunscreen protection reapply immediately after towel drying after 80 minutes of swimming or sweating at least every 2 hours Do not exceed 9 applications per day

STORAGE AND DISPOSAL	
STORAGE	Store in cool dry place away from heat or flame
DISPOSAL	<b>If empty</b> Nonrefillable container Do not reuse or refill this container Place in trash or offer for recycling if available <b>If partly filled</b> Call your local solid waste agency for disposal instructions Never place unused product down any indoor or outdoor drain

Protect this product from sun

**PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS Caution** For external use only Causes moderate eye irritation **When using this product** keep out of eyes **Do not use** on damaged or broken skin **Stop use and ask a doctor** if rash occurs **Keep out of reach of children Skin Cancer/Skin Aging Alert** Spending time in the sun increases your risk of skin cancer and early aging This product has been shown only to prevent sunburn **not** skin cancer or early aging

FIRST AID	
If in eyes	<ul style="list-style-type: none"> <li>Hold eye open and rinse slowly and gently with water for 15 – 20 minutes</li> <li>Remove contact lenses, if present, after the first 5 minutes then continue rinsing eye</li> </ul> Call a Poison Control Center or doctor for treatment advice
Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment You may also contact 1 800 FOR AVON for emergency medical treatment information	

ACTIVE SUNSCREEN INGREDIENTS Octinoxate 7 5%, Oxybenzone 6% Octisalate 5%

OTHER INGREDIENTS Water Butylene Glycol Glycerin, PVP/Eicosene Copolymer Aloe Barbadensis Gel Isostearic Acid Propylene Glycol Myristyl Ether Acetate, Stearic Acid Benzyl Alcohol, Cetyl Alcohol DEA Oleth 3 Phosphate, Diglycol/CHDM/Isophthalates/SIP Copolymer Dimethicone Glyceryl Stearate Magnesium Aluminum Silicate Tocopheryl Acetate Barium Sulfate Fragrance, Imidazolidinyl Urea, Xanthan Gum, Disodium EDTA, [Blue 1], [Red 33]

TO ORDER SEE AN AVON REPRESENTATIVE OR CALL 1 800 FOR AVON [www.avon.com](http://www.avon.com)  
Not for sale or use after expiration date  
EPA Reg No 806 14 EPA Est No 806 IL 1  
AVON PRODUCTS INC DISTR  
777 THIRD AVE NEW YORK, N Y 10017  
©AVON 200X ALL RIGHTS RESERVED

Day Lot Code  
Exp Year / Month

**Note to reviewer The following statements, including those within brackets, are optional AND may appear on the product label AND / OR in marketing collateral materials AND the use of punctuation marks for each statement is optional**

[Bracketed information confined to use on Disappearing Color Lotion]

- IR3535® is a registered trademark of Merck KGaA
- Avoid contact with plastics costume jewelry leather and synthetic fibers
- May damage painted or varnished surfaces, including nail polish
- With vitamin E and aloe
- REPELLENCY – IR3535<sup>○</sup> provides effective and dependable repellency against mosquitoes deer ticks black flies sand flies gnats no seeums and biting midges
- Suitable for the entire family
- Mild gentle formula does not need to be washed off when returning from the outdoors
- Pediatrician Tested
- Hypoallergenic
- SPF 30 water resistant (80 minutes)
- Helps prevent sunburn
- PABA Free
- Moisturization
- Non greasy formula helps replenish moisture and leaves skin soft and smooth

[Disappearing color has a] Fresh summer scent developed especially for the entire family  
[Care of Fabrics

- Color can be cleaned from most fabrics
- Avoid direct contact with silk nylon and cotton
- Color does not stain skin
- If necessary, color can be cleaned from skin with soap and water]