



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 30, 2020

Micah T. Reynolds
Regulatory Consultant
Australian Gold, LLC
c/o Technology Sciences Group, Inc.
1150 18th Street, N.W., Ste. 1000
Washington, DC 20036

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – Submission of Label Amendment updating flammability statements in Physical and Chemical Hazards section per request of California DPR.
Product Name: Australian Gold SPF Continuous Spray Sunscreen with Insect Repellent
EPA Registration Number: 61617-2
Application Date: 06/5/2020
OPP Decision Number: 563688

Dear Mr. Reynolds:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims

Page 2 of 2
EPA Reg. No. 61617-2
OPP Decision No. 563688

made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA 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 Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Sydnie Hetzel by phone at (703) 347-0220 or via email at Hetzel.sydney@epa.gov.

Sincerely,

A handwritten signature in blue ink that reads "Andrew C. Bryceland". The signature is fluid and cursive, with the first name being the most prominent.

Andrew Bryceland, Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

(MASTER LABEL)

Australian Gold SPF 30 Continuous Spray Sunscreen with Insect Repellent

(Alternate Brand Names:

- Australian Gold Botanical SPF 30 Continuous Spray Sunscreen with Insect Repellent;
- Australian Gold Botanical SPF 30 Pump Spray Sunscreen with Insect Repellent;
- Botanical SPF 30 Continuous Spray Sunscreen with Insect Repellent;
- Botanical SPF 30 Pump Spray Sunscreen with Insect Repellent;
- California Tan SPF 30 Continuous Spray Sunscreen with Insect Repellent;
- California Tan SPF 30 Pump Spray Sunscreen with Insect Repellent;
- CT SPF 30 Continuous Spray Sunscreen with Insect Repellent;
- CT SPF 30 Pump Spray Sunscreen with Insect Repellent;
- Raydiant Gold SPF 30 Continuous Spray Sunscreen with Insect Repellent;
- Raydiant Gold SPF 30 Pump Spray Sunscreen with Insect Repellent;
- Raydiant by Australian Gold SPF 30 Continuous Spray Sunscreen with Insect Repellent;
- Raydiant by Australian Gold SPF 30 Pump Spray Sunscreen with Insect Repellent;
- Justice by Australian Gold SPF 30 Continuous Spray Sunscreen with Insect Repellent;
- Justice by Australian Gold SPF 30 Pump Spray Sunscreen with Insect Repellent;
- Metro 365 SPF 30 Continuous Spray Sunscreen with Insect Repellent;
- Metro 365 SPF 30 Pump Spray Sunscreen with Insect Repellent;
- Defense Zone SPF 30 Continuous Spray Sunscreen with Insect Repellent;
- Defense Zone SPF 30 Pump Spray Sunscreen with Insect Repellent)

Water Resistant (80 minutes)

Active Ingredient

3-((N-butyl-N-acetyl)amino)propionic acid ethyl ester*.....20.00%

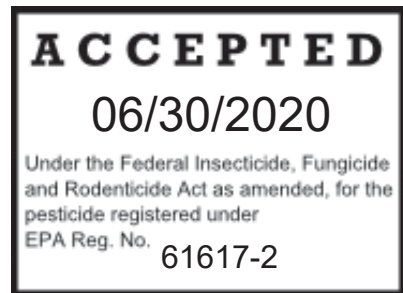
Other Ingredients.....80.00%

TOTAL.....100.00%

*IR3535® Insect Repellent

KEEP OUT OF REACH OF CHILDREN

CAUTION



[See] [back] [other] [side] [panel] [Peel back] for [first aid] [Drug Facts] [Directions for Use] [and][&] additional precautionary statements].

(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

[Manufactured for:] [Produced for:]
Australian Gold, LLC
8001 Woodland Drive
Indianapolis, IN 46278

EPA Reg. No. 61617-2
EPA Est. No.

Net Contents: X [fl.] oz. [(X ml)] [(X g)]

[NDC _____]

[Country of origin {insert country}]

[Manufactured in {insert country}]

[Barcode]

[IR3535® is a trademark of Merck KGaA, Darmstadt, Germany]

[Lot] [Batch] No: (Note to reviewer: Lot or batch code may also be stamped or printed directly on container.)

(Note to Reviewer: Since this product is also regulated as an over-the-counter sunscreen by the FDA, the following information required by 21 CFR §201.327 will appear in accordance with the formatting requirements of 21 CFR §201.66.)

Drug Facts [(continued)]

Active ingredients

Purpose

Octinoxate 7.5%, Octisalate 5.0%, Octocrylene 5.0%, Oxybenzone 4.0%.....Sunscreen

Uses

- helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not skin cancer or early skin aging.**

For external use only

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

Flammable: Avoid fire, flame, heat and smoking. **Contents under pressure.** Do not puncture or incinerate. Store at temperatures below 130°F

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

Directions

- shake well before use
- apply [liberally] [generously] [and evenly] 15 minutes before sun exposure and rub into skin
- reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours

(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

- **children under 6 months of age:** Ask a doctor

Inactive ingredients

Acrylates/Octylacrylamide Copolymer, Aloe Barbadensis Leaf Extract, Fragrance [(Parfum)], Glycine Soja [(Soybean)] Oil, Melaleuca Alternifolia [(Tea Tree)] Leaf Oil, SD Alcohol 40-B, Tocopheryl Acetate

Other information

- Protect the product in this container from excessive heat and direct sun. May stain some fabrics or surfaces.

Questions or comments?

1-XXX-XXX-XXXX

[Arrow graphic (if Drug Facts section is to be continued on another label panel)]

(Note to reviewer: Boxed format or bullets may be used in First Aid section if label space permits.)

FIRST AID

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.

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 855-548-4653 [or] [the National Pesticide Information Center at 1-800-858-7378, Monday through Friday, 8:00 AM to 12:00 PM PST, or at <http://npic.orst.edu>].

(Note to reviewer; "For additional information" statement may be substituted by alternative company preferred comments, questions 800 number located on front panel)

PRECAUTIONARY STATEMENTS

Hazards to Humans: CAUTION: For external use only. Causes moderate eye irritation. Avoid contact with eyes. Use on children under 6 months of age only with the advice of a physician.

(Note to Reviewer: *Storage & Disposal Language for pump spray packaging.*)

PHYSICAL OR CHEMICAL HAZARDS: Flammable. Keep away from heat, sparks, and open flame.

(Note to Reviewer: *Storage & Disposal Language for continuous spray/BOV pressurized packaging.*)

PHYSICAL OR CHEMICAL HAZARDS: Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

[INSECT REPELLENT] DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply liberally and evenly over dry, exposed skin. Hold container 4 to 6 inches from the skin to apply. Do not apply in windy conditions. Use in well-ventilated area. Do not spray directly on face. Spray on palm of hand and apply to face. An adult must apply this product to children under 10. For continued protection from mosquitoes and deer ticks, reapply after 8 hours, and from biting flies, reapply after 5 hours. Do not exceed 7 applications per day for adults, 3 applications per day for children. Do not apply over cuts, wounds, or irritated skin. Do not apply to excessively sunburned skin. Do not apply to children's hands. Do not allow children to handle this product.

(Note to Reviewer: Storage & Disposal Language for pump spray packaging.)

STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry area inaccessible to children.

DISPOSAL: Nonrefillable container. Do not reuse or refill this 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.

(Note to Reviewer: Storage & Disposal Language for continuous spray/BOV packaging.)

STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry area inaccessible to children.

DISPOSAL: 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 for disposal instructions.

www.AustralianGold.com

Optional Marketing Statements

General claims (including sunscreen effectiveness):

- Suitable for the entire family
- For active lifestyles
- Formula doesn't require washing off of skin upon return to indoors.
- Does not need to be washed off when returning from the outdoors
- Dermatologically tested
- Lightweight protection from mosquitoes and deer ticks [for 8 hours] and biting flies [for 5 hours]
- Protection from mosquitoes [and][&],[,] [deer ticks] [and][&] [biting flies] easily sprays over entire body at any angle for a convenient, mess free application
- Keep out of reach of children
- Family Friendly
- May stain some fabrics or surfaces

(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

- Gentle on skin
- Provides protection against UV rays, deer ticks, mosquitoes, [and][&] biting flies
- [Dependable] insect repellent [and][&] sunscreen
- 2-in-1 sun [and][&] mosquito and deer tick protection easily sprays over entire body at any angle for a convenient, mess free application
- Water resistant (80 minutes)
- SPF 30 Continuous Spray Sunscreen with Insect Repellent
- Protect yourself [and][&] your family from harmful UV rays [and][&] mosquitoes that may transmit West Nile virus and deer ticks that may transmit Lyme disease.
- Sunscreen [with Insect Repellent] [IR3535]
- SPF 30
- UVB Protection
- Sunscreen + Insect Repellent

Product formulation or packaging related claims

- PABA Free
- Contains 20% IR3535® Insect Repellent
- Contains Aloe [and][&] Vitamin E to soothe [and][&] moisturize skin
- Hypoallergenic
- Non-comedogenic – won't clog pores
- Pleasant fragrance
- Pleasant scent
- Fresh fragrance
- Uniquely designed fragrance is neutral [and][&] discreet, specially created to mask odors found in most repellents [and][&] leaves user with an enjoyable experience
- Gluten Free
- Paraben Free
- Protect this product from heat [and][&] direct sun
- Vitamin E
- Exotic Oils
- Dye Free
- DEET Free
- Aloe: Known as a wonderful moisturizer, Aloe provides naturally soothing [and][&] conditioning to skin
- No CFCs
- DOT 2P M5655

Product performance related claims (Repellency)

- Repels [mosquitoes] [for] up to 8 hours
- Repels Mosquitoes [and][&] deer Ticks for [Up To] 8 Hours
- Repels mosquitoes, deer ticks [and][&] biting flies
- Repels mosquitoes [up to 8 hours] that may [carry] [transmit] [the] West Nile virus [and][&] [encephalitis].
- Provides protection against mosquitoes that may transmit West Nile virus [and][&] deer ticks that may transmit Lyme disease.
- Repels mosquitoes [for] [up to 8 hours] that may [carry] [transmit] Zika Virus
- Repels mosquitoes [for] [up to 8 hours] that may [carry] [transmit] Chikungunya Virus
- Repels mosquitoes [for] [up to 8 hours] that may [carry] [transmit] Dengue Fever
- Repels deer ticks [for] [up to 8 hours] that may [carry] [transmit] Lyme Disease
- Provides protection against deer ticks [that may [carry] [transmit] Lyme Disease]

(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

- Repels biting flies [for] [up to 5 hours]
- Provides effective, dependable, [and][&] long-lasting repellency against mosquitoes [and deer ticks].
- Strong protection from mosquitoes [and deer ticks] for 8 hours, and biting flies for 5 hours
- Effective protection from mosquitoes [and deer ticks] for 8 hours, and biting flies for 5 hours
- Provides protection against deer ticks, mosquitoes, [and][&] biting flies
- Strong [and][&] long-lasting repellent against mosquitoes [and][&] deer ticks [for up to 8 hours]
- Dependable insect repellent for mosquitoes [and][&], [deer ticks] [and][&] [biting flies]
- Guards against mosquitoes [and][&], deer ticks [and][&] biting flies
- Protect yourself [and][&] your family from disease carrying insects - mosquitoes that may [carry][transmit] West Nile virus and deer ticks that may [carry][transmit] Lyme disease
- Images of target pests (mosquitoes, deer ticks, and biting flies)

Product application related claims

- Continuous Spray
- No Rubbing Required
- One Touch Pump
- Fine Mist Spray
- No Mess
- Convenient, no mess, no rub protection
- Fine mist spray goes on clear for convenient, no mess, no rub protection.
- Sprays Upside Down
- Dries Instantly – no greasy residue
- Non-greasy
- Non-oily
- Goes on clear
- Easy application
- Easy to use spray formula for no hassle application
- Light spray gel won't drip – or cause your grip to slip
- Dual Use 360° Protection
- Convenient application
- Spray at any angle
- Quick drying
- Fast drying
- Quick dry water-resistant spray
- Quick Drying: Dries fast to allow user to return to active lifestyle with a clean, fresh feel
- Non-sticky

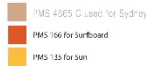
Optional Company Brand and Marketing Logos

(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)



3.

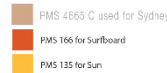
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3.



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Australian Gold® BOTANICAL



(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

METRO³⁶⁵™



RAYDIANT By Australian Gold.

Justice™ By Australian Gold®



Australian Gold®