

88165-4

5/2/2014

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Sciessent, LLC
c/o Technology Sciences Group, Inc.
1150 18TH ST., NW, SUITE 1000
Washington, DC 20036
Attn: Abigail Downs

MAY 2 2014

Subject: Label Update and CSF Amendment
EPA Reg. No. 88165-4
Amendment Letter dated August 19, 2013

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, to update the product label and Confidential Statement of Formula (CSF), is acceptable:

Label:
Updated Precautionary Statements

Updated CSF:
Agion Silver Antimicrobial Type ACU – Basic Formulation – dated August 19, 2013

If you have any questions concerning this letter, please contact Seiichi Murasaki at murasaki.seiichi@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "M Swindell".

Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510C)

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Agion® Copper Antimicrobial Type ACU

A preservative and bacteriostatic agent for use in the
manufacture of polymer, plastic, latex products.
For commercial and industrial use.

Active Ingredient:

Copper	6.1 %
Other Ingredients	93.9 %
Total	100.0 %

KEEP OUT OF REACH OF CHILDREN

CAUTION

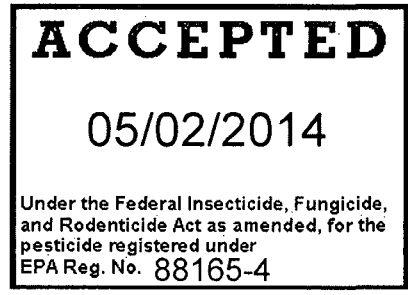
SEE INSERT LABEL FOR PRECAUTIONARY STATEMENTS

Supplied by:
Sciessent LLC
60 Audubon Road
Wakefield, MA 01880

EPA Registration No. 88165-4
EPA Establishment No. 71227-JPN-001

Net Wt. XXXX

Lot No. XXXXXXXXXX



Directions for Use

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

For all uses listed*:

- * **Do not incorporate this product into any food contact polymer unless the subject food contact polymer is approved and listed in 21 CFR, Parts 174 through 186 (inclusive), or in the United States Food and Drug Administration's "Food Contact Substance Notification System." Any incorporation of this product into an approved and listed food contact polymer must comply with the specific use conditions listed in 21 CFR, Parts 174 through 186 (inclusive), or in the United States Food and Drug Administration's "Food Contact Substance Notification System," for such food contact polymer. Any incorporation of this product into any food contact substance (including but not limited to non-polymer substances) other than an approved and listed food contact polymer is prohibited.**
- * **For applications involving direct or indirect food or human drinking water contact, Agion Copper Antimicrobial Type ACU must be used with an FDA approved polymer or coating. Non-food and non-drinking water contact applications can use either FDA or non-FDA approved coatings.**
- * **This product may be used for the following human drinking water contact uses:**
 - water filter components and housing units**
 - water bottle dispensers and components**
 - water dispensers**
 - ice machine trays**
 - ice machine bins**
 - ice machine water hoses**
 - ice dispensers and other ice machine components**
 - water bottles**
 - cups**
 - water storage vessels**
- * **This product may be incorporated into food and water bowls, dishes and other containers used by domestic animals. Do not use for any food or drinking water applications involving non-domestic animals.**

Agion® Copper Antimicrobial Type ACU is an antimicrobial additive to be used by compounding into many polymeric materials. It is designed to be incorporated during the manufacturing process to impart antimicrobial activity to the manufactured products. *Agion® Copper Antimicrobial Type ACU* suppresses the growth of algae, mold, mildew, fungi and bacteria which cause unpleasant odors, discoloration, staining, deterioration or corrosion only. No finished product incorporating *Agion® Copper Antimicrobial Type ACU* may make any public health claims relating to antimicrobial activity without first obtaining an EPA registration for the finished product which permits such claims. When incorporated into treated articles, this product does not protect users of any such treated article or others against food borne or disease causing bacteria, viruses, germs or other disease causing organisms.

Types of Finished Products

Plastics - including films, sheets, slabs, and molded plastic parts

The additive may be incorporated into the finished product at up to 5.0% by weight or at least 0.3% for bulk plastics. Contact Sciessent LLC to determine the appropriate amount of Agion® Copper Antimicrobial Type ACU for individual finished products.

Food contact* and non-food contact uses (in all food contact cases, when the article itself is a FDA-approved polymer):

- | | |
|--|--|
| Packaging | countertops |
| gaskets | sinks |
| general purpose containers | tiles |
| food and drink containers | dishes, cups, bottles |
| food trays and covers | conveyor belts |
| sponges | food processing equipment (including |
| tubing | slicers, formers, juicers, washers, canners, |
| brush bristles (including personal care | freezers, refrigerators, shelving, cookers, |
| grooming items, toothbrushes), and | grinders, choppers, peelers and |
| cosmetic brushes | countertops) |
| liners | beverage processing equipment (including |
| non-woven fabrics, | mixers, transfer equipment, pumps, |
| plastic sheeting for construction and | bottlers, canners, dispensers and |
| agricultural applications | fermenters) |
| appliances and equipment | building materials and components |
| kitchen and food processing utensils and | (including walls, hardware, floors, ceilings |
| supplies | and components thereof for kitchen, |
| cutting boards | commercial and industrial applications) |

Non-food contact uses only:

- | | |
|--|--|
| Automobile Parts | keyboards, mice |
| Mats | Medical devices, equipment and supplies |
| Waste containers | Shower curtains |
| Mops | Protective Covers |
| Plumbing supplies and fixtures | Brush handles |
| Siding for housing | Vacuum cleaner bags |
| Flooring | Drain pan liners |
| Insulation for wire and cable | Kitchen and bathroom hardware |
| Indoor and outdoor furniture | Floor coverings |
| Spas, bathtubs, showers, filters and | Insulators |
| components thereof | Plastic building materials |
| Office equipment and supplies (including | Garbage bags and garbage cans |
| binders, filing and storage systems, pens, | Telephones, mobile devices, head phones, |
| pencils, markers, printers, facsimile | head sets and |
| machines, desk accessories, computers, | Cameras and imaging equipment |

Fibers – including cotton, rayon and synthetically derived fibers

The additive may be incorporated into the finished product at up to 5.0% by weight or at least 0.5% for fibers. Contact Sciessent LLC to determine the appropriate amount of Agion® Copper Antimicrobial Type ACU for individual finished products.

Food contact* and non-food contact uses (in all food contact cases, when the article itself is a FDA-approved polymer, or as a FDA-approved polymer coating on an article):

Synthetic and Natural Fibers	outerwear, gloves, aprons, coats and shoes)
napkins, tablecloths and wiping cloths	sponges
bags	packaging (including bags, sacks, wraps, cushion and absorbent materials, and containers)
brush bristles (including personal care grooming items, toothbrushes and cosmetic brushes)	conveyor belts
filters	kitchen, commercial and industrial wipes and fabrics
clothing apparel (including uniforms,	

Non-food contact uses only:

Synthetic and Natural Fibers	socks and hosiery
Paper for gypsum board.	caps
Paper, paperboard, composite building materials	undergarments
<i>Interior furnishings -</i>	inner liners for jackets
mattress cover pads and filling	trim for outerwear and garments
pillow covers	medical devices, equipment and supplies
sheets	<i>Transportation –</i>
blankets	automotive and truck upholstery
fiberfill for quilts and pillows	carpeting
curtains	rear decks
draperies	trunk liners
carpet and carpet underlay	convertible tops
rugs	interior liners
upholstery	<i>Industrial and Other Household Items -</i>
mops	artificial leather
towels	filters
wall covering fabrics	book covers
cushion pads	mops
sleeping bags	cloth for sails
<i>Apparel –</i>	ropes
umbrellas	tents and other outdoor equipment
outerwear	tarps
sportswear	awnings
sleepwear	drain pan liners ¹
stockings	

Coatings, Films and Laminates

The additive may be incorporated into the finished product at up to 5.0% by weight, or at least 0.5% for coatings. Contact Sciessent LLC to determine the appropriate amount of Agion® Copper Antimicrobial Type ACU for individual finished products. Types of coatings include water-borne, solvent-borne, 100% solids, radiation cure, liquid and powder emulsion, starch, cellulosic, lacquer, thermoset, thermoplastic, thermal spray coatings including pre-dispersions and components thereof.

Food contact* and non-food contact uses (in all food contact cases, when the article itself is a FDA-approved polymer, or as a FDA-approved polymer coating, film or laminate on an article):

packaging
 paper products (including wipes and tissues)
 natural and synthetic fibers and fabrics
 sinks
 countertops
 cutting boards
 dishes
 cookware
 general purpose containers
 kitchen, commercial and industrial utensils and supplies
 collection and storage equipment (including conveyor belts, piping systems, silos, tanks and process vessels)
 appliances and food processing equipment (including slicers, formers, juicers, washers, canners, freezers, refrigerators, shelving, cookers, grinders, choppers, peelers and countertops)
 beverage processing equipment (including mixers, transfer equipment, pumps, bottlers, canners and fermenters and dispensers)
 building materials and components (including walls, hardware, floors, ceilings and components thereof for kitchen, commercial and industrial applications)

Non-food contact uses only:

Building Materials (including gypsum board, insulation, cellulose or fiberglass ceiling tile, and polymer flooring.)
 Heating, Ventilation and Air Conditioning equipment and related materials (including insulation, ducts, heat exchangers, drain pans, air filters, air purifiers, diffusers, and parts and components thereof)
 Industrial equipment

Furniture
 Automotive and vehicular parts
 Packaging
 Siding
 Roofing
 Shingles

Industrial equipment
 Medical devices, equipment and supplies

Adhesives and Sealants

The additive may be incorporated into the finished product at up to 5.0% by weight, or at least 0.5% for adhesives and sealants. Contact Sciessent LLC to determine the appropriate amount of Agion® Copper Antimicrobial Type ACU for individual finished products.

Food contact* and non-food contact uses (in all food contact cases, when the article itself is a FDA-approved polymer incorporated into FDA-approved adhesives or sealants):

plumbing adhesives
pipe sealants and insulating materials
grout and joint compound for; countertops, building materials and components, and food and beverage related equipment

Non-food contact uses only:

Adhesives, joint compound and grout for gypsum board, ceramic tile, wood, paper, cardboard, rubber and plastic.
Medical devices, equipment and supplies

Miscellaneous Applications

The additive may be incorporated into the finished product at up to 5.0% by weight. Contact Sciessent LLC to determine the appropriate amount of Agion® Copper Antimicrobial Type ACU for individual finished products.

Food contact* and non-food contact uses (in all food contact cases, when the article itself is a FDA-approved polymer or coating.

Interior paints and coatings
Stucco
Plaster
Leather
Medical devices, equipment and supplies

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: Caution. Harmful is absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes and clothing. Prolonged contact with this product may cause skin discoloration. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID	
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water of 15 – 20 minutes. • Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none"> • 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 inhaled	<ul style="list-style-type: none"> • 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. • Call a poison control center or doctor for further treatment advice.
If swallowed	<ul style="list-style-type: none"> • Call poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

Storage and Disposal

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

Pesticide Storage: Do not store in areas accessible to children. Keep product dry and containers covered during storage; store below 130°F.

Container Disposal: Nonrefillable container. Do not reuse or refill inner plastic bag or outer steel can. **Inner Plastic Bag:** Completely empty plastic bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke. **Outer Steel Can:** Offer for recycling if available or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities.

Pesticide Disposal: Wastes from the use of this product may be disposed of on site or at an approved waste disposal facility.