UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 2, 2020

Mr. Andrew McCarthy
President
Seal Shield, LLC
915 W. Second Ave.315
Windemere, Florida 34786
andrew@sealshield.com

Subject: Claims for Seal Shield Treated Articles

Dear Mr. McCarthy:

During our meeting on August 28, 2020, to discuss claims Seal Shield could make under the Treated Articles Exemption, we agreed to provide feedback on the proposed claims in your August 13, 2020 letter to Alexandra Dunn, Assistant Administrator of EPA's Office of Chemical Safety and Pollution Prevention. The following is our determination.

The following claims are acceptable under the Treated Articles Exemption:

- Antimicrobial-Guards against degradation from microorganisms.
- This product contains an antimicrobial agent to prevent microorganisms from degrading the product.
- This keyboard contains an antimicrobial agent to prevent microorganisms from degrading the product.
- This mouse contains an antimicrobial agent to prevent microorganisms from degrading the product.
- This cabinet contains an antimicrobial agent to prevent microorganisms from degrading the product.
- This screen protector contains an antimicrobial agent to prevent microorganisms from degrading the product.

The following claims are not acceptable under the Treated Articles Exemption because "microbes," "microbe," "microorganisms," etc., are not clearly qualified that they only include non-public health bacteria, mold, mildew, etc., or that may cause deterioration, odor, discoloration, etc., of the article itself. Also, "antimicrobial" without appropriate qualification is not acceptable.

- Antimicrobial-A microbe resisting component has been incorporated in this product to make its surface microbe resistant.
- Antimicrobial-This product contains silver ions which inhibits the growth of microbes on its surface.

- Antimicrobial-This keyboard contains silver ions which inhibits the growth of microbes on its surface.
- Antimicrobial-This mouse contains silver ions which inhibits the growth of microbes on its surface.
- Antimicrobial-This cabinet contains silver ions which inhibits the growth of microbes on its surface.
- Antimicrobial-This screen protector contains silver ions which inhibits the growth of microbes on its surface.
- Antimicrobial-The surface of this keyboard resists microbes.
- Antimicrobial-The surface of this mouse resists microbes.
- Antimicrobial-The surface of this cabinet resists microbes.
- Antimicrobial-The surface of this screen protector resists microbes.
- Antimicrobial-Product resists microbes.
- Antimicrobial-Keyboard resists microbes.
- Antimicrobial-Mouse resists microbes.
- Antimicrobial-Cabinet resists microbes.
- Antimicrobial-Screen Protector resists microbes
- Antimicrobial-Product surface resists microbes.
- Antimicrobial-Keyboard surface resists microbes.
- Antimicrobial-Mouse surface resists microbes.
- Antimicrobial-Cabinet surface resists microbes.
- Antimicrobial-Screen Protector surface resists microbes.
- Antimicrobial-A microbe resisting component has been incorporated in this keyboard to make its surface microbe resistant.
- Antimicrobial-A microbe resisting component has been incorporated in this mouse to make its surface microbe resistant.
- Antimicrobial-A microbe resisting component has been incorporated in this cabinet to make its surface microbe resistant.
- Antimicrobial-A microbe resisting component has been incorporated in this screen protector to make its surface microbe resistant.
- Antimicrobial-Specially formulated to resist the growth of microbes on its surface.
- Antimicrobial-The product contains an antimicrobial additive to inhibit the growth of bacteria on the product.
- Antimicrobial properties are built-in to inhibit the growth of bacteria that may affect this product.
- This product features antimicrobial product protection which helps reduce microbial growth on the product surface.
- A fresher and more pleasing surface can be maintained through antimicrobial properties built into the product.
- This product is protected with Silver SealTM, an antimicrobial, fungistatic agent which makes the product greener and fresher by inhibiting the growth of microbes, odor-causing bacteria, mold, mildew and fungi on the product's surface.
- This product is waterproof and contains antimicrobial surface protection. Seal Shield's waterproof technology protects the user by enabling the keyboard to be washed and disinfected with an appropriate EPA registered disinfectant.

- Seal Shield's keyboards and mice feature waterproof & dishwasher-safe washability, in combination with antimicrobial plastic construction, that provide additional resistance to microbe contamination on the product surfaces between required product cleaning & disinfection cycles, which waterproof construction alone cannot provide.
- Seal Shield Screen Protectors: Advanced Antimicrobial Screen Protection.

The following are claims not acceptable under the Treated Articles Exemption because *implied* or explicit public health claims are not allowed. Any article or substance making such a public health claim must be registered as a pesticide.

- The SEAL SHIELD™ keyboard or mouse is designed to work with virtually all medical grade, commercial grade, antibacterial, antiviral and antifungal sprays to kill most known surface contaminants including SARS, Influenza, Staph and MRSA.
- The SEAL SHIELD™ screen protector is designed to work with virtually all medical grade, commercial grade, antibacterial, antiviral and antifungal sprays to kill most known surface contaminants including SARS, Influenza, Staph and MRSA.
- SEAL SHIELD™ keyboards and mice contain an additive for antimicrobial product protection. The antimicrobial Silver Ions are actually embedded in the molten plastic during the manufacturing process, protecting your keyboards and mice by inhibiting up to 99.9% of surface microbial growth. It is completely safe for people, animals and the environment.
- SEAL SHIELD™ screen protectors contain an additive for antimicrobial product protection. The antimicrobial Silver Ions are actually embedded in the TPU and during the manufacturing process, protecting your keyboards and mice by inhibiting up to 99.9% of surface microbial growth. It is completely safe for people, animals and the environment.
- SEAL SHIELD™ Prevents Infection. Saves Lives., the company's logo.

The following claims are not acceptable under the Treated Articles Exemption because they are not properly qualified that they have no connection to the antimicrobial found in the article or substance.

- Medical keyboards have recently become recognized as an important and cost-effective tool for infection prevention.
- Seal Shield's waterproof products stand up to most common hospital cleaning agents, the regular utilization of which can reduce the risk of cross-contamination and hospital acquired infections.
- Seal Shield products are an important line of defense to help prevent infections and save lives. Seal Shield keyboards and mice are 100% waterproof, washable and include antimicrobial product protection.
- "Seal Shield's screen protector with Antimicrobial Product Protection was developed with healthcare in mind for Surgical Monitors, Touch Screens, Computers and Tablets.
- Seal Shield antimicrobial product protection technology provides a level of protection of the product between cleaning procedures.
- We protect the user by reducing cross contamination with regular cleaning and disinfection.
- Seal Shield recommends that its medical keyboards be washed regularly, to eliminate pathogens on the surface, thereby protecting the users.

- Seal Shield's technology allows IT equipment to be washed, making it possible to rid that equipment of dangerous pathogens.
- The world today reflects unparalleled risks for contamination and infection all around us. Founded in 2006, Seal Shield is helping to address this public health challenge - in partnership with healthcare providers and institutions globally. Through innovations like the industry's first medical-grade, washable keyboards & computer peripherals, or new SaaS disinfection management technologies, Seal Shield is serving professionals on the frontlines in healthcare, commercial and public institutions around the world.
- Seal Shield. First In Infection Prevention. (A general company marketing tagline – not product specific – as we introduced the industry's first waterproof keyboard in 2006.)
- Seal Shield is a world leader in innovative infection-control and healthcare technology. Seal Shield designs, develops and manufactures medical-grade solutions including waterproof keyboards and mice, screen protectors, antimicrobial polymers and UV-C technology.

While the following do not appear to be treated article claims, they are more consistent with marketing claims for pesticidal devices. Regardless, these claims are not fully acceptable. The EPA does not register, approve, officially "validate," etc., devices or approve "research results" associated with devices. Any statement implying EPA's endorsement are false and misleading which are prohibited (see 40 CFR 156.10(a)(5). Furthermore, as stated in EPA's June 15, 2020 review of information you provided to support your device claims, the EPA does not have testing standards for devices. OPP's review confirmed that Seal Shield's submitted data/studies demonstrated that the ElectroClave is 99.9% effective against four named virus causing bacteria: Staphylococcus, Escherichia coli, MRSA and CRE on non-porous hard surfaces. However, use of the terms such as "Superbug" and "Nightmare Bacteria" to describe pests are not acceptable and should not be used. Text that has not been struck through is acceptable.

- The Seal Shield ElectroClave™ UV-C Mobile Device Disinfection system ~~has been validated by the U.S. Environmental Protection Agency, (EPA), to~~ effectively reduces 99.9% ~~of the "Superbug"~~ MRSA and ~~the "Nightmare Bacteria,"~~ CRE, on hard, nonporous surfaces, such as cell phones and tablets.
- ~~The EPA has approved research results, confirming that~~ the ElectroClave™ achieves a 99.9% reduction of Staphylococcus, Escherichia coli, MRSA and CRE on hard, nonporous surfaces. ~~This is the first time that the EPA has granted this approval of efficacy for a UV disinfection chamber~~.
- ~~The ElectroClave. The only EPA-Approved UV-C Disinfection Box.~~

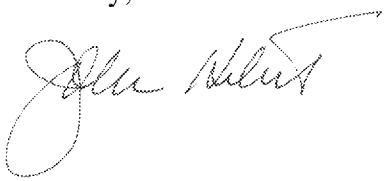
The following claim is non-pesticidal and is therefore allowed for your device(s). However, non-pesticidal cleaners do not typically have "dwell" times as part of their direction for use.

- The waterproof Seal Shield Keyboard or Mouse is compatible with dwell time requirements for major hospital cleaners and disinfectants.

Please note that this review is only applicable for the claims as they appear in this document. Any changes or modifications may affect our determination. Also, any treated article claims made on articles or substances such as medical devices that also make (non-pesticidal) public health or drug claims will most likely require further qualification to ensure there is no confusion

with non-public health pesticidal claims. If you have any further questions, please contact me at hebert.john@epa.gov.

Sincerely,



John Hebert, Chief
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

cc: Kimberly Bingham, EPA Region IV