

No-Tox AM[®] Guidance Document

Treated Article Claim

NS25
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This guidance document clarifies what treated article claims are acceptable for products treated with the AgION[®] antimicrobial compound. However, it only focuses on acceptable EPA claims; it does not explain Federal Trade Commission (FTC) advertising requirements.

It is important to note that AgION antimicrobial compound is registered with the Environmental Protection Agency (EPA) as a preservative and bacteriostatic agent for use in the manufacture of polymer, plastic and latex products. Under the EPA registration, the compound may be incorporated into No-Tox AM[®] coatings for purposes of protecting the coating; the coating then may be applied to the packaging product. The AgION compound is not registered with the EPA as a disinfectant, which kills human pathogens. That is, the antimicrobial is not incorporated into the No-Tox coating or onto the end use product to protect the consumer, but rather only to protect the coated article from deterioration. No claim should express or imply that the consumer is protected or that the AgION product does anything other than protect the coating itself. Other claims may be considered as public health claims by the EPA and are not permissible.

The following claims are examples of both unacceptable and acceptable claims. Please contact Colorcon to review claims, which differ from the “acceptable claims” below:

Unacceptable Health Claims:

- A claim that a specific microorganism is controlled, e.g., “Prevents E. Coli”.
- An unqualified claim of “Antimicrobial”, i.e., the claim must accompany additional language, which clarifies the intended non-public health use, e.g., “prevents mold and mildew”. The claim “antimicrobial” may in itself be unacceptable to EPA if it is in bolder text than the accompanying information on the packaging; it must be located with the qualifying language and in the same type. A treated article claim must accompany the statement “Antimicrobial”.

Acceptable Non-Health (Treated Article) Claims:

- No-Tox AM inhibits the growth of bacteria inside the package.
- AgION antimicrobial is effective against a broad spectrum of bacteria.
- Built-in protection to prevent the growth of mold and mildew on the coating used in this packaging.

Note:

The verbs, “prevent, inhibit, suppress, resist, guard against”, and “reduce” may be interchanged in all the acceptable claims; the terms prevent, inhibit, resist, guard against, and reduce are expressly used in examples given by EPA of acceptable claims.

Food Contact Applications – Required Disclaimer

The following or a similar disclaimer must be incorporated into advertising claims for food contact articles:

- This product does not protect users or others against food borne bacteria (or illnesses).

Other EPA Claim Limitations

In addition to the non-health claims, which apply to treated articles, EPA regulates what a seller can claim in regards to a product's safety. Recognize that the antimicrobial compound is intended to kill organisms. To that end, EPA Regulations stipulate that the compound cannot be advertised as "safe" or "non-toxic" even when qualified with "when used as directed" or by other means.

EPA also forbids the use of the phrases "contains all natural ingredients" and any statement, which directly or indirectly, implies that the compound is recommended or endorsed by any agency of the Federal Government. However, AgION Technologies is willing to claim that the compound is EPA registered.

Acceptable claims, which may be used to communicate these ideas in an acceptable manner, include:

- *No-Tox AM[®] coatings and inks are FDA acceptable for direct food contact.*
- *AgION Antimicrobial is FDA acceptable for direct food contact.*
- *AgION Antimicrobial is EPA Registered.*
(Note: The compound, not the end use product, is registered.)
- *The AgION ingredient is registered with the EPA.*
- *The AgION active ingredient is silver.*
- *AgION protects the coated article from deterioration.*