Livinguard Self-Disinfecting Textile for Emergency Use in N95 Facemasks: Statement of Biocompatibility

Background

COVID-19 is an infectious disease caused by the SARS-COV-2 virus that has been declared a global pandemic by the World Health Organization. The spread of SARS-COV-2 has resulted in immense stress on global healthcare systems and produced a shortage of lifesaving medical devices and personal protective equipment used by medical professionals, including face masks. Livinguard, Inc. manufactures a range of self-disinfecting materials including textiles that are fabricated through the integration of disinfectants directly into the material. Livinguard wishes to use their self-disinfecting textile in the fabrication of an N95 facemask. This use would classify the device as an N95 Respirator with Antimicrobial/Antiviral Agent (product code ONT) regulated by 21CFR878.4040 which specifies that "the user contacting components of the device must be demonstrated to be biocompatible." The FDA has raised a specific question on the point of biocompatibility of the treated textile when used as a mask.

The textile in question is treated with polyhexamethylene biguanide (PHMB, Manufactured by Arch UK Biocides as Vantocil IB). This active agent is bonded to the textile fibers, with effectiveness that persists after multiple washes (data on file with Livinguard). This document summarizes what is known about the biocompatibility of the Livinguard self-disinfecting textile in question, and evaluates the appropriateness of its use in N95 masks from the perspective of biocompatibility.

Summary of Biocompatibility Testing Completed on MED610

A suite of biocompatibility tests have been conducted on a worst-case version of the textile that contains PHMB among other ingredients at a concentration 250% above normal.

Table 1. Biocompatibility Tests Performed on Livinguard's Self-Disinfecting Textile

Biological Endpoint	Testing Standard	Result
Sensitization	EPA P328 Buehler Method	Pass
Irritation	EPA P326 Primary Skin Irritation	Pass
Acute Dermal Toxicity	EPA P322 Acute Dermal Toxicity	Pass

Gap Assessment, Testing Conducted, and Regulatory Expectations for Mask Applications

Testing was conducted on the textile per EPA protocols assuming household use, not necessarily as a mask. For masks that are marketed as a medical device, a biocompatibility evaluation should be conducted per ISO 10993-1. According to this standard, N95 masks would be categorized as surface devices with a cumulative contact to intact skin possibly greater than 30 days. The biological endpoints for evaluation of this contact type are cytotoxicity, sensitization, and irritation.

Based on the passing results of sensitization and irritation per EPA standards, it is likely that the material would pass these tests when tested per ISO 10993-1, and the risks associated with these endpoints are acceptable. Cytotoxicity testing was not conducted. This test would not be a good indicator of biocompatibility for the textile in question, as it is designed to be anti-microbial and is expected to be cytotoxic. Cytotoxicity testing should be considered on the same textile not treated with the active agent. Nevertheless, the absence of these test results should not prevent the material from being used in PPE during the COVID-19 pandemic.

FDA Feedback Regarding Use

In preliminary conversations, the FDA indicated to Livinguard a concern that the charged fibers of the textile could act as a cationic surfactant that may damage respiratory tissue.

Vantocil IB is an aqueous solution of PHMB, which is applied to the textile and then fully dried. PHMB is a polymer, typically with 10-40 repeating units and a molecular weight in excess of 700 g/mol. Therefore, it is expected to be non-volatile and has a reported vapour pressure of 4.11×10^{-7} Pa at 25 °C and not able to vaporize for inhalation at any appreciable amounts (see CLH Monograph on PHMB). Because the active agent on the treated textiles is permanently applied, persisting over several washes, and non-volatile they are not available to be inhaled and interact with respiratory tissues.

Potential Risks Associated with VOCs and Particulates: While VOCs released from the textile were not explicitly measured, the non-volatile nature of active agents and their persistence on the textile mitigate this concern. Therefore, any risks potentially associated with VOCs and particulates from the textile are considered acceptable in emergency situations associated with the COVID-19 pandemic.

Limits and Recommendations
The risks related to use of Livinguard's self-disinfecting textile in masks is considered minimal. It is recommended that representative samples of material are fabricated into masks and tested per the most current FDA recommendations to explicitly demonstrate compliance to the standards and to completely mitigate risk. It is however acceptable to proceed with use in applications related to the COVID-19 pandemic ahead of the conclusion of this testing.

Conclusion
The minimal biocompatibility risks associated with use of Livinguard self-disinfecting textile is masks are acceptable in emergency situations associated with the COVID-19 pandemic.

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Important Information: *This document is not equivalent to regulatory approval by any regulatory body. It is a third-party expert evaluation of the potential risks of the material when used described and in accordance with Emergency Use Authorization (EUA) being issued in response to concerns relating to insufficient supply and availability of FDA-cleared PPE for use in healthcare settings to treat patients during the Coronavirus Disease 2019 (COVID-19) pandemic. For more information visit US FDA at: https://www.fda.gov/media/136423/download.*