Justification Surgical Mask Color

Armbrust, Inc.
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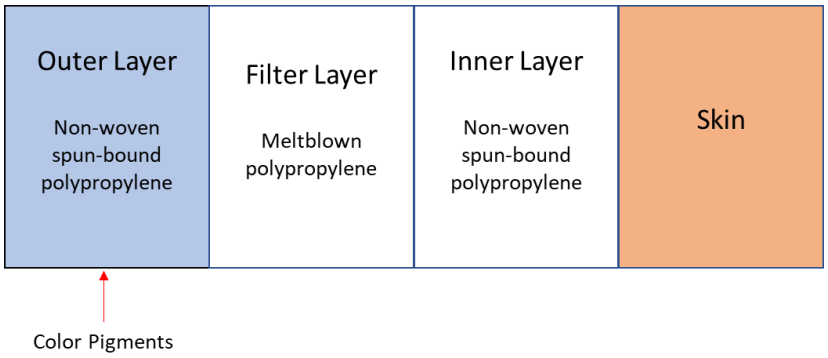
Product: USA-Made Surgical Masks
Project No.: MJ21061-ARM01

To Whom It May Concern:

Armbrust, Inc. manufactures USA-Made Surgical Masks, a Class 2 medical device, that is available in various colors (dark blue, grey, green, orange, and red). In filing for a 510(k), Armbrust Inc has conducted biocompatibility evaluation on the product, where all tests were conducted using blue masks. Specifically, cytotoxicity, irritation and sensitization tests were conducted. In addition to biocompatibility studies, bacterial filter efficiency, differential pressure, flammability, particle filter efficiency and synthetic blood penetration resistance tests were also completed using blue masks as test specimens. This document aims to justify that the tests completed are applicable to masks of all colors.

All masks have masterbatch pigments added to the outermost layer of the surgical mask during the raw material manufacturing to color the outer layer. The outer layer of the mask, where color pigments are added has no intended skin contact, so any potential risks associated with the difference in color are expected to be inherently minimal.

Figure 1. Mask Layers showing Location of Colored Layer in Question



Evaluation
ISO 10993-1:2018 describes the principles governing the biological evaluation of medical devices. This standard applies to the non-clinical testing of devices. It should be noted that Clause 4.5 states: "All known possible biological hazards shall be taken into account for every material and final product, but this does not imply that testing for all possible hazards will be necessary or practical." Clause 4.1 of this standard

specifies: "Evaluation may include both a study of relevant preclinical and clinical experience and actual testing. Such an evaluation might result in the conclusion that no testing is needed if the material has a demonstrable safe history of use in a specified role and physical form that is equivalent to that of the device under design." ISO 14971:2019 Medical devices – Application of risk management to medical devices states that "Risk estimation incorporates an analysis of the probability of occurrence of harm and the severity of the harm. Depending on the area of application, only certain elements of the risk estimation process might need to be considered in detail." The standard goes on to state that the information or data for estimating risks can be obtained, for example, from:

- published standards;
- scientific or technical investigations;
- field data from similar medical devices already in use, including publicly available reports of incidents;
- usability tests employing typical users;
- clinical evidence;
- results of relevant investigations or simulations;
- expert opinion; or
- external quality assessment schemes for *in vitro* diagnostic medical devices.

Material Evaluation

The mask layer in question is made from polypropylene, a commonly used material with face masks. The colors are added to the outer layer raw material as a masterbatch pellet. Masterbatch pellets are non-volatile solid plastic pigment colorants added in extremely small quantities to the virgin polypropylene pellets during the non-woven spun-bound raw material manufacturing. The masterbatch pellets are composed of polypropylene, titanium dioxide, polyethylene wax, and the color pigment, all of which are commonly used materials in skin contact products such as masks, cosmetics, and skincare products. The only difference between the blue mask and the other colors of masks are the color pigments which are a non-volatile solid plastic material color additive, also typically used in cosmetics. The pigments themselves comprise only a fraction of the master batch (10% to 20%) and the master batch is let-down or mixed with the polymer at low levels (0.4% by weight is typical); therefore the final polypropylene is less than 0.1% by weight colorant. These amounts do not alter the bulk material or chemical properties of the mask layer and therefore the likelihood that they pose any additional risk is low. As such, the performance testing conducted on blue masks is applicable to all colored masks as well.

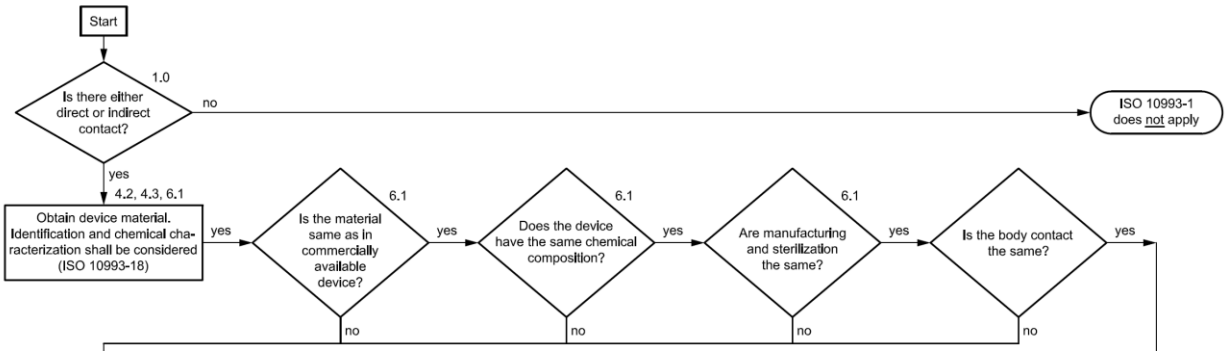
Furthermore, as the mask layer raw material is sourced from the same manufacturer, the risk of any variation in the raw material manufacturing process is mitigated. The colored sheet material is then used by Armbrust, Inc to construct the mask using the same process for all mask colors.

Biocompatibility Testing

Biological safety should be considered giving special attention to the ISO 10993 series for a particular application. Evaluation of prior use, information on previous uses of the device/materials or intended additives, and any adverse reactions encountered should be reviewed. Account should be taken of the intended use, the concentration of the ingredients, and current toxicological information. The need for testing should be reviewed on a case-by-case basis.

Figure 1 of ISO 10993-1 is a flow chart describing the situations in which biological testing might be necessary and is partially reproduced below.

Figure 1. Portion of Flow Chart in Figure 1 of ISO 10993-1



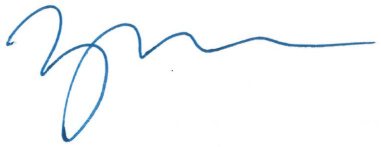
The portion of the mask in question is isolated from skin by two layers of materials, including the directly contacting inner layer. Because there is no intended direct or indirect contact, ISO 10993-1 does not apply to this layer. However, as the inner layer of the mask is in direct contact with skin, testing was executed on finished masks for cytotoxicity, sensitization, and irritation, all of which, passed. The likelihood that a different color pigment composed of non-volatile plastic material on the outer layer of the mask would impact the outcome of any of these tests is low.

More importantly, there is inherently minimal risk to the user from any color pigment since there is no intended skin contact of the colored layer. Furthermore, as the added material is non-volatile, there is no unintended skin contact expected from the breathing pathway while wearing the mask. In the event that there is skin contact between the outer layer and the patient skin due to misuse, the risk to the user has been shown to be low from the results of the test and the similarities in material properties and manufacturing processes of all colors. Additionally, the duration of extreme misuse scenarios (such as use of the mask while wet) are expected to be short and produce negligible potential differences in exposure due to extraction of colorants.

Conclusion

Armbrust Inc is evaluating the potential impact of different colors of their mask against the biocompatibility testing conducted with blue masks. The potential impact has been evaluated and confirm that the conducted biocompatibility tests are applicable to masks of all colors due to the inherent similarity in material properties and manufacturing process. This same rationale applies to the applicability of performance tests conducted on blue masks to all color variations of the mask.

Assessment reviewed by:



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