VibroX Pods – Black Discoloration

Description
EMA Aesthetics Ltd. has received feedback from the market regarding the appearance of black spots on the surface of a small number of VibroX Pods. The observations relate to isolated black markings visible on the external surface of sealed VibroX Pods prior to use. The affected products remain sealed within their original packaging, with no reported damage to the packaging or the VibroX Pod itself.  

Investigations
Following receipt of market feedback, EMA Aesthetics initiated an investigation in collaboration with the physical manufacturer of the VibroX Pods. The physical manufacturer's investigation confirmed that the observed black markings originate from the desiccant sachet contained within the product packaging. The desiccant sachet contains two functional components: • **Silica beads**, which control moisture within the packaging. • **Activated charcoal**, which absorbs odours and volatile compounds during storage. Under certain transport or handling conditions, contact or friction between the desiccant sachet and the external surface of the VibroX Pod may result in superficial transfer of activated charcoal onto the abrasive capsule, producing the black spots observed. The investigation further confirmed that: • The markings originate from the packaging component rather than the VibroX Pod itself. • The transfer is superficial and limited to the external surface of the abrasive capsule. • There is no evidence of degradation or damage to the VibroX Pod. • The integrity of the sealed packaging remains unaffected. • There is no evidence that the observation affects the intended function or performance of the VibroX Pod. Activated charcoal is a well-characterised material that is widely used in pharmaceutical, medical and cosmetic applications due to its established safety profile.
Conclusion
The investigation confirmed that the observed black spots result from superficial transfer of activated charcoal from the desiccant sachet contained within the product packaging. The observation is cosmetic in nature only and does not originate from the VibroX Pod itself.

Based on the investigation completed by the physical manufacturer and the assessment performed by EMA Aesthetics, there is no evidence that the observed markings affect the integrity, intended performance or safety of the VibroX Pod. Accordingly, the VibroX Pods remain suitable for their intended use
Actions
EMA Aesthetics has confirmed the source of the observed black spots and has completed an assessment of the potential impact on product quality and user safety. The VibroX Pods remain suitable for their intended use, with no identified impact on product safety, performance or efficacy. EMA Aesthetics is working with the physical manufacturer to further reduce the potential for superficial transfer during storage and transportation through continued evaluation of the packaging configuration and handling conditions. Market feedback will continue to be monitored as part of EMA Aesthetics' ongoing Post-Market Surveillance activities to ensure the continued quality and safety of the product.
Summary
EMA Aesthetics investigated reports of black spots observed on the external surface of a small number of VibroX Pods. The investigation confirmed that the markings originate from superficial transfer of activated charcoal from the desiccant sachet contained within the product packaging. The transfer is limited to the external surface of the abrasive capsule, does not originate from the VibroX Pod itself, and does not affect the product's integrity, intended performance or suitability for use. EMA Aesthetics therefore concludes that the VibroX Pods remain safe, effective and suitable for their intended use. EMA Aesthetics remains committed to the continual improvement of its products and packaging and will continue to work with the physical manufacturer to minimise the potential for this cosmetic presentation. Any significant findings or improvements will be communicated through EMAs established quality processes.

We appreciate feedback from our customers and remain committed to continually improving the quality and presentation of our products. If you have any questions or require further information, please contact EMA Aesthetics.

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EMA Aesthetics Ltd.