



Tronox Titanium Dioxide

September 22, 2017

Medical Device

Tronox titanium dioxide pigments are not suitable for Class III medical devices (medical devices, implant, and applications which come in contact with internal body fluid or tissue). Therefore, Tronox has not acquired a 510(k) premarket notification approval.

Tronox does not manufacture any titanium dioxide products that meet U.S. Pharmacopeia requirements.

Please contact Tronox product stewardship manager with questions regarding this statement, ChemProdSteward@tronox.com

Tronox titanium dioxide may not be directly added to food, pharmaceuticals, or cosmetics. Tronox titanium dioxide may not be used for implantable medical devices used for life-sustaining or life-supporting applications in humans.

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