

# RMO<sup>®</sup>

# PRODUCT SAFETY DATA SHEET

Product Information: 303.592.8200

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## 1. PRODUCT IDENTIFICATION

Elgiloy<sup>®</sup> Products

Arch

Wire, Straight

Wire Forms, Auxiliaries, Quad-Helix, Coil Springs

## 2. COMPOSITION, PHYSICAL CHARACTERISTICS

These products are manufactured from Elgiloy<sup>®</sup> material which in their physical form and size under normal use for their intended purpose do not constitute a physical or health hazard composition.

## 3. TOXICOLOGICAL INFORMATION

No toxic effects are expected from exposure to the solid form of these products. These products contain nickel which for some persons prolonged contact could result in development of nickel sensitization. The product should not be used or its use should be discontinued for such persons.

These products are sold as single use products. RMO, Inc. expressly disclaims any liability for the spread of disease or personal injury caused by reuse.

## 4. REGULATORY INFORMATION

These products are manufactured using Good Manufacturing Practices and are regulated as Class I medical devices by U.S.

Food and Drug Administration and Class IIa medical devices under Medical Device Directive 93/42/EEC for European Community.

These are manufactured articles which do not require a Material Safety Data Sheet. This information is sent in compliance with the Hazard Communication Program of OSHA.

These products are supplied clean, but not sterilized. These can be sterilized using any sterilizing method.

## 5. ADDITIONAL INFORMATION

The information in this Product Safety Data Sheet was obtained from sources believed to be reliable; however, the information is provided without any representation of warranty, express, or implied regarding the accuracy of correctness.

The conditions of handling, storage, preparation for use, use and discarding of the product are beyond RMO, Inc.'s control. For this and other reasons, RMO, Inc. does not assume responsibility and expressly disclaims liability for loss, damage, or expense arising out of or in any way connected with the handling, storage, preparation for use, use and discarding of the product.