

KRATON™

Making Healthcare Safer

Advanced Polymer Solutions for Medical Devices



Proven Performance

Over the past three decades, Kraton has enabled medical designers to improve patient safety, health and comfort. Today, our most versatile polymer selection continues to inspire medical designers in hospital, homecare, therapy, rehabilitation, diagnostics and drug delivery systems.

Our Cariflex™ isoprene rubber products are found in a variety of applications including medical stoppers, syringes, tubing and surgical gloves. The high molecular weight, anionically-polymerized polyisoprene replaces natural rubber and/or natural rubber latex, which can cause Type I allergies. Kraton unhydrogenated styrenic block copolymers (USBC) are used in adhesive formulations designed for ostomy care and wound care management. Our hydrogenated styrenic block copolymers (HSBC) are also in TPE compounds or blends to make medical stoppers, IV bags (film), IV bottles, IV tubing, IV connectors, IV drip chambers, comfort bedding, orthopedics and respiratory applications.

Powering Innovation

Kraton values our connection to the medical design community, from organizing regional workshops to collaborating with original equipment manufacturers (OEM) on technology demonstrations. We are proud to be part of the healthcare value chain and help deliver the key benefits that make the work of saving lives possible. Whether you need a safer alternative to latex gloves or more durable medical IV bags, you can depend on Kraton to help push the boundaries of performance that power the future of innovation.



Safe, Reliable Solutions

Kraton develops, manufactures and markets biobased chemicals and specialty polymers that deliver exceptional value and enhance the lives of people all over the world. From healthcare professionals to the patients who rely on their care, all of them depend on safe, reliable medical equipment to perform the daily job of saving lives. Kraton helps make that possible through advanced, engineered synthetic polymers that meet the demanding requirements of medical devices while minimizing health concerns.

As the inventor and a leading global producer of styrenic block copolymers (SBC), Kraton has served the medical market for more than 30 years – delivering clear, soft, sterilizable and strong elastomer solutions. Our polymers and polymer-modified systems can replace natural rubber or polyvinyl chloride (PVC) and are formulated without PVC, phthalates and plasticizers. With a deep expertise of the medical industry and its demanding requirements, Kraton focuses on the following key areas:

- Formulation consistency
- Careful selection and monitoring of ingredients and additives
- Supply continuity according to medical needs
- Shelf life of up to five years
- Change management procedure
- Pharmacopeia compliance
- Certified testing according to FDA, USP, ISO 10993

Features

- Sterilization resistance
- Puncture resistance
- Resealability
- Low coring risk
- Low weight
- No phthalates are intentionally added
- No natural rubber or natural rubber latex

Benefits

- High purity
- Reliable durability
- Excellent transparency
- Advance protection and comfort
- Eco-friendly, hypoallergenic properties
- Comply with demanding medical requirements

Extensive Regulatory Experience

United States Pharmacopeia (USP) and/or
ISO 10993 – Toxicology



Kraton has performed biological reactivity tests on representative grades in each major product line. Based on our experience, we can apply these results to other products in each product line. On this basis, we can provide compliance statements according to the USP Class VI biological reactivity tests, which includes system toxicity study in mice, intracutaneous toxicity study in rabbits and muscle implantation study in rabbits; and/or the ISO 10993 standard test, which includes:

- Intracutaneous Extract Study in Rabbits (Part 10). Equivalent to USP Class VI Biological Reactivity Tests.
- Systemic Toxicity Extract Study in Mice (Part 11). Equivalent to USP Class VI Biological Reactivity Tests.
- Muscle Implantation Study in Rabbits (Part 6).
- Cytotoxicity Study using acceptable methods such as the ISO Elution Method. (Part 5).
- Hemolysis [Compatibility with Blood] using acceptable methods such as ASTM F756-00 and ISO 10993-4).

Drug Master File (DMF)

Kraton maintains a DMF with the Food and Drug Administration (FDA) at the Center for Drug Evaluation and Research in Beltsville, Maryland, USA. Kraton's Drug Master File is DMF number 1180. For more information and details on specific grades, consult with your local Kraton sales manager.

Kraton Cosmetics, Drugs and Medical Device Policy (CDMD)

No customer of Kraton Polymers, or any other party, shall, without the express written consent of Kraton Polymers for each specific, individual application, be permitted to manufacture, use, sell, process, or otherwise supply, directly or indirectly, any Kraton Product, or any compound containing or made from any Kraton Product, in any of the following end-use products or applications:

1. Cosmetics products, other than: (a) cosmetics products containing Kraton product grades designated for cosmetics use, and (b) products designed for the packaging or delivery of cosmetics. For purposes hereof, a product shall be deemed a "cosmetic product" if it satisfies the definition of cosmetic product contained in any applicable law or regulation of the United States, China or the European Union (or any member state thereof).
2. Drug and other pharmaceutical products, other than products designed for the packaging or delivery of drugs and other pharmaceuticals.
3. Medical devices, other than: (a) any medical device falling within the definition of either a Class I or Class II medical device, as defined in any federal law or regulation of the United States or Canada, or (b) any medical device falling within the definition of a Class I or Class II(a) medical device, as defined by any applicable regulation of the European Union or any member state thereof.



The responsibility for the final product approval resides with the customer. Please consult your local Kraton sales manager for more information.

REACH

Kraton complies with the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulations and obligations. For more information and details on specific grades, consult with your local Kraton sales manager.

Substances of Very High Concern (SVHC)

Based on our analysis of raw materials, process chemicals and additives used in the manufacturing process for Kraton Polymers Segment products, we are not aware of SVHC published by the ECHA on the Candidate List* that are used or added on purpose for the manufacture of our products in concentrations at or exceeding the reporting threshold**.

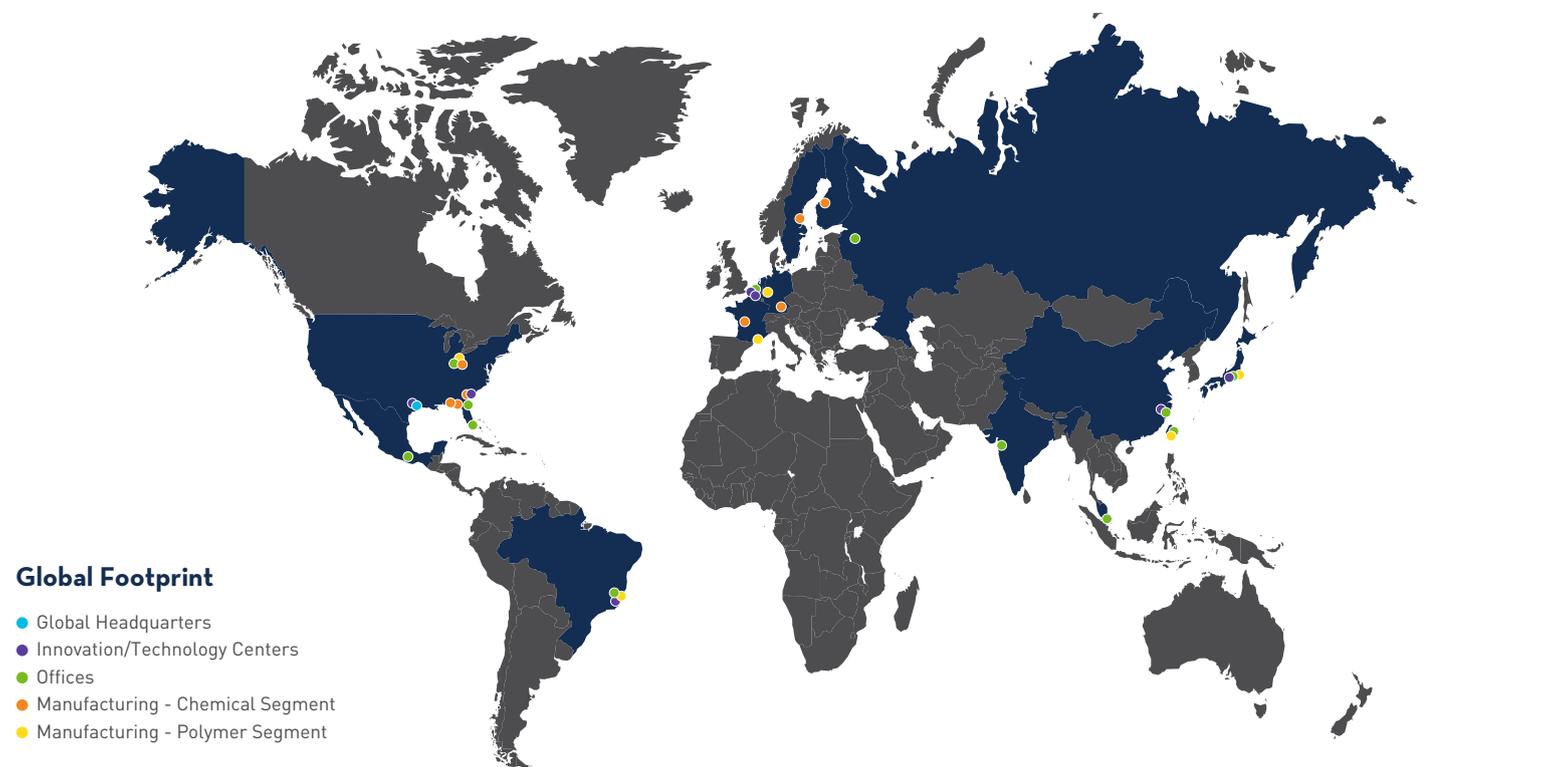
We do not routinely analyze for these substances and cannot guarantee that they are not present in trace or other amounts.

*Last updated June 27, 2018

**more than 0.1 percent

About Kraton Corporation

Kraton Corporation (NYSE: KRA) is a leading global producer of styrenic block copolymers, specialty polymers and high-value performance products derived from pine wood pulping co-products. Kraton’s polymers are used in a wide range of applications, including adhesives, coatings, consumer and personal care products, sealants and lubricants, and medical, packaging, automotive, paving and roofing applications. As the largest global provider in the pine chemicals industry, the company’s pine-based specialty products are sold into adhesive, road and construction and tire markets, and it produces and sells a broad range of performance chemicals into markets that include fuel additives, oilfield chemicals, coatings, metalworking fluids and lubricants, inks and mining. Kraton offers its products to a diverse customer base in numerous countries worldwide.



Kraton Corporation (NYSE:KRA)

For more information, visit our website at www.kraton.com or email info@kraton.com.

Locations

U.S.A. HEADQUARTERS
Houston, Texas

ASIA PACIFIC
Shanghai, China

EUROPE, MIDDLE EAST, AFRICA
Almere, The Netherlands

SOUTH AMERICA
Paulinia, Brazil

INDIA
Mumbai, India

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