



## GLOBAL REGULATORY BULLETIN FOR KRATON POLYMER SEGMENT PRODUCTS

Date: July 2017

### OVERVIEW

This product stewardship information is a global regulatory summary of Kraton's polymer segment products and is our regulatory disclosure to customers.

Kraton's SDSs and labels are aligned with the UN Global Harmonized System of Classification and Labels. Based on our regulatory and health assessment there is a list of substances cited by regulation that are not intentionally added, are not reasonably expected to be present in our products, nor should they exceed a threshold identified in the regulations. *If a substance exceeds the regulatory threshold, it will be identified; otherwise, it meets the requirements.* We do not routinely analyze our products for all of these substances. Based on knowledge of our raw materials, and our manufacturing operations we do not reasonably expect their presence. (See Attachment 1).

The information is given based on our current knowledge as of the date of this bulletin and made to our reasonable ability in good faith with no warranty or guarantee. It is the user's responsibility to evaluate the information based on regulatory action and intended use(s).

For additional information, please contact the Kraton Product Stewardship & Regulatory Affairs Department at [product.safety@kraton.com](mailto:product.safety@kraton.com)

### EUROPEAN UNION DIRECTIVES, REGULATIONS

#### EU Regulation No 10/2011 and amendment

For specific information, contact [product.safety@kraton.com](mailto:product.safety@kraton.com).

#### Food Allergen Labeling - EU Directive 2000/13/EC, amended by 2007/68/EC, Annex IIIa

Cereals containing gluten, celery, mustard, sesame seeds, lupin, molluscs, sulphur dioxides and sulphites above 10 mg/kg expressed as Sulphur Dioxide, and the categories in the FALCPA (milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, and soybeans).

Kraton polymer segment products are man-made synthetic substances manufactured in chemical plants and are not manufactured with or from any derivatives or proteins of the fifteen food ingredients noted.

#### Genetically Modified Organisms (GMO's) - EU Directive 2001/18/EC and Regulations (EC) No 1829/2003 & 1830/2003

Kraton polymer segment products are neither genetically modified nor genetically derived.

#### REACH, CLP Regulation - (EC) No 1272/2008 (CLP) and Regulation (EC) No 1907/2006 Annex XVII (Reach)

Presence of carcinogens, mutagens, and reproductive toxins not exceeding the specified concentration limits.

## **REACH Substances of Very High Concern (SVHC)**

Based on our current knowledge of the materials used in the manufacturing process for the Kraton polymer segment products, we are not aware of any Substances of Very High Concern (SVHC - as published by ECHA on the current Candidate List) that are intentionally used, added, or formed in concentrations at or exceeding the reporting threshold (> 0.1%). Since we do not routinely analyze for every SVHC substance in all of our products, we cannot guarantee that they are not present in trace amounts. (For the complete list access the website <http://echa.europa.eu/candidate-list-table>)

## **Restrictions of Hazardous Substances (RoHS2) - EU Directive 2011/65/EC as amended**

Lead, Mercury, Hexavalent chromium, Polybrominated biphenyls (PBB), Polybrominated diphenyl ethers (PBDE), Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), and Diisobutyl phthalate (DIBP) not exceeding 0.1% or Cadmium not exceeding 0.01%.

## **End of Life Vehicles - EU Directive 2008/112/EC**

Absence of cadmium, hexavalent chromium, lead or mercury - *Meets the requirements*

## **Waste Electrical and Electronic Equipment Directive (WEEE) - EU Directive 2012/19/EC**

Absence of cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls (PBB's) and polybrominated diphenyl ethers (PBDE's), polychlorinated biphenyls (PCB's), polychlorinated terphenyls (PCT's), brominated flame retardants, asbestos, chlorofluorocarbons (CFC's), hydrochlorofluorocarbons (HCFC's), hydrofluorocarbons (HFC's), hydrocarbons (HC), refracting ceramic fibers, radioactive substances. *Meets the requirements*

(Like all plastics, Kraton polymer segment products are hydrocarbons, but are not expected to contain low molecular weight volatile hydrocarbons.)

## **Biocides - EU Directive 98/8/EC on biocidal products and EU Directive 2009/251/EC on products containing biocide dimethylfumarate (DMF)**

Kraton does not sell biocidal products.

## **PFOS Compounds - EU Directive 2006/122/EC**

Restricting perfluorooctane sulfonates (PFOS) - *Meets the requirements*

## **Phthalates in toys and childcare articles - EU Directive 2005/84/EC, 1999/815/EC**

DEHP, DBP, BBP, DINP, DIDP, and DNOP not exceeding 0.1%, and lead not exceeding 0.03% as per CPSA

## **Ozone Depleting Substances (ODS) - Regulation (EC) No 1005/2009/EU**

Halogenated-hydrocarbons - *Meets the requirements*

## **Volatile Organic Compounds - EU Directive 2004/42/EC - *Meets the requirements***

## **Epoxy Glycidyl Ethers and Derivatives - EU Directive 2005/1895/EC**

BADGE, BFDGE, and NOGE - *Meets the requirements*

## **Polycyclic Aromatic Hydrocarbons (PAH) - Commission Regulation (EU) No 1272/2013 - *Meets the requirements***

## **Restrictions on marketing and use of certain dangerous substances and preparations - EU Directive 2003/53/EC**

Nonylphenol, nonylphenol ethoxylate and cement containing chromium VI - *Meets the requirements*

**PentaBDE and octaBDE - EU Directive 2003/11/EC**  
Halogenated Phenyls - *Meets the requirements*

**Toy Norm EN 71-3:2013 on migration of certain elements**

Based on our current knowledge of raw materials, process chemicals and additives used in the manufacturing of Kraton polymer segment products, and on recent testing data, we can inform you that none of the 19 elements is expected to be present above the limits specified in the norm.

**Persistent Organic Pollutants (POPs) - Regulation (EC) No 850/2004**

Including tetraBDPE, pentBDPE, hexaBDPE, heptaBDPE, PFOS and its derivatives, DDT, chlordane, hexachlorocyclohexanes, aldrin, dieldrin, endrin, heptachlor, hexachlorobenzene, hexabromobiphenyl, chlordecone, pentachlorobenzene, mirex, PCBP, toxaphene. - *Meets the requirements*

## USA LEGISLATION

**Food and Drug Administration (FDA) 21 CFR 170-199**

For specific information, contact [product.safety@kraton.com](mailto:product.safety@kraton.com).

**Food Allergen Labeling and Consumer Protection Act (FALCPA) 2004**

The following 8 major foods and any ingredient that contains protein derived from them, are designated as "major food allergens" by FALCPA. (milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans)

Kraton polymer segment products are synthetic substances manufactured in chemical facilities not using any protein derivatives from the above food groups.

**Bioterrorism Act, 2002 - Public Health Security and Bioterrorism Preparedness and Response Act**

In the Final Rule on October 10, 2003 FDA clarifies the regulation requiring the registration and import notification to cover "food for consumption" and **exempts** all materials and articles defined as "food contact substances".

Kraton polymer segment products are used as components in food packaging applications and meet the exemption for "food contact substances".

**Bovine Spongiform Encephalopathy (BSE) - Animal/Plant Derived substances - 21 CFR 700.27; 189.5 and Regulation (EC) No 999/2001**

Kraton polymer segment products are manufactured using petrochemical/synthetic raw materials without the use of animal or plant derived substances or by-products.

If derived from animals (This is usually tallow derived from bovine source used as a raw material in calcium or zinc stearates), the final product is produced under conditions that exceed those found in Section 6.4 TALLOW DERIVATIVES of EMEA/410/01 Rev. 2 (European Union) with hydrolysis at not less than 200 °C for not less than 20 minutes under appropriate pressure.

**Kosher Statement**

Kraton polymer segment products are not classified KOSHER. The manufacturing process does not use any ingredient of animal origin nor do Kraton products come in contact with animal products during storage and transportation.

## International Nomenclature Cosmetic Ingredient (INCI) Registered Names

### D Products

Styrene/Butadiene Copolymer (SBS)

Styrene/Isoprene Copolymer (SIS)

### G Products

Hydrogenated Styrene/Butadiene Copolymer (SEBS)

Hydrogenated Styrene/Isoprene Copolymer (SEP(S))

Hydrogenated Polyisoprene Crosspolymer (EP)

### IR and IR Latex Products

Polyisoprene

### *Conflict Minerals Rule* - Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act

For this information, contact [product.safety@kraton.com](mailto:product.safety@kraton.com).

### The Lacey Act as amended - 16 U.S.C. 3371 et seq.

For this information, contact [product.safety@kraton.com](mailto:product.safety@kraton.com).

### Consumer Product Safety Act (CPSA), August 14, 2008

Lead in children's products not to exceed 100 ppm. - *Meets the requirements*

### Consumer Product Safety Commission (CPSC) - 16 CFR Part 1107

Establishes protocols, standards, testing, labeling and certification for children's products. - *Meets the requirements*

### Consumer Product Safety Act, 2008

DEHP, DBP, BBP, DINP, DIDP, and DNOP not exceeding 0.1%, and lead not exceeding 0.03% as per CPSA

### Ozone Depleting Substances (ODS) - 40 CFR 82, Subpart E - *Meets the requirements*

### Water pollutants - 40 CFR Part 423, appendix A

Priority pollutants are a set of chemical pollutants the US EPA regulates, and developed analytical test methods. The current list of 129 Priority Pollutants can be found at

<http://water.epa.gov/scitech/methods/cwa/pollutants.cfm> - *Meets the requirements*

### Coalition of Northern Governors (CONEG) association of the Governors of seven Northeastern states

The sum of the concentration of lead, mercury, cadmium and hexavalent chromium does not exceed 100 ppm in packaging or packaging components.

### Drug Master File (DMF)

Select products are listed in DMF# 1180. Contact [product.safety@kraton.com](mailto:product.safety@kraton.com) for a DMF letter of authorization (LOA) to be sent to FDA for your use(s).

### Pharmacopeia (USP)

Representative products have been tested to meet USP Class VI. For this information, contact [product.safety@kraton.com](mailto:product.safety@kraton.com).

California Safe Drinking Water and Toxic Enforcement Act, 1986 (Proposition 65)

For this information, contact [product.safety@kraton.com](mailto:product.safety@kraton.com).

## Export Administration Regulation

Does not require a license: EAR 99

## Export Control Classification Number (ECCN)

Our products are not regulated, and do not require a permit.

## Shelf Life Information

Product Family	Years - From Date of Manufacture	Temperatures	Relative Humidity
A Products	5	60-80°F range	< 85% levels
D and D Milled Products	3	60-80°F range	< 85% levels
FG and G Products	5	60-80°F range	< 85% levels
IR Solid Products	2	60-80°F range	< 85% levels
IR Latex Products	See Data Document		
DX, MD and RP Products	For this information, contact <a href="mailto:product.safety@kraton.com">product.safety@kraton.com</a>		

Product that is exposed to airflow, sunlight, or chemical agents may degrade more quickly, so it is recommended that product packaging be kept intact to limit such exposure.

Materials Declaration Standard for the Electrotechnical Industry developed by trade associations in Europe, Japan and the United States to report certain materials and substances.

**Joint Industry Guide (JIG 101) Material Composition Declaration for Electrotechnical Products - JIG-101 Ed.4.1, (5/21/12)** - Not intentionally added to our products nor are the threshold exceeded.

**Joint Industry Guide (JIG 201) Material Composition Declaration for Packaging of Electrotechnical Products - JIG-201 Ed.1.1, (8/27/12)** - Not intentionally added to our products nor are the threshold exceeded.

<http://www.ce.org/CorporateSite/media/Standards-Media/Standards%20Listings/JIG-101-Ed-41-120521.pdf>

<https://www.ce.org/CorporateSite/media/Standards-Media/Standards%20Listings/JIG-201-Ed-1-1.pdf>

## INTERNATIONAL CONVENTIONS

**Rotterdam Convention of *Prior Informed Consent (PIC)* for Certain Hazardous Chemicals and Pesticides in International Trade - *Meets the requirements***

**Montreal Protocol - Ozone Depleting Substances - *Meets the requirements***

## Stockholm Convention on Persistent Organic Pollutants (POPS)

Substances classified as PBT's including; aldrin, endrin, dieldrin, chlordane, DDT, heptachlor, mirex, hexachlorobenzene, PCB's, toxaphene, polychlorinated dibenzo-p-dioxins, polychlorinated dibenzofurans, PAH's, brominated flame retardants, and tributyltin. - *Meets the requirements*

## Chemical Weapons Convention

Controlled substances of Schedule 2, 3, and Precursors which are used in chemical industrial applications - *Meets the requirements*

## United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988, Tables 1&2 of substances

Not intentionally added to Kraton polymer segment products nor are the threshold exceeded.

## JAPANESE DOMESTIC LAWS

### Industrial Safety and Health Law (ISHL)

Prohibition of Manufacturing, and Permission for Manufacturing (amended June 25, 2014). - *Meets the requirements*

### Poisonous and Deleterious Substances Control Law

Specified Poisonous Substances (amended June 19, 2015). - *Meets the requirements*

### Chemical Substances Control Law (CSCL)

**Class I Specified Chemical Substances** - Chemicals that are Persistent, Highly Bioaccumulative and have long-term toxicity to Humans or the Environment. - *Meets the requirements*

[http://www.safe.nite.go.jp/jcheck/list6.action?category=211&request\\_locale=en](http://www.safe.nite.go.jp/jcheck/list6.action?category=211&request_locale=en)

**Class II Specified Chemical Substances** - Chemicals that are Persistent, are Toxic to Humans and cause long-term toxicity to the Environment, including Non-Persistent chemicals. - *Meets the requirements*

[http://www.safe.nite.go.jp/jcheck/list6.action?category=212&request\\_locale=en](http://www.safe.nite.go.jp/jcheck/list6.action?category=212&request_locale=en)

### Japan Hygienic Olefin and Styrene Plastic Association (JHOSPA)

Registered products meet the voluntary standards (specifications) for use in food containers, packaging materials, and utensils in Japan requiring registration on the Positive List (PL). For specific information, contact [product.safety@kraton.com](mailto:product.safety@kraton.com).

## ATTACHMENT 1

**List of Regulated Substances:** We do not intentionally add any of the chemicals listed in the Regulated Substance list below in the manufacturing of Kraton polymer segment products nor do we routinely analyze for these substances.

Acetaldehyde	Endocrine disruptors	Phthalates
Acetone	Ethylamine	Polybrominated Biphenyls
Acrolein	Ethylene Glycol	Polybrominated Diphenyl Ethers
Acrylamide	Ethyl Glycol Acetate	Polychlorinated Biphenyl
Acrylic Acid and its Acrylate of Butyl, Ethyl, Methyl	Formaldehyde	Polycyclic Aromatic Hydrocarbons
Aliphatic Amine	Genetically Modified Organisms (GMOs)	Polyvinyl Chloride (PVC)
Alkylphenols and Ethoxylates	Halogenated Phenols	Pyridine
Aniline	Halogens	Selenium and its Compounds
Antimony and its Compounds	Hexachlorobenzene	Short-chain Chlorinated Paraffins
Aromatic Amine	Melamine	Tetrachloroethylene
Arsenic and its Compounds	Mercaptans	Thallium and its Compounds
Asbestos	Methyl Acrylate	Thioethers
Azo Compounds	Methyl ethyl ketone	Thiols
Benzyl Chloride	Methyl isobutyl ketone	Toluene 2,4-diisocyanate
Beryllium and its Compounds	Monomethyl-dibromo-diphenyl methane	Tribromo Bisphenol A
Brominated Flame Retardants	Monomethyl-dichloro-diphenyl methane	Trichloroethylene
Butyl Acrylate	Monomethyl-tetrachlorodiphenyl methane	Triethylamine
Butyl Glycol	Natural Rubber Latex	Trimellitic anhydride
Carbon Tetrachloride	Nitrobenzene	Triphenylphosphine
Chlorinated paraffins	Nitrocresol	Triphenylphosphine Oxide
Chloroacetaldehyde	Nitrophenol	Tris(nonylphenol) phosphite
Chloroacetic Acid	Nitrosamines	Xylene
Chloroform	Nonanal	1,1-dichloroethene
Chloromethane	Nonylphenol	1,1,2-trichloroethane
Cosmetic (CMR Substances)	Nonylphenol Ethoxylates	1,1,2,2-tetrachloroethane
Creosote	Octylphenol	1,4-Dioxane
Cresol	Octylphenol Ethoxylates	2-Furaldehyde (furfural)
Cyclohexanone	Organotin Compounds	2-Nitrotoluene
Dichloromethane	Ortho-phenylphenols and salts	2,4-dichlorophenol
Diethylamine	o-Toluidine	2,4,5-trichlorophenol
Diglycidyl Ether	Perchloroethylene	2,4,6-trichlorophenol
Dimethylamine	Perfluoroalkyl Sulfonate (PFAS)	4-Nitrotoluene
Dioxins and Furans	Perfluorooctane Sulfonate (PFOS)	4,4'methylenebis(2,6-diethylaniline)
Diphenols/Biphenols	Perfluorooctanoic Acid (PFOA)	



## Kraton Polymers LLC - Cosmetics, Drugs and Medical Device Policy

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.

### DISCLAIMER

We believe the information set forth above to be true and accurate as of the date of this letter, but such statements are made without any warranty, and shall establish no legal duty or responsibility on the part of the undersigned or any affiliate of the undersigned. Nothing herein should be construed as implying a legal guarantee for specific properties of the products or for their suitability for a particular application. Unless otherwise stated in writing, our products are sold without warranty.

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