April 04, 2024

Pete Ross

Ark-Plas Products, Inc
165 Industry Lane
Flippin AR USA 72634

KYNAR® 720 PLT (200005158)

To whom it may concern:
Thank you for your interest in the referenced product. This letter is provided in response to your request for regulatory compliance information. Please note that this letter is effective on the date created and supersedes any prior documents received.

REACH AND INVENTORY STATUS

Global Inventory Status

Global inventory information may be available for EU – EINECS /ELINCS, US - TSCA, Australia - AICS, Canada – DSL/NDSL, Japan - ENCS/ISHL (JP), Korea - KECI (KR), New Zealand - NZIOC (NZ), Philippines - PICCS (PH), and China - IECSC (CN).

Details on the inventory status for the product is available in the appropriate chapter of the SDS.

Substance of Very High Concern (SVHC)

This paragraph concerns substances listed in the Candidate List of Substances of Very High Concern, in accordance with Article 59 of the European Regulation 1907/2006 effective: 01/23/2024

Based on the final product composition this product is not a Substance of Very High Concern and does not contain any SVHC substance(s) above the declaration threshold.

REACh-Annex XIV-Authorisation list

This paragraph concerns substances subject to authorisation listed in Annex XIV of Regulation (EC) No 1907/2006. 01/23/2024

Based upon a review of the final product composition, substances listed in Annex XIV are not known to be present in this product.

REACh-Annex XVII-CMR

A “Carcinogenic”, “Mutagenic” or “Toxic for Reproduction” (CMR) for purposes of this review is defined by EU Regulation (EC) No 1272/2008 and regulated by Annex XVII of Regulation (EC) No 1907/2006, entries 28, 29 and 30 (restrictions regarding the placing on the market and uses) as of the effective date: 01/23/2024

Based upon a review of the final product composition, CMR substances categories 1A and 1B listed on appendices 1-6 of REACH Annex XVII are not known to be present in the above-mentioned product above the declaration threshold.

HEAVY METALS

CONEG Model Toxics in Packaging

Model Toxics in Packaging Legislation (also referred to as CONEG) concerns restrictions on the use of certain hazardous substances in packaging or packaging components (including printing inks used in packaging), and restricts the sum of the incidental concentration levels of lead, mercury, cadmium and hexavalent chromium present in the product to a level equal to or less than 100 parts per million by weight

Based on a review of the final product composition, this product is not known to contain CONEG substances at or above the 100 ppm reporting threshold.

AUTOMOTIVE

Global Automotive Declarable Substances List (GADSL)

The Global Automotive Declarable Substances List covers substances that are expected to be present in a material or part that remains in the vehicle or part at point of sale. The list is available on the GADSL website. 02/01/2024

Substances listed in the Global Automotive Declarable Substances List are not known to be present in this product above the reporting threshold. The review was based on the known final product composition.

POLLUTION PREVENTION-WASTE MANAGEMENT-ECOLABELING

EPA TSCA Section 6(h) Persistent, Bioaccumulative, and Toxic Chemicals (PBTs)

Under the U.S. Environmental Protection Agency (EPA) Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, EPA issued final rules to reduce exposures to certain chemicals that are persistent, bioaccumulative and toxic (PBT). EPA is prohibiting either the manufacture (including import), processing, and/or distribution in commerce unless use is specifically exempted in the final rule for the substance. Arkema is providing the information about the presence of these PBTs in the product(s) to aid its customers. Customers should consult the final rules in docket EPA-HQ-OPPT-2019-0080 for their specific situation.

Based on a review of the product composition, this product is not known to contain TSCA Section 6(h) PBTs.

2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP)	732-26-3	Not Present
Decabromodiphenyl ether (DecaDBE)	1163-19-5	Not Present
Hexachlorobutadiene (HCBD)	87-68-3	Not Present
Pentachlorothiophenol (PCTP)	133-49-3	Not Present
Phenol, isopropylated phosphate (3:1) (PIP 3:1)	68937-41-7	Not Present

Hazardous Air Pollutants - US Clean Air Act Section 112

Under the Clean Air Act, US EPA is required to regulate emissions of hazardous air pollutants (HAPs). This original list included 189 pollutants. Since 1990, EPA has modified the list through rulemaking to include This assessment is based on the 187 substances identified by the EPA as hazardous air pollutants including the general class of glycol ether substances as defined by the Toxic Release Inventory (TRI) (EPA 745-R-00-004).

Based on the final product composition, this product is not known or expected to contain US HAPs as defined by the regulation.

Ozone Depleting Substances - US Clean Air Act

Ozone depleting substances (ODS) as defined in accordance with section 602 of the United States Clean Air Act (40 CFR Part 82).

Based on the product composition this product is not known or expected to contain Ozone Depleting Substances as defined by the regulation.

Restriction of Hazardous Substances (RoHS) - EU

Restrictions on the use of certain hazardous substances in electric and electronic equipment as defined in the Annex III of the Directive 2011/65/EU and amendments in force.
Effective date: 03/25/2023

The RoHS substances (and their reporting thresholds) are: Lead (0.1%), Mercury (0.1%), Cadmium (0.01%), Hexavalent chromium (0.1%), Polybrominated biphenyls (PBB) (0.1%), Polybrominated diphenyl ethers (PBDE) (0.1%), Bis(2-ethylhexyl) phthalate (DEHP) (0.1%), Butyl benzyl phthalate (BBP) (0.1%), Dibutyl phthalate (DBP) (0.1%), Diisobutyl phthalate (DIBP) (0.1%).
Based on a review of the final product composition, there are no RoHS substances known to be present above the reporting threshold.

Restricted Substances in Electronic Information Products- China RoHS

As defined by the 2006 Chinese Ministry released Administrative Measures on the Control of Pollution Caused by Electronic Information Products (EIP) # 39.

Based on a review of the final product composition, there are no listed substances known to be present above the reporting threshold.

MISCELLANEOUS REGULATORY LISTS

California Proposition 65

Substances as defined in Proposition 65 of the California Safe Drinking Water and Toxic Enforcement Act of 1986 and its amendments. Effective: 03/19/2023

Based on the final product composition this product is not known to contain CA Proposition 65 substances.

OTHER

BPA and Phthalates

The following BPA and Phthalates were reviewed at a threshold of 100ppm.

1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich (DIDP)	68515-49-1	Not Present
1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich (DINP)	68515-48-0	Not Present
Bis(2-methoxyethyl) phthalate	117-82-8	Not Present
Bisphenol A 0.002	80-05-7	Not Present
Bisphenol-F (BPF)	87139-40-0	Not Present
Butyl benzyl phthalate (BBP) 0.0005	85-68-7	Not Present
Di-2-ethylhexyl phthalate 0.002	117-81-7	Not Present
Dibutyl phthalate 0.0005	84-74-2	Not Present
Diisobutyl phthalate	84-69-5	Not Present
Diisodecyl phthalate (DIDP) 0.005	26761-40-0	Not Present
Diisononyl phthalate (DINP) 0.005	28553-12-0	Not Present
Diisopentylphthalate	605-50-5	Not Present
Di-n-octyl phthalate (DnOP) 0.0005	117-84-0	Not Present

Glycol Ethers

The following of the glycol ethers were reviewed at a threshold of 100ppm.

2-Methoxyethanol 0.001	109-86-4	Not Present
Butyldiglycol	112-34-5	Not Present
Diethylene glycol dimethyl ether (DEGDME)	111-96-6	Not Present
Diethylene glycol methyl ether (DEGME)	111-77-3	Not Present
Ethyldiethyleneglycol	111-90-0	Not Present
Ethylene glycol dimethyl ether (EGDME)	110-71-4	Not Present
Ethylene glycol ethyl ether acetate (EGEEA)	111-15-9	Not Present
Ethylene glycol methyl ether acetate (EGMEA)	110-49-6	Not Present
Ethylene glycol monobutyl ether (EGBE)	111-76-2	Not Present
Ethylene glycol monoethyl ester 0.001	110-80-5	Not Present
Triethylene glycol dimethyl ether (TEGDME)	112-49-2	Not Present

Natural Rubber and Rubber Latex

The subject product composition was reviewed for the presence of the following substances identified as natural rubber:

cis 1,4 Polyisoprene	Not Present
Natural Rubber	Not Present
Polyisoprene, cis	Not Present

Halogenated (Cl and Br) Organic Compounds

The following halogenated organic compounds were reviewed at a threshold of 100 ppm.

Epichlorohydrin	Not Present
Polybrominated Biphenyls (PBBs)	Not Present
Polybrominated Diphenyl Ethers (PBDEs and DecaBDE)	Not Present
Polybrominated Terphenyls (PBTs)	Not Present
Polychlorinated biphenyls (PCB)	Not Present
Polychlorinated naphthalenes (PCN)	Not Present
Polychlorinated terphenyls (PCT)	Not Present
Short Chain Chlorinated paraffins (SCCP)	Not Present
Tris(2-chloroethyl) phosphate 0.005	Not Present

Please note that we do not routinely analyze for additional substances that are not listed in the SDS. Unless otherwise indicated, the information provided herein is based upon information from raw material suppliers, product composition and knowledge of our manufacturing process. If a questionnaire was submitted we note that, as global regulatory requirements expand, we are receiving increasing numbers of requests from customers regarding the regulatory status of our products. Given this, it is no longer possible for us to individually complete each company's specific form. To respond to each customer in a timely and efficient manner, our company has developed a system to store and report the requested information. Use of this standardized system will allow us to properly track requests and responses and notify your company of changes when appropriate.

Johanna Didizian

Sr. Product Safety Specialist

Arkema
900 First Avenue
King of Prussia PA USA 19406

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Arkema has implemented a Medical Policy regarding the use of Arkema products in medical device applications that are in contact with the body or circulating bodily fluids (http://www.arkema.com/en/social-responsibility/responsible-product-management/medical-device-policy/index.html) Arkema has designated Medical grades to be used for such Medical Device applications. Products that have not been designated as Medical grades are not authorized by Arkema for use in Medical Device applications that are in contact with the body or circulating bodily fluids. In addition, Arkema strictly prohibits the use of any Arkema products in Medical Device applications that are implanted in the body or in contact with bodily fluids or tissues for greater than 30 days. The Arkema trademarks and the Arkema name shall not be used in conjunction with customers' medical devices, including without limitation, permanent or temporary implantable devices , and customers shall not represent to anyone else, that Arkema allows, endorses or permits the use of Arkema products in such medical devices.

It is the sole responsibility of the manufacturer of the medical device to determine the suitability (including biocompatibility) of all raw materials, products and components, including any medical grade Arkema products, in order to ensure that the final end-use product is safe for its end use; performs or functions as intended; and complies with all applicable legal and regulatory requirements (FDA or other national drug agencies) It is the sole responsibility of the manufacturer of the medical device to conduct all necessary tests and inspections and to evaluate the medical device under actual end-use requirements and to adequately advise and warn purchasers, users, and/or learned intermediaries (such as physicians) of pertinent risks and fulfill any postmarket surveillance obligations. Any decision regarding the appropriateness of a particular Arkema material in a particular medical device should be based on the judgment of the manufacturer, seller, the competent authority, and the treating physician.

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