September 22, 2021

KYNAR® 740 (200005165)

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

REACH registration

The Regulation (EC) No 1907/2006 known as REACH (acronym for Registration, Evaluation, Authorization and restriction of Chemicals) has been published in the Official Journal of the European Union on December 18, 2006 and has entered in force on June 1, 2007.

This text regulates the manufacture, the importation and the placing on the European market of chemicals.

Our company manufactures, imports and markets substances on their own, and/or included in preparations and/or in articles in compliance with REACH.

We can state that the above-mentioned product supplied by Arkema within the European Economic Area (EEA) complies with the obligations linked to the registration of chemical substances, as well as to the authorization and the restrictions of uses.

In compliance with REACH means that all substances contained in this product:
- have been registered by our company and/or its suppliers, and/or
- are excluded from the Regulation, and/or
- are exempted from registration.

For polymeric substances: all monomers and other reactants have been registered by our company and/or its suppliers and/or are exempted from registration. In order to fulfil our REACH obligations for our products, we are in close contact with our suppliers to ascertain that all raw materials used within the European Economic Area fulfil the requirements of the European legislation.

For Arkema products NOT purchased in the European Economic Area (EEA): customers who buy products from Arkema outside the EEA and subsequently wish to import into the EEA are responsible to manage their own obligations under REACH and CLP unless Arkema has nominated an Only Representative to cover the import into Europe.

Substances which have been manufactured and registered by Arkema in the EEA and then exported might be eligible for a re-import exemption under certain conditions. Proof of these conditions and compliance with the regulations is in the responsibility of the importer.

For more information, please contact your regulatory contact at pars-drp-fds@arkema.com.

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: 07/08/2021

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-Authorization list

This paragraph concerns substances subject to authorization listed in Annex XIV of Regulation (EC) No 1907/2006. 12/18/2020

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: 12/16/2020

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.

FOOD CONTACT MATERIALS

US FDA Food Packaging

Compliance with the US Federal Food, Drug and Cosmetic Act and all applicable food additive regulations requires that a product used as a food packaging material be evaluated based on regulatory status of each individual substance that comprises the product for each application food type and condition of use.

This evaluation encompasses a review of all listings in Title 21 Code of Federal Regulations, GRAS approvals, prior sanction letters, Threshold of Regulation (TOR) exemptions, or effective Food Contact Substance Notifications (FCN). Based on this review, the following applications of the subject product can be said to fully comply with the US Federal Food, Drug and Cosmetic Act and all applicable food additive regulations subject to the limitations provided herein. It is the responsibility of our customer to determine if the following clearances or cross-references to the clearances are appropriate for the final intended use.

21 CFR Sec. 177.2510

Polyvinylidene fluoride resins

Intended for repeated use applications only and provided that the food contact article in its finished form meets the extractive requirements of paragraph (b). Extraction testing to verify compliance with this section is the responsibility of the finished article manufacturer. Further, paragraph (c) requires that in accordance with good manufacturing practice, finished food-contact articles containing the polyvinylidene fluoride resins shall be thoroughly cleansed prior to their first use in contact with food.

MERCOSUR Food Packaging (Brazil, Argentina, Uruguay, Paraguay, Venezuela)

Resolution GMC 03/92 applies to packages, packaging equipment, and articles intended for direct contact with foodstuffs during the manufacture, production, portioning, handling, storage, distribution, commercialization, and consumption of foods. The criteria defined by this resolution stipulate that any and all substances used in packaging and packaging materials intended to come in contact with foodstuffs must be included in the positive list and comply with overall migration limits, specific migration limits, and composition limits when applicable.

This product is formulated with one or more substances authorized for use in food contact articles subject to the limitations and provisions of the resolutions provided herein.

Furthermore, this product is manufactured with sufficient quality standards to meet the suitable purity requirements of materials used in the manufacturing of food contact articles.

Customer is responsible for ensuring that the final food package is suitable for its intended use and meets the General Criteria of Packaging and Food Equipment in Contact with Foodstuffs (GMC/Res. No. 03/92 and/or ANVISA RDC 91/2001 Annex I).

GMC/RES. No. 02/12

MERCOSUR Technical Regulation on Positive List of Monomers, Other Starting Substances and Polymers Authorized for Manufacture of Food-Contact Plastic Packaging and Equipment

Vinylidene fluoride [REF:26140] [CAS:75-38-7] SML = 5 mg/kg

GMC/RES. No. 39/19

MERCOSUR Technical Regulation on "Positive List of Additives for Plastic Materials Intended for the Manufacture of Food-Contact Packages and Equipment"

All substances that are added to plastic to obtain a desired effect, such as antioxidants, foaming agents, lubricants, and plasticizers, and all substances that are used to produce an appropriate polymerization medium, such as surfactants, pH-regulating agents, and solvents, are present on the positive list without limitation.

EU-Food Contact Status

Please find below information related to the European Food Contact status of this product.

It is the responsibility of the converter of food packaging that brings the finished product on the market to check its compliance with Regulation (EC) No 1935/2004 especially Article 3 or with Regulation (EU) No 10/2011 and amendments in force at the date of this statement, laying down the basic rules necessary, for migration testing of the constituents of plastic materials and articles intended to come into contact with food.

EU-Food Contact Materials-Monomers & Additives

This section is dedicated to EU regulations associated with the monomers and additives used in the manufacturing process of materials and articles intended to come into contact with foodstuffs.

This product contains only substance(s) authorized by :

» Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food
Effective date:
08/08/2019

Subject to the following restriction(s):

Ethylene oxide	75-21-8		
FCM #: 129			
Material #: 17020			
Migration Restrictions: SML = ND. The specific migration limit is non-detectable (ND). A detection limit of 0.01mg substance per kg food is applicable unless specified differently for an individual substance.			
Specifications: 1 mg/kg in final product			
Compliance Verification Note: Verification of compliance by residual content per food contact surface area (QMA) in case of reaction with food or simulant.			
vinylidene fluoride	75-38-7		
FCM #: 132			
Material #: 26140			
Migration Restrictions: SML = 5 mg/kg			
Propylene oxide	75-56-9		
FCM #: 135			
Material #: 24010			
Migration Restrictions: SML = ND. The specific migration limit is non-detectable (ND). A detection limit of 0.01mg substance per kg food is applicable unless specified differently for an individual substance.			
Specifications: 1 mg/kg in final product			

EU-Food Contact Materials-Aids to Polymerization

This section is dedicated to EU regulations associated with Aids to Polymerization (AP) used in the manufacturing process of materials and articles intended to come into contact with foodstuffs.

This product contains only AP(s) authorized by:

» Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with foodstuffs.

This(These) AP(s) is(are) not included in the Union list but it(they) may be present in the plastic layers of the plastic materials or articles according to Article 6(4)(b) and Article 19 of this Regulation.

» Resolution AP (92) 2 of the Council of Europe on Aids to Polymerization for plastic materials and articles intended to come into contact with foodstuffs.

Subject to the following restriction(s):

► Restriction for Alkanes

Specific migration limit (SML(T)) : 6 mg/kg

► Restriction for Peroxides

Specific migration limit (SML(T)) : 0,05 mg/kg (as active O, when extracted into distilled water)

EU-Food Contact Materials-Pigments/Colorants

This section is dedicated to EU regulations associated with pigments and colorants used in the manufacturing process of materials and articles intended to come into contact with foodstuffs.

This product does not contain any pigment/colorant.

EU-Food Contact Materials-Good Manufacturing Practices

This section is dedicated to Regulation (EU) No 2023/2006 on the Good Manufacturing Practices applicable to materials and articles intended to come into contact with foodstuffs.

Only substances authorized by the current food contact legislations in force, including Regulation (EU) No 10/2011, which should be considered as specific measures for plastic within the meaning of Article 5 of Framework Regulation (EC) No 1935/2004, are used for the manufacture of this product.

This product is manufactured according to the Good Manufacturing Practices, as defined by the specific requirements of Article 3 of Framework Regulation (EC) No 1935/2004.

Particular measures have been implemented to confirm the compliance of the raw materials and to assure a good level of traceability of this product, in accordance with the requirements of Articles 16 and 17 of Framework Regulation (EC) No 1935/2004.

EU-Food Contact Materials-Epoxy derivates

This section is dedicated to Regulation (EC) No 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food.

The following substances as listed in Annex I of this Regulation are not known to be present in this product, based on the final product composition and the chemical nature of the raw materials:

•Novolac glycidyl ethers (NOGE)
•Bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers (BFDGE) (CAS: 39817-09-9)
•2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (BADGE) (CAS: 1675-54-3) and some of its derivatives:
-BADGE.H2O (CAS: 76002-91-0)
-BADGE.2H2O (CAS: 5581-32-8)
-BADGE.HCl (CAS: 13836-48-1)
-BADGE.2HCl (CAS: 4809-35-2)
-BADGE.H2O.HCl (CAS: 227947-06-0)

PHARMACEUTICALS AND MEDICAL DEVICES

ISO 10993 & USP Biocompatibility

Biocompatibility testing of our products related to USP Class VI and certain requirements of ISO Standard 10993-1 cannot assure the biocompatibility of final or intermediate products made from our products or the suitability of such products for their use in medical applications.

The test summaries provided herein are for informational purposes only and do not imply approvals for any specific medical device application:

ISO 10993-4: Modified ASTM Hemolysis (Direct Contact Method) Tested on Human Blood. Result: Pass

ISO 10993-4: Modified ASTM Hemolysis (Extract Method) Extracted in Phosphate Buffered Saline at 37°C for 3 hours. Tested with Human Blood. Result: Pass

ISO 10993-5: Cytotoxicity (MEM Elution) Extract tested on L-929 Mouse Fibroblast cells for 72 hours. Result: Pass

USP Class VI: Acute Systemic Injection Test Extracted in Normal Saline, Alcohol in Saline, PEG 400 and Vegetable oil (Cottonseed or Sesame oil) at 50°C, for 72 hours. Injected in Mouse. Result: Pass

USP Class VI: Intracutaneous Irritation Test Extracted in Normal Saline, Alcohol in Saline, PEG 400 and Vegetable oil (Cottonseed or Sesame oil) at 50°C, for 72 hours. Tested with Rabbit. Result: Pass

USP Class VI: Intramuscular Implantation Test Implanted in Rabbit for 1 week. Result: Pass

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. 02/01/2021

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 (DecaBDE)	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.

ILFI - Red List Chemicals

The International Living Future Institute (ILFI) has developed the “Red List” materials. Builders seeking to meet the certification requirements of the Living Building Challenge must verify the materials of construction do not contain the substance on the “Red List” above 100 ppm.
Review valid for listing of
01/01/2021

Based on a review of the product composition, this product is not known to contain substance(s) identified as ILFI Red List Chemicals above the reporting threshold.

Restriction of Hazardous Substances (RoHS) - EU

Restrictions on the use of certain hazardous substances in electric and electronic equipment as defined in the Annex II of the Directive 2011/65/EU and amendments in force.
Effective date: 03/08/2021

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.

INTERNATIONAL CONVENTIONS

PERSISTENT ORGANIC POLLUTANTS (POP) - EU

The objective of Regulation (EU) No 2019/1021 on persistent organic pollutants is to protect human health and the environment from persistent organic pollutants by prohibiting, phasing out as soon as possible, or restricting the manufacturing, placing on the market and use of substances subject to the Stockholm Convention on Persistent Organic Pollutants or to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants.
Effective date: 03/15/2021

ARKEMA does not intentionally use substances listed in Annexes I, II, III and IV of Regulation (EU) No 2019/1021 and its amendments for the manufacture of the above-mentioned product.
Therefore, such substances are not expected to be present in the above-mentioned product.

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: 03/19/2021

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

BSE/TSE and Animal Derived

Bovine Spongiform or Transmissible Spongiform Encephalopathy BSE/TSE transmission risk is associated with substances derived from certain animal tissues sourced from at risk regions as determined by The World Organisation for Animal Health (OIE). Disease transmission risk may be eliminated based on the substance position in the manufacturing chain. Chemical substances that are determined to meet the definition of highly refined or transformed have an insignificant risk of BSE/TSE infectivity.

Based on a review of the product composition, this product is not known or expected to contain substances which are animal derived or associated with BSE/TSE infectivity.

OTHER

Specific Substance Review

This section contains information on the presence of certain substances or substance groups without regard to a specific regulation. These substances may be subject to multiple regulations which have differing reporting thresholds.

All reviews for specific substances in this section are based on the known product composition at the threshold stated. No analyses were conducted.

Bisphenols and Phthalates

The following Bisphenols 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
Benzyl butyl phthalate (BBP)	85-68-7	Not Present
Bis(2-ethyl-1-hexyl)tetrabromophthalate	26040-51-7	Not Present
Bis(2-ethylhexyl)phthalate (DEHP)	117-81-7	Not Present
Bis(2-methoxyethyl) phthalate	117-82-8	Not Present
Bisphenol A (BPA)	80-05-7	Not Present
Bisphenol AF	1478-61-1	Not Present
Bisphenol B	77-40-7	Not Present
Bisphenol F (BPF)	620-92-8	Not Present
Bisphenol F (BPF)	87139-40-0	Not Present
Bisphenol S	80-09-1	Not Present
Dibutyl phthalate (DBP)	84-74-2	Not Present
Dicyclohexyl phthalate	84-61-7	Not Present
Diethyl phthalate	84-66-2	Not Present
Diisobutyl phthalate	84-69-5	Not Present
Diisodecyl phthalate (DIDP)	26761-40-0	Not Present
Diisohexyl phthalate (DIHxP)	71850-09-4	Not Present
Diisononyl phthalate (DINP)	28553-12-0	Not Present
Diisopentylphthalate	605-50-5	Not Present
Di-n-hexyl phthalate (DNHP)	84-75-3	Not Present
Di-n-octyl phthalate (DNOP)	117-84-0	Not Present
Di-n-pentyl phthalate	131-18-0	Not Present
Mono-n-butyl phthalate	131-70-4	Not Present
Phthalic anhydride	85-44-9	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.

Bob Burns

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