

September 12, 2024

James Wagner

Ark Plas Products
165 Industry Lane
Flippin AR UNITED STATES 72634

High Performance Polymers

Subject : **KYNAR® 720**

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.

TABLE OF CONTENT :

- REACH AND INVENTORY STATUS
- FOOD CONTACT MATERIALS
- FOOD SAFETY
- PHARMACEUTICALS AND MEDICAL DEVICES
- DRINKING WATER
- HEAVY METALS
- AUTOMOTIVE
- POLLUTION PREVENTION-WASTE MANAGEMENT-ECOLABELING
- INTERNATIONAL CONVENTIONS
- MISCELLANEOUS REGULATORY LISTS
- OTHER

REACH AND INVENTORY STATUS

Global Inventory Status

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

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 dated: 27 Jun 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-Authorization list

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

Dated: 11 Apr 2022

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).
Dated: 14 Dec 2021

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. 174.5

General provisions applicable to indirect food additives

This product is produced under conditions of good manufacturing practice as required by 21 C.F.R. § 174.5(a) and is of a purity suitable for its intended use in food contact applications in accordance with the 21 CFR citations as described herein.

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), and General Provisions for Plastic Packaging and Food Contact Equipment (GMC/RES. No. 56/92 and its amendment GMC/RES. No. 20/21) if it is plastic.

GMC/RES. No. 02/12 and 19/21

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 and 11/20

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 Materials - Regulatory Background

It is the responsibility of the converter of food packaging that places the finished product on the market to ensure its compliance with Regulation (EC) No 1935/2004, especially Article 3 or with Regulation (EU) No 10/2011 as amended.

Arkema, has requested its supplier to provide certificate pursuant to Regulation (EC) No 1935/2004. As of today, and despite our best effort, we were not able to obtain in certain cases this information from our supplier. Please note that the current certificate is based on the information available, and that we believed accurate, at this date.

In the area of food contact materials, plastics materials and articles are regulated by a specific measure harmonized at EU level by Regulation (EU) 10/2011.

Some materials such as but not limited to coatings, adhesives, printing inks, silicones, rubbers, are not covered by Regulation (EU) No 10/2011 and do not have such specific EU harmonized legislation. These materials are nevertheless subject to the general requirements of EU framework Regulation (EC) 1935/2004 and where existing, to the relevant national legislations. In such case, this statement and any information provided herein does not constitute a legally binding obligation for Arkema and is provided for your guidance only.

EU - Food Contact Materials Status

Please find below information related to the European Food Contact status of the above-mentioned product.

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 as amended - last dated: 10 Aug 2023

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 Notes: 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	

Methyloxirane	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	

The above-mentioned product contains one or several Aid(s) to Polymerization which is(are) not included in the Union List. However, 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 Regulation (EU) No 10/2011.

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.

Disclaimer on China Food Contact Regulation

Please be reminded that it is the responsibility of the manufacturer of food packaging that brings the finished product on the market to check its compliance with GB4806.1-2016 (China National Food Safety Standard: General Safety Requirements for Food Contact Materials and Articles) and GB31603-2015(China National Food Safety Standard: Good Manufacturing Practice for Food Contact Materials and Articles).

FOOD SAFETY

NSF Standard 51

"NSF STD 51: Food Equipment Materials" certification standard for plastics, materials, and components used in the production of food equipment.

For information on all current NSF certifications, please visit [nsf.org](http://www.nsf.org) at <http://www.nsf.org/certified-products-systems>

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 50°C for 72 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

DRINKING WATER

NSF Standard 61

"NSF/ANSI Standard 61: Drinking Water System Components -- Health Effects" certification standard for all devices, components and materials in contact with drinking water.

For information on all current NSF certifications, please visit [nsf.org](http://www.nsf.org) at <http://www.nsf.org/certified-products-systems>

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 : <https://www.gadsl.org/>. Dated: 01 Feb 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.

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
30 Apr 2024

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.

Dated: 16 May 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.

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: 28 Aug 2023

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: 29 Dec 2023

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

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

Nitrosamines

Nitrosamine impurities can form during manufacturing process under certain processing conditions and in the presence of some types of raw materials, starting materials, and intermediates.

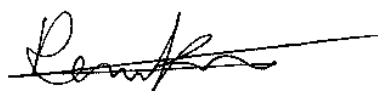
Nitrosamines may be subject to multiple regulations.

It is the responsibility of the company that brings the finished product on the market to check its compliance with these regulations.

To the best of our knowledge, none of the following substances are intentionally added in the manufacturing process of this product :

- nitrosatable substances,
- nitrosating agent that may form nitrosamines,
- nitrosamines.

Therefore, no nitrosamines are expected in the final product composition.



Renee Kontos

Sr. Product Stewardship and Regulatory Affairs Specialist

Arkema Inc
900 First Avenue
King of Prussia PA UNITED STATES 19464

All information contained herein is believed to be accurate as of the date of publication, is provided “as-is” and is subject to change without notice. This is not a warranty, an agreement, or substitute for expert or professional advice. Arkema Inc. (“Company”) expressly disclaims and assumes no liability for the use of the products or reliance on this information. It is the sole responsibility of the user to determine the suitability of any products for user’s application(s). NO WARRANTY OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED (INCLUDING SUITABILITY FOR USE IN ANY MEDICAL DEVICE OR MEDICAL APPLICATION), IS MADE CONCERNING THE PRODUCTS OR THE INFORMATION PROVIDED HEREIN. The information provided relates only to the specific products designated herein and may not be valid where such products are used in combination with other materials or in any process. The performance of the product, its shelf life, and application characteristics depends on many variables, and changes in these variables can impact product performance. You are responsible to test the suitability of any product in advance for any intended use or application and before commercialization. Nothing herein shall be construed as a license for the use of any product in a manner that might infringe any patent and it should not be construed as an inducement to infringe any patent. Please carefully review the Safety Data Sheet for the product.

The Company adheres to a strict policy that applies to the use of any of its products in medical device applications. This policy can be found at <https://www.arkema.com/global/en/social-responsibility/innovation-and-sustainable-solutions/responsible-product-management/medical-device-policy/> which is incorporated herein by reference and made a part hereof. Except as expressly authorized, the Company (i) has designated specific medical grade compositions for products used in medical device applications and Company products not so designated are not authorized for use in medical device applications and (ii) strictly prohibits the use of any of its 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 Company does not design, manufacture and/or directly sell any medical devices. The Company does not co-design, or offer assistance to any purchaser of its products, in their design, manufacture and/or sale of products for medical devices. It is the sole responsibility of the manufacturer of medical devices to determine the suitability of all raw material, products and components, including any medical grade products, in order to ensure that the medical device is safe for end-use and complies with all applicable legal and regulatory requirements and to conduct all necessary tests and inspections.

KYNAR® is a registered trademark of Arkema.

Internal specification : 200005157