



LIMITED

LIAISON OFFICE:

Ground Floor, G&T Tower,
18 Beaumont Road, Civil Lines-10,
Karachi-75530, Pakistan.

Phone : (+92 21) 35659585-7
Fax : (+92 21) 35659549
E-mail : headoffice@novatex.com
Web Site : www.gatronova.com

PLANT

117-83, Off. Railway Siding
Export Processing Zone Road,
Near Wheat Godown, Landhi,
Karachi – 75160, Pakistan.
Phones : (+92 21) 35017484 to 85
Fax : (+92 21) 35017750
E-mail : novafac@novatex.com

06th July, 2024

To Whom It May Concern

Subject: - Gatronova PET Resin All Grades- EC 10/ 2011 Migration Compliance:

We, **Novatex Limited** hereby declare that its brand **Gatronova PET resin -All Grades** complies with European Commission regulations 2002/72/EC and its latest amendment (EC) No 975/2009. And we also comply with its substituted form as **EC/10/2011** and all of its amendment directives from which the latest one is as **EC/2020/1245**.

The use of additives and other raw materials for the manufacturing of this product complies with the requirements of EU 10/2011; further details can be obtained under NDA. Regarding compliance with the dual use additives provision of Directive 2004/19/EC, there are no additives subject to restrictions on concentrations in food as a food additive. Use is made of a dual use additive, phosphoric acid, which is listed as approved additive in the positive list under EU 10/2011.

The above resin is particularly suitable for use in bottles which may be used to pack still and sparkling mineral water.

The testing methodology used to comply for this regulation is:

Overall migration Results:

Into aqueous simulants (A and B – Ethanol and Acetic Acid respectively) 10 days at 40 C:

After exposure to the simulants, under conditions specified, test specimen were removed from the contact; the aqueous solution is then transferred to a weighed container and evaporated to full dryness and constant weight.

Into aqueous simulant (D2 – Rectified Olive Oil) 10 days at 40 C:

After exposure to the simulant, under conditions specified, test specimen were removed from the contact; excess oil blotted off, and re-weighed. Absorbed oil was determined by extraction and GC quantification.

Overall migration is expressed as amount (in milligrams-mg) of material lost from one (01 dm²) decimeter square surface.

Monomers / Co-monomers	OML Set forth in EC/10/2011	Ethanol 10% v/v – Simulant A EN-1186-3	Acetic Acid 3% w/v – Simulant B EN-1186-3	Rectified Olive Oil Simulant D2 EN-1186-2
Total Material lost	10 mg/dm2	0.4 mg/dm2	0.4 mg/dm2	N.D.

N.D. = Not detectable.

Specific migration Results:

MEG+DEG = Specific migration was determined into simulants A, B and D2 using exposure conditions of 10 days at 60 C. The level of MEG and DEG in exposed food simulants was determined by cold on column GC and FID detection.

PTA = Specific migration was determined into simulants A, B and D2 using exposure conditions of 10 days at 60 C. The level of PTA in exposed food simulants was determined by HPLC.

IPA = Specific migration was determined into simulants A, B and D2 using exposure conditions of 10 days at 60 C. The level of IPA in exposed food simulants was determined by HPLC.

Antimony = Specific migration was determined into simulant B using exposure conditions of 10 days at 60 C. The level of Sb in exposed food simulant was determined by Inductively coupled Plasma – Mass spectrometry.

Monomers / Co-monomers	SML Set forth in EC/10/2011	Ethanol 10% v/v – Simulant A	Acetic Acid 3% w/v – Simulant B	Rectified Olive Oil Simulant D2
MEG + DEG ENV 13130-7:1999	30 mg/kg	<3.6 mg/kg	<3.6 mg/kg	<3.6 mg/kg
PTA ENV 13130-2	7.5 mg/kg	<0.5 mg/kg	<0.5 mg/kg	<0.5 mg/kg
IPA ENV 13130-2	5.0 mg/kg	<0.5 mg/kg	<0.5 mg/kg	<0.5 mg/kg
Antimony (Sb)	40 ppb	-	4.4 ppb	-

So, from above tables, it is evident that SML values for the above mentioned compounds are either Not Detectable (ND) or under the compliance ranges. The overall migration limit (OML) is also found to be ND.

The resins are particularly suitable for use in bottles which may be used to pack still and sparkling mineral waters, carbonated soft drinks, alcoholic beverages, juices and edible oils.

As PET Polymer must be further processed in order to make finished materials or articles, compliance with the migration requirements of Commission Regulation (EU) No 10/2011 can only be demonstrated by tests that are carried out on the final article. These tests are the sole responsibility of the manufacturer of the finished material or article.

Furthermore, Novatex Limited confirms that the **Gatronova PET resin - All Grades** is absolutely free from the substances listed below,

- BPA
- GMO (Genetically Modified Organisms)
- Biocides
- Melamine and dioxins
- Phthalates
- Epoxy derivatives
- Persistent Organic Pollutants
- BPS
- Dual Use Additives
- MOSH/MOAH
- amines

Subject: Gatronova PET Resin-All Grades – Allergens Compliance:

Novatex Limited, hereby declare that its brand Gatronova PET Resin is free from any of the following allergens:

- Egg & egg products	- Mustard
- Milk & dairy products.	- Corn & corn derivatives
- Peanut & peanut products.	- Seeds & derivatives
- Shellfish (crustaceans & mollusks)	- Gluten
- Soy & soy derivatives	- Mono sodium Glutamate
- Wheat	- FD&C colors, Sudan red, Cochineal extract, Carmine
- Sulfites and SO2	- Celery
- Sesame	- Lupin and its products
- Fish and its products	- Diacetyl
- Tree nuts	- Nutmeg

Although Novatex Limited has not specifically tested for the presence of the aforesaid substances in **Gatronova PET resin - All Grades**, the company would not expect it to be present in any of its PET resin grades. These substances are not used in the manufacturing of **Gatronova PET resin -All Grades**, nor, to the best of its knowledge, are they present as component of, or as impurity in the raw materials used in its manufacturing. These substances are also not generated through any known side reactions during the PET polymerization process.

Subject: Gatronova PET resin - All Grades– RoHS II Compliance:

Novatex Limited, hereby declare that its brand Gatronova PET Resin are also in full compliance for the presence of Lead, Mercury, Cadmium, Hexavalent Chromium and Bromine against the requirements of RoHS II (2011/65/EC).

The limits specified in RoHS II for the presence of Lead, Mercury, Cadmium, Hexavalent Chromium and Bromine are as follows:

Cadmium	< 100	mg/kg
Chromium VI	< 1000	mg/kg
Lead	< 1000	mg/kg
Mercury	< 1000	mg/kg
Bromine	< 1000	mg/kg

Subject: Gatronova PET resin - All Grades – US FDA Compliance:

Novatex Limited herewith confirm that the solubility results of our PET resin **Gatronova PET resin -All Grades** were found to comply with the requirements as specified sections f(1), g(1), h(1) (i) and h(1)(ii) of the USA FDA Code of Federal Regulations CFR21 Section 177.1630 (Polyethylene Phthalates Polymers).

Accordingly, the above stated resin grades are in compliance with the test requirements specified in the USA FDA Code of Federal Regulations CFR21 Section 177.1630 f(1), g(1), h(1) (i) and h(1) (ii) and are suitable for use in packaging, transporting or holding foods, including strong alcoholic beverages at temperatures above or below 250°F.

The resins is particularly suitable for use in bottles which may be used to pack still and sparkling mineral waters.

To the best of our understanding, there is no specific limitation outlined in FDA regulations with regards to the use of our PET for its normal purposes.

As far as it is in the knowledge of Novatex, we will endeavor to continue to comply with the applicable provisions of FDA.

Subject: Gatronova PET resin -All Grades – Heavy Metals Compliance:

Novatex Limited hereby confirms that its brand **Gatronova PET resin -All Grades** are in compliance with ultimate limit (in force from 30 June 2001) specified in EC directive 94/62/EC 'The Packaging and Packaging Waste Directive' for the combined levels of Lead, Mercury, Cadmium and Hexavalent Chromium. The product therefore also complies with the heavy metal requirements of UK Statutory Instrument 1940 (2003) as amended, which enforces this directive in the UK.

The above Resin is also in compliance with the limit for heavy metals contained in the **CONEG regulation** which are in force in a number of the states in the USA and Canada.

The limits specified in CONEG regulation and 94/62/EC for the combined total of Lead, Mercury, Cadmium and Hexavalent Chromium is as follows:

- 100 mg/kg of packaging material.

Measurement protocol and level of metals content:

Portions of the sample were dissolved in acid digestion bomb and the resultant solutions were analyzed by Atomic Absorption Spectrophotometry (AAS).

Metals	Limit	Legal Set forth in EC/94/62 in mg/kg	Test Result in mg/kg
Lead (Pb)	<1000	Combined metals content should be <100	<20
Cadmium (Cd)	<100		<20
Mercury (Hg)	<1000		<20
Hexavalent Chromium (Cr)	<1000		<20
Bromine)	<1000		<20
Combined	<1000		<20

Subject: Gatronova PET resin -All Grades – REACH Compliance:

With regard to Regulation EC NO 1907/2006 concerning the Registration, Evaluation Authorization and Restriction of Chemicals (REACH), please note the following:

We, hereby declare that in the production of our Polyethylene Terephthalate (PET) resin **Gatronova PET resin -All Grades**, it only use monomers and other substances subject to Registration that have been Pre-registered by our Suppliers and ourselves through an Only Representative (OR) and now they are officially registered.

Monomer / Substances	% of Monomer In Gatronova PET	Producer Only Representative	Registration Number	Contact
Terephthalic Acid (CAS # 100-21-0)	70 %	Producer: Indorama Ventures Europe B.V. Registrant: Indorama Ventures Europe B.V. Only Representative: Indorama Ventures Europe B.V. Markweg 201, 3198 NB Europort (Rotterdam), The Netherlands.	Registration Completed Contact Indorama Ventures Europe B.V. for details.	Indorama Ventures Europe B.V. Mr. Fornara Wout email: wout.fornara@nl.indorama.net Phone: +31 (0) 181 285 422 Fax: +31 (0) 181 285 405
Monoethylene Glycol (CAS # 107-21-1)	27.0 %	Producer: SABIC, KSA Registrant: Novatex Limited. Only Representative: ReachLaw Limited, Viikinkaari 4, 00790 Helsinki, Finland	Registration Status Completed	ReachLaw Limited Mr. Gagan Kumar gagan.kumar@dynamicorbits.com Surinder.Kumar@dynamicorbits.com

Novatex also confirms that our polymer brand **Gatronova PET resin -All Grades** are free from any of the substances of very high concern (SVHC) as published by European Chemical Agency (ECHA) and last updated on **June 27th, 2024 (all 241 members)**.

<https://echa.europa.eu/candidate-list-table>

Subject: Gatronova PET resin - All Grades – California Proposition 65 compliance:

Gatronova PET resin - All Grades is in compliance with respect to California's Safe Drinking Water and Toxic Enforcement Act (Proposition 65) which places restrictions on "known carcinogens and reproductive toxicants." No California Proposition 65 listed chemicals are present in **Gatronova PET resin - All Grades**.

Novatex Limited recognizes and acknowledges its obligation to update its certification as necessitated by Proposition 65 list revisions promulgated by California Environmental Protection Agency's (CAEPA) Office of Environmental Health Hazard Assessment (OEHHA).

The above compliance is updated as per list released by OEHHA till 29 December 2023.

<https://oehha.ca.gov/media/downloads/proposition-65//p65list122923.pdf>

Subject: Gatronova PET resin - All Grades – Halal & Kosher Declaration:

Novatex Limited, hereby declares that its brand Gatronova PET Resin are free from any traces of 'Substances of Animal Origin' as Gatronova PET Resin are formulated with no primary substances derived from animal origins, and therefore are in compliance with USDA / APHIS regulations (i.e., 9 CFR 94.18) and/or international regulations (e.g.: European Commission Directives) governing exposures to transmissible spongiform encephalopathy (TSE) / bovine spongiform encephalopathy (BSE) and Kosher offending substances.

This means Gatronova PET Resin are deemed **Halal** and **certified as per Kosher dietary laws**, as it does not contain any chemicals, enzymes or additives that is sourced from any animal, making it perfectly suitable to package any food related items considered **Halal, Vegan or Kosher** certified.

Novatex Limited, hereby also declares that we have reviewed the ingredients of our purchased manufactured resins, and evaluated them against Kosher requirements. The raw materials contain no animal fat and will comply with the acceptable guidelines of the Kosher dietary laws.

Products that are submitted for formal Kosher certification need not be made of ingredients that are Kosher certified, but merely those that meet the guidelines of the Kosher dietary laws. You should anticipate no difficulty in obtaining Kosher certification with the use of our purchased PET Resins.

We cannot however be held responsible for any subsequent addition of, or contamination with, kosher-offending substances which may occur during shipment, receiving, or storage of your finished products.

Novatex Limited relies without further investigation or testing, on the certification of our suppliers that the raw materials we purchase from our suppliers comply with the above regulations.

Novatex Limited, hereby, also declare that its brand **Gatronova PET resin -All Grades** are in compliance with EU regulation **1935/2004** for articles and materials intended to come into contact with foodstuff. Novatex Limited also complies with Good Manufacturing Practice (**GMP**) **2023/2006** in the production of all of its PET grades.

It is the responsibility of our customers to determine that their use of our product(s) is safe, lawful, and technically suitable in their intended applications. Because of possible changes in the law and in regulations, as well as possible changes in our products, we cannot guarantee that the status of this product will remain unchanged. We, therefore, recommend that customers continuing to use this product verify its status periodically.

For Novatex Limited,



Muhammad Aslam
Head Of Quality Assurance
Tel. no. 0092 21 35017484 –85 (ext. 314)
E-mail: aslam@novatex.com