



Our Ref : QA- 241217

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To : PT. Bukitmega Masabadi

Re: TPC COSMOTHENE® G215, F210, L420, L705, L712, G811 & G811F

- 1) **Regulation (EC) No 1935/2004**
- 2) **Regulation (EC) No 2023/2006**
- 3) **Commission Regulation (EU) No 10/2011**

LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F comply with the general requirements and traceability of Regulation (EC) No 1935/2004 (Framework Regulation) for plastic material. In addition, TPC has established a documented Quality Management System as per ISO9001-2015 which meets the relevant requirements of Commission Regulation (EC) No 2023/2006 on good manufacturing practice for material and articles intended to come into contact with food in that effective quality assurance and quality control systems, and appropriate documentation have been implemented.

As these are non-additive grades, they are not subjected to the additive's requirements of this regulation. The monomer used in the manufacture of these grades is listed in EU Directive No 10/2011 up to its latest amendments COMMISSION REGULATION (EU) No 2023/1442 of 11 Jul 2023 and (EU) No 2023/1627 of 10 Aug 2023, and there is no restriction set on its specific migration limit (SML).

These grades are not intentionally added with any dual-use additive, as they are non-additive grades.

Metal elements regulated under Commission Regulation (EU) No 2022/1245 of 2 Sep 2022, and compounds containing these elements, are not intentionally added in the manufacture of these grades.

Phthalate esters regulated under Commission Regulation (EU) No 2023/1442 of 11 Jul 2023, are not intentionally added in the manufacture of these grades.

4) **US FDA Regulation 21 CFR**

LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F meet the US FDA Regulation 21 CFR 177.1520(c) 2.1 for food contact application, for all food types I to IX in Table 1, and under conditions of use C through G in Table 2, of 21 CFR 176.170(c) when processed according to good industry practice.

5) China Regulations on Materials for Food Contact Application

a) GB4806.1-2016 – General Safety Requirements for Food Contact Materials and Articles

LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F meet the basic requirements and traceability as required under Article 3 and Article 7 of this regulation.

b) GB31603-2015 – General Hygiene Practices for Production of Food Contact Materials and Articles

TPC has established a documented Quality Management System as per ISO9001-2015 which meets the relevant requirements of this regulation for material and articles intended to come into contact with food in that effective quality assurance and quality control systems, and appropriate documentation, have been implemented.

c) GB4806.7-2023 – Food Contact Plastic Materials and Articles

LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F are listed in this regulation under S/No 139 - ethylene homopolymer: polyethylene, with CAS No 9002-88-4. There is no restriction on the SML/QM and SML(T), and “Other Requirements” specified for this polymer. These grades are also in compliance with the sensory requirement of this regulation in that they are produced in their natural colour and with the usual slight odour of hydrocarbon. As for the soaking test requirement of this regulation, it is only applicable to the finished products.

d) GB9685-2016 – Standard for Uses of Additives in Food Contact Materials and Articles

LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F are non-additive grades, hence they are not subjected to the additive's requirements of this regulation. The monomer used to manufacture these grades is listed in this regulation without any restriction set on their specific migration limit (SML).

6) Japan Food Sanitation Law

LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F are classified as ethylene homopolymer, CAS No 9002-88-4 (Group 5) according to the Positive List of Polymers of the Japan Food Sanitation Law up to the version 6 Mar 2023, with the following basic characteristics:

Substance Code	Substance Type	Resin Section	CAS No	Food Type					Maximum Temperature (°C)
				Acid Food	Oil, Fat and Fatty Food	Dairy food	Liquor	Others	
2b-102	Ethylene	5	9002-88-4	Y	Y	Y	Y	Y	> 100

As these are non-additive grades, they are not subjected to the requirements of the Positive List of Additives of the Japan Food Sanitation Law.

7) Food Allergens – Annex II of Regulation (EU) No 1169/2011

LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F are not intentionally added with the following list of substances or products causing allergies or intolerances:

- Cereals containing gluten, (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridized strains) and products thereof
- Crustaceans and products thereof
- Eggs and products thereof
- Fish and products thereof
- Peanuts and products thereof
- Soybeans and products thereof
- Milk and products thereof (including lactose)
- Nuts i.e. almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia nuts and Queensland nuts and products thereof
- Celery and products thereof
- Mustard and products thereof
- Sesame seeds and products thereof
- Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO₂.
- Lupin and products thereof
- Molluscs and products thereof

8) Absence of Tallow and Other Animal Derived Materials / Bovine Spongiform Encephalopathy (BSE) / Transmissible Spongiform Encephalopathy (TSE)

LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F are non-additives grades. The base polymer of these grades is manufactured from petroleum-based products.

Tallow and other animal derived materials are not intentionally used in the manufacture of these grades. As such there is no risk of contracting BSE/TSE from the use of these grades based on their source of origin.

However, we are not able to certify that these grades comply with Halal or Kosher requirements.

9) Mineral Oils

Mineral Oil Saturated Hydrocarbons (MOSH) and Mineral Oil Aromatic Hydrocarbons (MOAH) are not intentionally added in the manufacture of LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F.

However, a small amount of Polyolefin Oligomeric Saturated Hydrocarbon (POSH) is intrinsically generated in any polyolefin grade during production. POSH may be mistakenly identified as MOSH during analysis.

10) REACH Regulation (EC) No 1907/2006 (SVHC)

The chemical substances as per REACH Candidate List of Substances of Very High Concern (up to latest date of inclusion 7 Nov 2024, total 242 substances, reference link: <http://echa.europa.eu/candidate-list-table>) are not intentionally added in the manufacture of LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F.

We also hereby certify that no unintentional contamination of these substances over 0.1wt% occurred during their production processes.



11) EU Commission Regulation (EC) No 1895/2005(Epoxy Directives)

The following chemical substances as regulated under this regulation are not intentionally added in the manufacture of LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F.

- Bisphenol A diglycidyl ether (BADGE)
- Bisphenol F diglycidyl ether (BFDGE)
- Novolac glycidyl ether (NOGE)

12) EU Directive 94/62/EC Article 11 on Packaging and Packaging Waste and amendment 2009/292/EC / US Model Toxics in Packaging Legislation

The heavy metals – Lead, Cadmium, Mercury and Hexavalent Chromium, are not intentionally added in the manufacture of LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F. These grades are also in compliance with the requirements of both regulations in that the sum of the incidental concentration levels of the four heavy metals does not exceed the defined level of 100ppm by weight.

13) Recycled Plastics

Post-consumer and post-industrial recycled contents are not intentionally added in the manufacture of LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F.

14) Directive 2011/65/EC(RoHS)

LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F meet the requirement of Directive 2011/65/EU up to its latest amendment under Directive (EU) 2024/232 in that the following regulated chemical substances are not intentionally used in the manufacture of these grades.

Restricted Substances	Maximum concentration values tolerated by weight in homogeneous materials
Lead (Pb)	0.1wt%(1000ppm)
Mercury (Hg)	0.1wt%(1000ppm)
Cadmium (Cd)	0.01wt%(100ppm)
Hexavalent chromium (Cr ⁶⁺)	0.1wt%(1000ppm)
Polybrominated biphenyls (PBB)	0.1wt%(1000ppm)
Polybrominated diphenyl ethers (PBDE)	0.1wt%(1000ppm)
Bis(2-ethylhexyl) phthalate (DEHP)	0.1wt%(1000ppm)
Butyl benzyl phthalate (BBP)	0.1wt%(1000ppm)
Dibutyl phthalate (DBP)	0.1wt%(1000ppm)
Diisobutyl phthalate (DIBP)	0.1wt%(1000ppm)



15) Conflict Minerals

LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F are not intentionally added with the following minerals or products containing these minerals, classified as Conflict Minerals as per Dodd-Frank Wall Street Reform and Consumer Protection Act & EU Conflict Minerals Regulation, in the manufacture of these grades:

- Tantalum (Ta)
- Tin (Sn)
- Gold (Au)
- Tungsten (W)

16) EU Toy Directive EN71-3

LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F are not intentionally added with any chemical substance containing the following elements as listed under EN71-3:2019+A1:2021 (Safety of toys Part 3: Migration of certain elements) in the manufacture of these grades.

Elements	Migration Limit		
	Category I mg/kg	Category II mg/kg	Category III mg/kg
Aluminium	2250	560	28130
Antimony	45	11.3	560
Arsenic	3.8	0.9	47
Barium	1500	375	18750
Boron	1200	300	15000
Cadmium	1.3	0.3	17
Chromium (III)	37.5	9.4	460
Chromium (VI)	0.02	0.005	0.053
Cobalt	10.5	2.6	130
Copper	622.5	156	7700
Lead	2.0	0.5	23
Manganese	1200	300	15000
Mercury	7.5	1.9	94
Nickel	75	18.8	930
Selenium	37.5	9.4	460
Strontium	4500	1125	56000
Tin	15000	3750	180000
Organic tin	0.9	0.2	12
Zinc	3750	938	46000

17) Nano Materials

LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F are not intentionally added with “ Nano materials ” or any raw material in nano form, in the manufacture of these grades.

18) EU Directive 2006/122/EC

Perfluorooctanic acid, perfluoro-alkyl sulfonates & perfluorooctane sulfonates are not intentionally added in the manufacture of LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F.

19) California's Safe Drinking Water and Toxic Enforcement Act of 1986(Proposition 65)

The chemical substances which are known to cause cancer or reproductive toxicity as listed in California Proposition 65 (last amended 29 Dec 2023) are not intentionally added in the manufacture of LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F.

20) CLP Regulation - Regulation (EC) No 1272/2008

The chemical substances which are classified as Carcinogenic, Mutagenic or Toxic for reproduction (CMR) Category 1A and 1B as per Regulation (EC) No 1272/2008 are not intentionally added in the manufacture of LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F.

21) Halogenated Flame Retardants

Polybrominated biphenyls (PBBs), Polybrominated diphenyl ethers (PBDEs), Decabromo diphenyl ether, Polychlorinated biphenyls (PCBs), Polychlorinated terphenyls (PCTs), Polychlorinated naphthalenes (PCNs) and Hexabromocyclododecane (HBCDD) are not intentionally added in the manufacture of LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F

22) Ozone Depleting Chemicals (ODCs)

CFCs and other substances related to ozone depleting substances (as defined by the Montreal Protocol and listed as Class I & II substances by the US Clean Air Act) are not intentionally used in the manufacture of LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F.



23) Other Substances of Concern

The chemical substances listed below are not intentionally added in the manufacture of LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F.

- Natural rubber latex
- Phthalates as plasticizers
- Bisphenols
- Organic Tin Compounds
- Melamine
- Dimethyl Fumarate
- Genetically Modified Organism (GMO)
- Alkylphenols and ethoxylates (Nonyl phenol (NP), Nonyl phenol ethoxylates, Tris nonylphenyl phosphate (TNPP))
- Asbestos
- Formaldehyde
- Acrylonitrile and Polyacrylonitrile
- Trisclosan
- Azo colourants/Pigments
- BHT and BHA
- Dioxin and Furans
- Nitrosamines & Nitrosating agents
- Vinyl chloride, Polyvinyl chloride & Polyvinylidene chloride
- Radioactive substances
- Bis(2-ethylhexyl) adipate (DEHA)
- Eposidised soyabean oil (ESBO)
- Primary Aromatic Amines (PAA)
- Polycyclic Aromatic Hydrocarbons (PAH)
- Benzophenones, 4 methyl benzophenone, Hydroxybenzophenone
- Aflatoxins
- Biocides & Fungicides
- Per and Polyfluoroalkyl substances (PFASs)
- Perfluorohexane-1-sulphonic acid and its salts (PFHxS)
- Phenol, Isopropylated Phosphate (3:1)
- 2,4,6-tris(tert-butyl) phenol
- Pentachlorothiophenol
- Hexachlorobutadiene

*Note that trace level of BHT may be present in these grades due to the nature of their production processes.



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24) Global Chemical Inventory Status

The components which are used in the manufacture of LDPE COSMOTHENE® grades G215, F210, L420, L705, L712, G811 & G811F are listed in the following chemical inventories:

Country	Name of Chemical Inventory	Status
United States	Toxic Substances Control Act (TSCA)	Listed (Active)
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS/ELINCS)	Listed (EINECS)
Canada	Domestic Substance List/Non-Domestic Substances List (DSL/NDSL)	Listed (DSL)
Japan	Japan Existing & New Chemical Substances (ENCS)	Listed
China	Chemical Inventory of Existing Chemical Substances (IECSC)	Listed
Korea	Korea Existing Chemicals Inventory (KECI)	Listed
Taiwan	Taiwan Chemical Substances Inventory (TCSI)	Listed
Australia	Australian Inventory of Chemical Substances (AICS)	Listed
New Zealand	New Zealand Inventory of Chemical Substances (NZIoC)	Listed
Philippines	Philippines Inventory of Chemicals and Chemical Substances (PICCS)	Listed

Disclaimer:

To the best of our knowledge, the information contained herein is accurate and reliable as of the date of publication. This information is based on and in accordance with the declarations provided by our suppliers of the materials used in our product and no specific analysis has been carried out by us. We do not assume any liability whatsoever for the accuracy and completeness of such information. Nothing herein shall constitute any implied warranty of merchantability or fitness for a particular purpose. It is the responsibility of the user to inspect and test our product in order to satisfy itself as to the suitability of the product for its intended application. The user is responsible for the appropriate, safe and legal use, processing and handling of our products.

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