



# Luban EP2348R

## Product Stewardship Declaration

Dear Customer,

We hereby declare that the LUBAN EP2348R grade has been formulated and manufactured in accordance with the compositional requirements of the following recommendations or regulations:

### FDA Compliance

The base resin in this product meets the FDA requirements contained in the Code of Federal Regulations in 21 CFR 177.1520(a)(3)(i) and (c)3.2a. According to our information, all other ingredients used in this product meet the requirements of their respective FDA regulations. FCNs and 21 CFR 177.1520(b).

This product meets the FDA criteria in 21 CFR 177.1520 for food contact applications, including cooking, listed under conditions of use A through H in 21 CFR 176.170(c), Table 2 and can be used in contact with all food types as listed in 21 CFR 176.170(c), Table 1.

### Regulation (EU) 10/2011: Food contact Applications

This product complies with Commission Regulation (EU) 10/2011 of January 14, 2011 on plastic materials and articles intended to come into contact with food and its latest amendments EU 2023/1627.

All the monomer and additives used in the composition of the above product are listed in the union list of authorized substances under Annex I of commission regulation (EU) 10/2011.

Regulations (EU) 10/2011 which applies to all EU member states specify 10mg/dm<sup>2</sup> as the maximum overall migration (OML) from finished plastic food contact articles. This is responsibility of converter.

### SML Components

This product contains one or more components with Specific Migration Limits (SMLs):

Ref.	SML Substance	Limit	Unit
39090	N,N-bis(2-hydroxyethyl) alkyl (C8-C18) amine	1.2	mg/kg
39120	N,N-bis(2-hydroxyethyl)alkyl(C8-C18)amine hydrochlorides*	1.2	mg/kg

\* SML(T) = 1.2 mg/kg (Expressed as tertiary amine excluding HCl)

### Dual Use Additives

This material does not contain intentionally incorporated dual use additives, which are subject to disclosure of adequate information as described in Annex IV of Commission Regulation (EU) 10/2011.

The product also complies with Regulation 1935/2004/EC, Restriction of use of certain epoxy derivatives 1895/2005/EC & amendments, Absences of Allergens 2007//68/EC, no use of allergens as reported into Regulation (EU) 1169/2011 annex II and Absences of GMO.

The production of the above mentioned grade is systematically reviewed with regards to good manufacturing practice (GMP) using our ISO 9001 system. Therefore, we can state that the above



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mentioned product meets the relevant requirements laid down in Regulation 2023/2006/EC on good manufacturing practice for materials and articles intended to come into contact with food. Users must verify that the finished items, manufactured according to good manufacturing practice (GMP) must not modify the organoleptic properties of the food.

This product could potentially contain Non Intentional Added Substances (NIAS), which required to be evaluated using recognized risk assessment method.

### **Regulation (EC) 1223/2009: Cosmetic Products**

The EU regulation (EC) 1223/2009 applies to cosmetic products and it does not apply to the polymer resins. However, we confirm that any of the substances listed in the Annex II of the regulation 1223/2009/EC is not used in the manufacture or formulation of this product. However, this product has not been tested for these chemical substances.

### **REACH (Regulation EC 1907/2006)**

OQ certifies that all components used in the formulation of this product do not contain, nor are they knowingly produced with any substances listed on Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and its latest amendments Commission Regulation (EU) 2023/2055.

#### **Substance of Very High Concerns (SVHC):**

ECHA has so far identified certain chemical substances as the substances of Very High Concerns (SVHC) updated as of 7<sup>th</sup> November 2024. These substances are mentioned in the following link:

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

We confirm that these substances of Very High Concerns (SVHC) are not added intentionally during manufacturing process of this product.

#### **REACH Registration Status:**

Polymers are generally exempted from the provisions on registration of Title II of REACH (Article 2(9)). However, the constituents of these polymers fall under the regulation of REACH. Therefore, all relevant substances like monomers and polymer additives were:

- Full registered under EU-REACH.
- Pre-Registered under UK-REACH.
- Pre-Registered under Turkey REACH

For the relevant substances in OQ polymers products, an Only Representative (OR) in accordance with the European Union legislation REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) has been appointed.

#### **Country Chemical Invention status:**

*(Listed on inventory or not listed on inventory/Compliance):*



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- **United States:** Toxic Substances Control Act Inventory (TSCA); Listed, Exempt from reporting under the Inventory Update Rule.
- **Canada:** Domestic Substances List (DSL), Non Domestic Substance List (NDSL); the substance is specified on the DSL.
- **Europe:** European Inventory of Existing Commercial Chemical Substances (EINECS or ELINCS); ELINCS are not effective anymore after REACH came in force. Under REACH all polymers are exempt from registration and evaluation.
- **Australia:** Australian Inventory of Chemical Substances (AICS); listed.
- **Korea:** Korean Existing Chemical List (ECL); Korea-Reach is in force and polymers are exempt from registration.
- **Japan:** Japanese Existing and New Chemical Substances (ENCS); listed. The draft Positive List (PL) published by MHLW (base polymers: plastics & additives) on November 30<sup>th</sup>, 2023; listed.
- **Philippines:** Philippines Inventory of Chemicals and Chemical Substances (PICCS); listed.
- **China:**
  - ✓ Inventory of Existing Chemical Substances Manufactured or Imported in China (IECSC); listed.
  - ✓ GB 9685-2016 "National Standard of Food Safety: on uses of additives in Food Contact Materials and their products"; compliant.
  - ✓ GB 31603-2015 "National Food Safety Standard General Hygienic Practice for Production of Food Contact Materials and Its Products"; compliant.
  - ✓ GB 4806.1-2016 "National Standard of Food Safety: General safety requirements on Food Contact Materials and their products"; compliant.
  - ✓ GB 4806.7-2023 "National Food Safety Standard – Food Contact Plastic Materials and Products"; listed.

The monomers and additives used on the formulation of this product are listed in the above regulations' positive lists including no specific migration limit (SML).

- **New Zealand:** New Zealand Inventory of Chemicals (NZIoC); listed.
- **Switzerland:** Swiss Federal Department of Home Affairs (FDHA) - Swiss Ordinance on Materials and Articles Intended to Come into Contact with Foodstuffs (Materials and Articles Ordinance, 817.023.2, Annex 2 listed under List of substances permitted for the manufacture of plastic materials and articles and related requirements Table 1 column 6, additive (without additives used in the production of colourants and pigments (AD) as of July 2024.
- **MERCOSUR** (Argentina, Brazil, Uruguay, Paraguay, Venezuela and Bolivia)  
This product meets the requirements of following regulations:
  - ✓ GMC Resolution No. 03/1992 of April 1st 1992, which "establishes the general criteria and classification of materials for packaging and equipment in contact with food"
  - ✓ GMC Resolution No. 02/2012 of April 19th 2012 which provides a "positive list of monomers, other starting substances and polymers authorized for the manufacture of plastic packaging and equipment that come into contact with food"
  - ✓ GMC Resolution No. 39/2019 of July 15th 2019, which provides the "Technical Regulation on the positive list of additives for plastic materials and polymeric coatings intended to contact food".

This product does not contain monomers and/or additive with SML and/or Total Specific Migration Limit (SML(T)) and/or QMA (residual content per food contact area). In order to guarantee the compliance with the above Resolutions, the end plastic product must be analyzed by the manufacturer concerning total migration limit and such limit must be less than 50 mg/kg or 8 mg/dm<sup>2</sup>.



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### **ROHS Directive 2011/65/EU**

The product complies with latest update of RoHS Directive (EU) 2015/863 and the substances mentioned in the directive are not intentionally introduced or not exceeding the maximum concentration values mentioned in the 'ANNEX II.

### **Medical**

#### ***European Pharmacopeia (EP)***

This product does not meet the EP requirements for 3.1.3, Polyolefins - 7th Edition of European Pharmacopeia.

#### ***USP Class VI***

This product has not been tested for USP Class VI.

### **Directive 94/62/EC and the regulation of the Coalition of Northeastern Governors (CONEG) of the USA on packaging and packing waste**

The product meets the requirement of CONEG and Directive 94/62/EC and its amendments (2005/20/EC and 2013/2/EU) in force. Cadmium, chromium (VI), lead and mercury are not used in the manufacture of or in the formulation of this product. This product meets the year 2001 requirements of less than 100ppm for total incidental Cadmium, chromium (VI), lead and mercury. In addition, the product has the potential to be recycled according to these requirements.

### **TSE/BSE Statement**

The derived from animal sources are not intentionally used in this product recipe. Our additive supplier confirmed that the blended polymer additives used for this product are synthetic derivatives of vegetable based materials and minerals, and are free of any animal basis materials.

### **Halal & Kosher Certification**

This product is certified for Halal.  
This product is not certified for Kosher.

### **Phthalates Compliance**

The product complies with Regulation (EU) 10/2011/EC. Plasticizers such as phthalates are not used in the manufacture of or the formulation of this product. However, trace of phthalate as minor component of the catalyst system (a "Technical Support Agent") could be used to manufacture this product. This is typical of polypropylene resins produced with high mileage catalysts. Historical testing with food stimulants demonstrated residual phthalates found to be less than 0.1%wt threshold as stated in REACH (Article 57, Regulation No. 1907/2006), which is the detection limit of the analytical method used.



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### Declaration on California Proposition 65

The monomer and additives incorporated comply with California Proposition 65 (updated on DECEMBER 29, 2023). The product represents 'no significant risk' for cancer to the people of California. The product contains no substances known to the State of California to cause reproductive toxicity at a level of exposure subject to the requirements of Propositions 65.

### Switzerland VOC Declaration

This product contains less than 3% VOC's of the substances in the positive lists of the Switzerland Regulations "VOC-LENKUNGSABGABE."

### Absence of Substances and Chemicals

We do not intend to use the Substances/Chemicals listed below in our product recipe:

- 2-Ethylhexylhexanoic acid
- Acetylacetone
- Acrylamide
- Aromatic amines
- Asbestos
- Azo pigments
- Benzo[a]pyrene
- Benzophenone, hydroxybenzophenone and 4-methylbenzophenone
- Benzotriazole
- Biocides
- Bisphenol-A, F, S
- Brominated flame retardants
- Butylated hydroxytoluene (BHT)
- CFC's
- Chlorinated paraffins
- CMR substances class 1A and 1B (Carcinogens, Mutagens and toxic for reproduction) according with Regulation CLP (1272/2008)
- Cyanides
- Dimethylfumarate
- Dioxins and furans
- Engineered nanomaterials
- Epoxidised Soya Bean Oil (ESBO)
- Epoxyderivates (BADGE, BFDGE or NOGE)
- Fluorine
- Formaldehyde
- Genetic modified organisms (GMO)
- Glycoethers
- Isopropylthioxanthone (ITX)
- Latex
- Melamine
- Mineral Oil Saturated Hydrocarbons (MOSH) and Mineral Oil Aromatic Hydrocarbons (MOAH) or any form of Oligomers.
- Nitrosamine
- Nonylphenol and its derivatives
- Organo-tin compounds as tributyl-tin (TBT), dibutyl-tin (DBT), monobutyl-tin (MBT)



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- Ozone depleting substances according to the Montreal protocol
- PBB or PBDE
- PBT/PCB/vPvB
- PCP/PCN
- Perfluorooctane sulfonate (PFOS)
- Perfluorooctanoic acid (PFOA)
- perfluoroalkyl & polyfluoroalkyl substances (PFAS)
- Pesticides
- Persistent Organic Pollutants (POPs)
- Polycyclic aromatic hydrocarbons (PAH)
- Radioactive substances
- Recycled materials
- Semicarbazide
- Sesame seeds or Wheat
- Substances with possible allergic properties such as Cereals, Crustaceans, Eggs, Milk, Nuts, ..etc.
- The heavy metals cadmium, mercury, lead or hexavalent chromium
- Triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether) (CAS 3380-34-5)
- Tris-nonylphenol phosphite (TNPP) (CAS No. 26523-78-4)
- Vinyl chloride monomer (VCM) and its polymers or copolymers (PVC, PVDC, ...)

This Product Stewardship Declaration is intended for information purpose only. OQ makes no representation or warranties with respect to the accuracy or completeness of the information contained herein. The information provided in this document applies to the product mentioned above as it leaves the production facility of OQ & does not cover any additive, pigment, or any third party material, subsequently included by the converter.

Prepared by OQ Polymer Marketing Product Stewardship Manager. For any further assistance, please contact the undersigned.

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### Disclaimer

This statement is submitted without prejudice and is based on our current knowledge and experience. It does not relieve the receiver of this information from the responsibility of carrying out their own tests and experiments; neither does it imply any legally binding assurance of certain properties or of suitability for a specific use of products made with or on the basis of this information. OQ assume no liability whatsoever in respect of application, processing or use of the aforementioned information or products or any consequences.