

Date: 23/12/2023

# **Certificate of Compliance**

This is to certify that the **UV Masterbatch UV 9000** comply with EU Plastics Regulation (EU) No 10/2011.

"Commission Regulation (EU) No 10/2011 and its amendment Commission Regulation (EU) 2017/752, Commission Regulation (EU) 2018/79, Commission Regulation (EU) 2018/831, Commission Regulation (EU) 2019/37, Commission Regulation (EU) 2019/1338, Commission Regulation (EU) 2020/1245, Commission Regulation (EU) 2023/1442 and Commission Regulation (EU) 2023/1627.

Sr. No.	FCM Substance Number	Reference Number	Content in Masterbatch	Permissible Specific Migration Limit (SML)	Remarks
Polyethylene Wax	549	80000	ND	NO SML	-
Aluminum	-	-	ND	NO SML	-
pentaerythritol tetrakis[3-(3,5-di- tert-butyl-4- hydroxyphenyl)- propionate]	496	71680	Max. 0.07%	NO SML	-
phosphorous acid, tris(2,4-di- tert- butylphenyl)ester	671	74240	Max. 0.13%	NO SML	-
Antimony	-	-	ND	0.04 mg/kg	(2)
Barium	Annex II	Annex II	ND	1 mg/kg	-
Cobalt	Annex II	Annex II	ND	0.05 mg/kg	-
Copper	Annex II	Annex II	ND	5 mg/kg	-
Iron	Annex II	Annex II	ND	48 mg/kg	-
Lithium	Annex II	Annex II	ND	0.6 mg/kg	-
Magnesium	-	-	ND	-	(1)

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Manganese	Annex II	Annex II	ND	0.6 mg/kg	-
Terbium			ND	0.05 mg/kg	(3)
Zinc	Annex II	Annex II	ND	25 mg/kg	-
Lanthanum	-	-	ND	0.05 mg/kg	(3)
Europium	-	-	ND	0.05 mg/kg	(3)
Gadolinium	-	-	ND	0.05 mg/kg	(3)
Calcium Oxide	395	41520	ND	NO SML	
Carbon Black	411	42080	ND	NO SML	
UV 622:	716	60800	Max. 10%	30 mg/kg	
Poly(4-hydroxy-					
2,2,6,6-					
tetramethyl-1-					
piperidine					
ethanol-alt-1,4-					
butanedioic acid)					
Titanium Dioxide	610	93440	ND	NO SML	

### Remarks:

- (1) The migration is subject to Article 11(3) and Article 12
- (2) The note in Annex I, Table 1, FCM No 398 applies: SML might be exceeded at very high temperature.
- (3) The lanthanide substances europium, gadolinium, lanthanum, and/or terbium can be used in accordance with Article 6(3)(a) provided that:
  - (a) The sum of all lanthanide substances migrating to the food or food simulant does not exceed the specific migration limit of 0,05 mg/kg; and
  - (b) analytical evidence using a well described methodology demonstrating that the lanthanide substance(s) used are present in dissociated ionic form in the food or the food simulant, forms part of the documentation referred to in Article 16.

#### Note:

(1) For substances for which no specific migration limit or other restrictions are provided in Annex I, a generic specific migration limit (SML) of 60 mg/kg shall apply as per "European COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food".

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- (2) Mg/kg: Milligram per kilogram of foodstuff in contact with
- (3) ND: Not Detected

### **Dual Use Additive:**

Europe - Dual Use Additives: Food additives EC 1333/2008 (incl2022/1038)

REGULATION (EC) No 1333/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on food additives up to and including Commission Regulation (EU) 2022/1038 **No food additives are used.** 

**Europe - Dual Use Additives: flavourings EC 1334/2008 (incl2022/1466)**No flavouring ingredients are used.

## • EU Regions

Title of the national regulation		YES	NO	restrictions
Europe	Resolution AP (89) 1			Not applicable. Additives are used.
France	Brochure 1227. <b>French positive list</b> as amended + Specific purity criteria as described in Circulaire n°176	٧		
Germany	BfR recommendation IX in its latest version	٧		
Italy	Decree of 21 March 1973 and subsequent amendments.	٧		

## 2. Other Regions

	Regulation	YES	NO	Unk.	Specify sections/ restrictions
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USA	FDA 21CFR or FCN FDA 21CFR or FCN	V		UV 622: Comply with 21 CFR 178.2010  Olefin Polymers FDA: CFR Title 21,177.1520 (a) (2)(i)("C 2.1,2.2"), olefin polymers
	<b>GB4806.1-2016</b> : National Food Safety Standard: General Safety Requirements on Food Contact Materials and Articles	٧		No specification
China	<b>GB4806.6-2016:</b> Plastic resin used in food contact	٧		No specification
<b>-</b>	GB9685-2016: Hygienic standards for use of additives in food packaging materials (List A.1 for plastic)	٧		UV 622, FCA0702, PE, PP: Maximum 6%
South America	MERCOSUR: GMC n°02/12, 39/19& 15/10 ANVISA: GMC n°56/12, 17/08 & 52/10		٧	
Japan	In regards to the Japanese Positive List published by the Ministry of Health, Labour and Welfare (MHLW) of Japan (MHLW Notification No. 196) and implemented from 1 June 2020, please confirm that:  a) The basic polymers characteristic in terms of: Resin Type: Food Type: Maximum temperature:	٧		
	b) The additives are listed in Appendix 1, Table 2 Additives with permitted concentration.		٧	Reference No Serial No
	c) The monomers are listed in Appendix 1, Table 1 (3).		٧	Reference No Serial No
Switzerland	Swiss Ordinance <b>817.023.21</b> of December, 2019, Annex 2		٧	

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	IS 16738-2018: Positive list of constituents for Polypropylene, Polyethylene and their Copolymers for its safe use in contact with foodstuffs and drinking water	٧			No specification
India	IS 9833-2018: List of pigments and colourants for use in plastics in contact with foodstuffs, pharmaceuticals and drinking water		√		Not applicable. Additives are used.
	Any other India food contact standards please specify.			٧	

## > Compliance with Regulation (EU) No. 1935/2004

The product complies with Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food.

## Compliance with Regulation (EC) No.2023/2006

The product complies with the requirements of Regulation 2023/2006/EC of 22 December 2006 on good manufacturing practices for materials and articles intended to come into contact with food (Good Manufacturing Practices). All used ingredients received from supply chain comply with the requirements of Regulation 2023/2006/EC.

### Compliance with EU RoHS Regulation 2015/863

Comply with limit set by RoHS heavy metals such as Lead (Pb), Cadmium (Cd), mercury (Hg), Hexavalent Chromium (Cr), Polybrominated Biphenyls (PBB), Polybrominated Diphenyl Ethers (PBDE), DEHP: Di(2-ethylhexyl) phthalate, BBP: Benzyl butyl phthalate, DBP: Dibutyl phthalate and DIBP: Diisobutyl phthalate.

### Compliance with REACH and SVHC

Comply with the European Union Regulation (EC) 1907/2006 (Updated 14/06/2023) governing the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and do not contain substances above 0.1% weight of a Substance of Very High Concern (SVHC) listed in Annex XIV.

## > Compliance with Directive 94/62/EC and CONEG:

The product meet the requirement of the Directive 94/62/EC and the CONEG regulation which limits the content of heavy metals less than 100 ppm (Cd, Pb, Hg, Cr (VI)).

## Compliance with EN71 (Safety of Toy):

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The product comply with the standard EN71-3:2019 and Toy safety 2009/48/EC Safety of Toys Part.

Compliance with EN 71-3: Migration of certain elements

## Compliance with MOSH, POSH & MOAH:

Mineral Oil Saturated Hydrocarbons (MOSH), Polyolefin Oligomeric Saturated Hydrocarbons (POSH), Mineral Oils Aromatic Hydrocarbons (MOAH) are not intentionally used in the manufacture or formulation of this product.

## > Animal Derived Components (BSE) / (TSE) (EC 999/2001)

The above grade is neither derived from animal or human origin nor manufactured utilizing intermediates and / or auxiliary agents which are of animal or human origin. The grade does not contain Bovine Spongiform Encephalitis (BSE) and Transmissible Spongiform Encephalitis (TSE). Hence the issue of Animal Spongiform Encephalopathy does not arise.

## Does this product contain one of the following substances:

Substance	Yes/No
Allergens listed in Regulation (EU) n°1169/2011, Annex II	NO
Ozone depleting substances listed in regulation (EU) n°2017/605	NO
Recycled plastics according to Regulation (EC) n°282/2008	NO
Substances on the list 1 "Substances identified as endocrine disruptors at EU level" https://edlists.org/the-ed-lists/list-isubstances-identified-as-endocrine-disruptors-by-the-eu	N0
Adipates / Phthalates	NO
Alkylphenols and derivatives	NO
Antimony trioxide	NO
Benzophenone	NO
Bisphenols (A, B, F, S,)	NO
Dimethyl fumarate (DMF)	NO
Dioxin	NO
Epoxydized Soya Bean Oil (ESBO)	NO
Formaldehyde	NO
Genetically modified organisms	NO
Isopropylthioxanthone (ITX)	NO
Latex	NO
Melamine / Cyanuric acid	NO
Mineral Oil	NO

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Organostannic compounds	NO
Substances listed in California Proposition 65	NO
Palm Oil or derivatives	NO
Parabens	NO
Pesticides / biocides / herbicides	NO
PFAS -Perfluoroalkyl and Polyfluoroalkyl Substances	NO
PFOA Perfluorooctanoic acid /	NO
PFOS Perfluorooctansulfonic acid /	
PFCA Perfluorocarboxylic acid	
Semicarbazide	NO

For Coraplast Industries,

Arvind Gupta Manager R&D Lab

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