kuraray

Kuraray Poval™

Kuraray Europe GmbH, Philipp-Reis-Straße 4,
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Regulatory Status and Product Information

2 May 2025

To whom it may concern

Statement

concerning

Regulation (EU) No 10/2011 as amended on Plastic Materials and Articles Intended to Come into Contact with Food

Kuraray Europe GmbH hereby confirms that KURARAY POVAL™ grades listed in table 1 compositionally meet the relevant requirements laid down in Regulations (EU) No 10/2011 and No 1935 /2004 as amended within the following general framework and limitations:

- All monomers and other starting substances used for manufacturing KURARAY POVAL™ are authorized for their use in food contact materials by inclusion in Annex I of Regulation (EU) No 10/2011.
- To the monomer vinyl acetate (acetic acid vinyl ester, Ref. No. 10120, FCM No. 231) a specific migration limit (SML) of 12 mg/kg food has been assigned. KURARAY POVAL™ may contain traces of vinyl acetate. In addition, hydroquinone (1,4-dihydroxybenzene, FCM No. 295), used as an inhibitor for the monomer vinyl acetate, is listed in Annex I of Regulation (EU) No 10/2011 with a SML of 0,6 mg/kg. Despite the removal process, residual hydroquinone may still be present as an impurity at a trace level.
- Methanol, used during the manufacturing processes, is present in the product as residual solvent in concentrations below 3 wt%. Methanol is an authorized substance listed in Annex I and, as a volatile solvent, it is not subject to further detail by Regulation (EU) No 10/2011.
- KURARAY POVAL™ is produced using metal equipment. Therefore, we cannot exclude the presence of metal traces – subject to Annex II – from construction materials. None of the substances analyzed below were detected in the ICP/MS screening tests. The detection limits were as follows:
  - <0.02 ppm for mercury
  - <1 ppm for antimony, barium, cadmium, chromium, copper, cobalt, lead, lithium, manganese, nickel, and zinc
  - <2 ppm for arsenic
  - <15 ppm for aluminium, calcium, iron, magnesium and potassium
  - Some substances listed in Annex II, such as ammonium, europium, gadolinium, lanthanum and terbium, were not included in the screening tests. However, they are not expected to be present in our products, as they are not intentionally used in our manufacturing process.
- To the best of our knowledge of the manufacturing processes and the type of raw materials used, we can confirm that no primary aromatic amines are used in the manufacture of our KURARAY POVAL™ product line or added after the manufacturing processes.

- KURARAY POVAL™ may contain traces of acetaldehyde (Ref. No. 10060, FCM No. 128, group restriction SML of 6 mg/kg food) and crotonaldehyde (EC No. 224-030-0, with a max. level of 16 ppm) and formaldehyde (Ref. No. 17260, FCM No. 98, group restriction SML of 15 mg/kg food) as impurities/ non-intentionally added substances.
- KURARAY POVAL™ contains up to 1.3% sodium acetate (E 262) as an impurity, which is a dual use additive regarding Regulation (EU) 231/2012 and Regulation (EC) 1333/2008. Sodium acetate is formed during manufacturing processes, and therefore no purity grade is applicable.

KURARAY POVAL™ is regarded as suitable for use in food contact materials, provided that the finished food contact materials meet the overall migration limit of 60 mg/kg and 10 mg/dm², respectively, as well as the substance-specific migration limits established by Regulation (EU) No 10/2011.

The above information is intended to support our customers in fulfilling their obligations regarding Regulation (EU) No 10/2011. However, the final verification of product compliance with migration limits and other applicable requirements of Regulations (EU) No 10/2011 and No 1935/2004 lies with the manufacturers of the finished products.

Table 1 (For grades with country of origin Germany)

Partially hydrolyzed KURARAY POVAL™ grades			Fully hydrolyzed KURARAY POVAL™ grades	
3-83	6-96	32-88	2-98	30-98
3-85	8-88	40-88	3-98	56-98
3-88	13-88	44-88	4-98	
4-85	18-88	47-88	6-98	
4-88	22-88	49-88	10-98	
5-82	23-88	50-92	15-99	
5-88 FA	26-88		20-98	
6-88	30-92		28-99	

The same applies to low volatile grades (LV grades), low ash grades (LA grades) and fine powder grades (S grades) in this context.
Some grades are also produced in USA, Singapore and Japan. For information regarding regulatory food contact compliance in these countries, please direct your requests to your Kuraray contact.

With our best regards,
Kuraray Europe GmbH

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i. V. Dr. Shu-Hsien Li
(Senior Manager Product Stewardship & REACH)

This statement is based on our current level of knowledge and covers commercial and experimental resins as supplied by Kuraray Europe GmbH at the date of issue. Since conditions of use are outside Kuraray Europe GmbH control, Kuraray Europe GmbH makes no warranties, express or implied, and assumes no liability in connection with any use of this information.

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