

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 the manufacture of 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.
- Methanol is used during the manufacturing processes and will be present in the product as residual solvent in concentrations below 3 wt%. Methanol is an authorized substance within Annex I and, as a volatile solvent, not considered in further detail by Regulation (EU) No 10/2011.
- Kuraray Poval™ is produced in metal equipment. Therefore, we cannot exclude the presence of metal traces – subject to Annex II – from construction materials. Metal spot checks via ICP/MS revealed concentrations (limits of detection) of
  - <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
  - The screening tests do not include ammonium, europium, gadolinium, lanthanum and terbium, 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 (CAS No. 4170-30-3, 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 (CAS 127-09-3, E 262) as impurity, which is a dual use additive regarding Regulation (EU) 231/2012 and Regulation (EC) 1333/2008. Because sodium acetate is formed during the manufacturing processes no purity grade is applicable.

Kuraray Poval™ is regarded as being suited for the use in food contact materials, provided that the finished food contact materials meet the overall migration limit of 60 mg/kg and 10 mg/dm<sup>2</sup>, respectively, as well as substance specific migration limits established by Regulation (EU) No 10/2011.

Above information is intended to support our customers in fulfilling their obligations with regard to Regulation (EU) No 10/2011. The final verification of their product's compliance with migration limits and other applicable requirements of Regulations (EU) No 10/2011 and No 1935/2004 is in the responsibility of the manufacturers of the finished products and can only be performed by them.

Table 1 (For grades with country of origin Germany)

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

Low ash grades (LA grades) and fine powder grades (S grades) are the same as standard grades.

Some grades are also produced in USA, Singapore and Japan: For regulatory food contact compliance information for these countries please send requests to your Kuraray contact.

With our best regards,  
Kuraray Europe GmbH



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

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