

FOOD CONTACT

BYK Regulatory Information

CERACOL 609 N

Dispersion of wax-modified lanolin for solvent-borne can coatings. Increases scratch resistance and surface slip without influencing flexibility.

Summary

CERACOL 609 N is suitable according to the following compositional provisions for food contact applications, as indicated:

| Coatings | | |
|----------|--------------------------------------|--|
| | Suitable for food contact coatings | Yes |
| EU | Regulation (EU) No. 10/2011 | No |
| | German BfR XIV 'Polymer Dispersions' | No |
| | CoE ResAP (2004) 1 | Yes |
| | USA | 21 CFR 175.300 'Resinous and polymeric coatings' |
| China | GB9685-2016, table A.2 'Coatings' | Yes |

Solvents and other formulation aids are not covered by the food contact status. For further details, please refer to the 'Explanation'.

This summary only reflects conducted evaluations on existing regulations. It does not exclude compliant use in additional regions or applications. Explanations below show details on considered regulations and evaluations.

Explanation

| Coatings | |
|-----------|--|
| EU | <p><u>Regulation (EU) No. 10/2011</u> This product does not comply with the COMMISSION REGULATION (EU) No. 10/2011 of 14 January 2011 (PIM) on plastic materials and articles intended to come into contact with food (including all amendments).</p> <p><u>German BfR XIV 'Polymer Dispersions'</u> This product does not comply with the compositional requirements of the German BfR-Recommendation XIV "Polymer Dispersions".</p> <p><u>CoE ResAP (2004) 1</u> The active components of this product are listed in CEPE "Code of practice for food contact coatings", Edition 4, Version Feb. 2009.</p> <p><u>Dual use additives</u> The product contains dual use additives for which restrictions apply:</p> |

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- E903 – carnauba wax (ca. 14%)

Therefore, the product can be recommended for use in food contact coatings in the EU.

Solvents and other formulation aids are not covered by the food contact status.

USA

21 CFR 175.300 ‘Resinous and polymeric coatings’

The active components of the product are listed. Therefore, the product can be recommended for use in applications described in Sec. 175.300.

Solvents and other formulation aids are not covered by the food contact status.

China

GB9685-2016, table A.2 ‘Coatings’

The active components of the product are listed in GB9685-2016 table A2 ‘Coatings’.

Therefore, the product can be recommended for use in food contact coatings in China.

Solvents and other formulation aids are not covered by above statement.

The product contains a significant amount of solvent [Solvent naphtha (petroleum), heavy aromatic, with a boiling range from 160 °C – 220°C]. Solvents are currently not regulated by food contact positive lists as it is assumed that solvents evaporate from the finished product so that only residues or traces of no toxicological concern should remain. Evaporation needs to be monitored by the manufacturer of the final product. Article 3 of the Framework Regulation (EC) 1935/2004 should be fulfilled.

General Remarks

Regulations apply within the context of respective regional framework regulations, e.g. Regulation (EU) No. 1935/2004 and FDA 21 CFR 174.5. Since traces of unknown processing aids cannot be fully excluded, compliance with general requirements is the responsibility of the end user.

BYK reserves the right to change or update the information without notice. At most, this letter deems to be actual for three years commencing the date of issue.

Food Contact Team
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