

FOOD CONTACT

BYK Regulatory Information

RHEOBYK-D 420

Summary

RHEOBYK-D 420 is suitable according to the following compositional provisions for food contact applications, as indicated:

| Coatings | | |
|---------------|--|-----|
| | Suitable for food contact coatings | Yes |
| Europe | Regulation (EU) No. 10/2011 | No |
| | German BfR XIV 'Polymer Dispersions' | Yes |
| USA | 21 CFR 175.300 'Resinous and polymeric coatings' | No |
| China | GB9685-2016, table A.2 'Coatings' | No |
| Printing inks | | |
| Europe | Suitable for food contact printing inks | Yes |
| | Swiss Ordinance 817.023.21, Annex 10 | Yes |
| Industry | Nestlé Printing Inks for Food Packaging (02/04/2024) | Yes |
| | EuPIA Exclusion List (March 2024) | Yes |

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

Europe Regulation (EU) No. 10/2011

The product consists of a polymeric active component and a carrier (solvent). The active component is manufactured using monomers/starting substances which are fully evaluated by EFSA as SCF-list 0-4 and directly listed in Annex I – Table I of 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). Specific migration limits apply. The main active component as such is not listed as ‘polymeric additive’ in the COMMISSION REGULATION (EU) No. 10/2011 of 14 January 2011 (PIM) on plastic materials and articles intended to come into contact with food (PIM, as amended).

German BfR XIV ‘Polymer Dispersions’

The product conforms with the compositional requirements of the German BfR-Recommendation XIV. “Plastic Dispersions” and XXXVI. “Paper and board in contact with food” (due to cross-reference).

Solvents

Additionally, the product contains a significant amount of solvent, which is not in scope of the regulation (See safety data sheet and/or BRIEF). Solvents are expected to evaporate while producing the finished food contact article resulting in traces of no toxicological concern. Evaporation needs to be monitored by the manufacturer of the final product. Article 3 of Framework Regulation (EC) 1935/2004 applies.

Therefore, the product can be recommended for 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 product does not comply with Title 21 CFR (FDA) Regulations for indirect food additives.

China GB9685-2016, table A.2 ‘Coatings’

This product is not in compliance with the National Standard of the People’s Republic of China, GB96852016.

Printing inks

Europe **Swiss Ordinance 817.023.21, Annex 10**

This product is conform with the compositional requirements of the part for printing inks for packaging of the Swiss Ordinance 817.023.21 (Version of February 2024). The monomers/starting substances for manufacturing the active components and all other components are listed in Annex 10. Specific migration limits apply.

Therefore, the product can be recommended for use in food contact printing inks in Europe.

Industry **Nestlé Printing Inks for Food Packaging (02/04/2024)**

According to the recipe, the product does not intentionally contain any of the substances listed in 4. 'General Nestlé Exclusions and Minimisations' and Table 5 – Table 8 of the Nestlé Printing Inks for Food Packaging (02/04/2024).

EuPIA Exclusion List (March 2024)

According to the recipe, none of the substances listed in Annex 1 (Group C – G) of the EuPIA Exclusion List (March 2024) are intentionally present. The product itself is not classified and labeled with any of the Hazard Statements given in Group A and B.

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.

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This issue replaces all previous versions - Printed in Germany.