

FOOD CONTACT

BYK Regulatory Information

CERAFLOUR 991

Micronized wax for solvent-borne coating systems and powder coatings for improving surface properties.

Summary

CERAFLOUR 991 is suitable according to the following compositional provisions for food contact applications, as indicated:

| Coatings | | |
|---------------|--|-----|
| Europe | Suitable for food contact coatings | Yes |
| | Regulation (EU) No. 10/2011 | Yes |
| | German BfR XIV 'Polymer Dispersions' | Yes |
| | CoE ResAP (2004) 1 | Yes |
| USA | 21 CFR 175.300 'Resinous and polymeric coatings' | Yes |
| | 21 CFR 175.320 'Resinous and polymeric coatings for polyolefin films' | Yes |
| China | GB9685-2016, table A.2 'Coatings' | Yes |
| 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 (07/04/2022) | Yes |
| | EuPIA Exclusion List (June 2023) | Yes |
| China | GB9685-2016, table A.4 'Inks' | No |
| Adhesives | | |
| Europe | Suitable for food contact adhesives | Yes |
| | Regulation (EU) No. 10/2011 | Yes |
| | German BfR XIV 'Polymer Dispersions' | Yes |
| | German BfR XXXVI 'Paper and board in contact with food' | Yes |
| USA | 21 CFR 175.105 'Adhesives' | Yes |
| China | GB9685-2016, table A.5 'Adhesives' | Yes |

| Paper and paperboard | | |
|----------------------|---|-----|
| Europe | Suitable for food contact paper and paperboard | Yes |
| | Regulation (EU) No. 10/2011 | Yes |
| | German BfR XXXVI 'Paper and paperboard in contact with food' | Yes |
| USA | 21 CFR 176.170 'Components of paper and paperboard in contact with aqueous and fatty foods' | Yes |
| | 21 CFR 176.180 'Components of paper and paperboard in contact with dry food' | Yes |
| China | GB9685-2016, table A.6 'Paper' | 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 wax-base of the product is directly listed in Annex 1- table 1 of Commission Regulation (EU) No. 10/2011 of 14 January 2011 (PIM) (as amended). No SML value applicable.

German BfR XIV 'Polymer dispersions'

The product complies with the compositional requirements of BfR Recommendation XIV 'Plastics dispersions'.

CoE ResAP (2004) 1

The product complies with the compositional requirements of Council of Europe Resolution AP (2004)1.

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

USA

21 CFR 175.300 'Resinous and polymeric coatings'

The product can be used in compliance with the compositional requirements of FDA 21 CFR 175.300 (Resinous and polymeric coatings).

21 CFR 175.320 'Resinous and polymeric coatings for polyolefin films'

The product complies with the compositional requirements of FDA 21 CFR 175.320 'Resinous and polymeric coatings for polyolefin films' and can be recommended accordingly.

China

GB9685-2016, table A.2 'Coatings'

The product can be used in compliance with table A.2 'Coatings' of the National Food Safety Standard of the People's Republic of China, Standard for Uses of Additives in Food Contact Materials and Articles (GB9685-2016), since its components are listed in table A.2 (Additives for coatings).

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 October 2022). 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 Guidance Note on Packaging Inks (07/04/2022)

According to the recipe, the product does not contain any of the substances listed in Table 1 – Table 7 of the Nestlé Guidance note on Packaging Inks (07/04/2022).

EuPIA Exclusion List (June 2023)

According to the recipe, none of the substances listed in Annex 1 (Group C – G) of the EuPIA Exclusion List (June 2023) are present. The product itself is not classified and labeled with any of the Hazard Statements given in Group A and B.

China **GB9685-2016, table A.4 'Inks'**

The product does not comply with table A.4 'Inks' of the National Food Safety Standard of the People's Republic of China, Standard for Uses of Additives in Food Contact Materials and Articles (GB9685-2016).

Adhesives**Europe** **Regulation (EU) No. 10/2011**

The wax-base of the product is directly listed in Annex 1- table 1 of Commission Regulation (EU) No. 10/2011 of 14 January 2011 (PIM) (as amended). No SML value applicable.

German BfR XIV 'Polymer dispersions'

The product complies with the compositional requirements of BfR Recommendation XIV 'Plastics dispersions'.

German BfR XXXVI 'Paper and Board for Food Contact'

The product complies with the compositional requirements of BfR Recommendation XXXVI 'Paper and Board for Food Contact'.

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

USA **21 CFR 175.105 'Adhesives'**

The product is covered by the compositional requirements of FDA 21 CFR 175.105 'Adhesives'.

China **GB9685-2016, table A.5 'Adhesives'**

The product complies with the compositional requirements of table A.5 'Adhesives' of the National Food Safety Standard of the People's Republic of China, Standard for Uses of Additives in Food Contact Materials and Articles (GB9685-2016), since its components are listed in table A.5 (Additives for adhesives).

Paper and paperboard

Europe **Regulation (EU) No. 10/2011**

The wax-base of the product is directly listed in Annex 1- table 1 of Commission Regulation (EU) No. 10/2011 of 14 January 2011 (PIM) (as amended). No SML value applicable.

German BfR XXXVI 'Paper and Board for Food Contact'

The product complies with the compositional requirements of BfR Recommendation XXXVI 'Paper and Board for Food Contact'.

Therefore, the product can be recommended for use in food contact paper and paperboard in Europe.

USA **21 CFR 176.170 'Components of paper and paperboard in contact with aqueous and fatty foods'**

The product complies with the compositional requirements of FDA 21 CFR 176.170 'Components of paper and paperboard in contact with aqueous and fatty foods'.

21 CFR 176.180 'Components of paper and paperboard in contact with dry food'

The product can be used in compliance with the requirements of FDA 21 CFR 176.180 'Components of paper and paperboard in contact with dry food'.

China **GB9685-2016, table A.6 'Paper'**

The product complies with the compositional requirements of table A.6 'Paper' of the National Food Safety Standard of the People's Republic of China, Standard for Uses of Additives in Food Contact Materials and Articles (GB9685-2016), since its components are listed in table A.6 (Additives for paper).

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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