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MONARCH® 4750: conformity to Food contact regulations for use in plastics

MONARCH® 4750 carbon black (CAS 1333-86-4) produced in the USA conforms to the purity requirements of the following legislation:

USA

FDA requirements Colorants for Polymers 21 CFR 178. 3297 (High Purity Furnace Black) and FCN 1789, except for use in contact with infant formula and human milk.

European Union

Resolution AP(89)1 from Council of Europe, on the use of colorants in plastic materials coming into contact with food.

Cabot has a traceability system in place in relation with the requirements of the European Regulation (EC) 1935/2004 and a Quality Assurance system in place which is compliant with the requirements of the European Commission Regulation (EC) 2023/2006 on Good Manufacturing Practices for materials and articles intended to come into contact with food.

This grade is compliant and is specifically tested to ensure continuous compliance with carbon black (CAS 1333-86-4, FCM Substance No 411) purity requirements and specific restrictions/specifications mentioned in Annex I of the Commission Regulation (EU) No 10/2011 (replacing Dir. 2002/72/EC) and its current amendments, concerning Plastics coming into contact with food.

Commission Regulation (EU) No 10/2011 authorises and regulates the use/manufacture/importation of food contact plastic materials and articles compliant with this legislation and **containing a maximum of 2.5 % carbon black** .

This Regulation supersedes all the legislation on the same subject previously applicable in all the countries of the European Union.

<u>Australia</u>

AS2070 -1999 Plastics Material for food contact use

<u>Japan</u>

This grade is listed on JHOSPA (revision 2010)

Page 1 of 2 M4750

China

Standard GB9685-2016, National Standard of Food Safety: uses of additives in Food Contact Materials and Articles.

This grade is compliant and is specifically tested to ensure continuous compliance with carbon black (CAS 1333-86-4, Substance FCA0409) purity requirements mentioned in Part 1, Appendix A, Table A1 Plastics materials.

Restriction for Plastics articles:

Maximum 2.5 % carbon black in PMMA, PVC, PVDC, PU, UP, PF, PEI, PPE, PBT, PPS, POM and LCP

Maximum 3 % carbon black in PE

Carbon Black dosage as necessary in PP, PS, AS, ABS, PA, PET and PC

Mercosur

Carbon black is listed in both Mercosur legislation hereafter applicable to plastics coming into contact with food. The grade is compliant with the purity requirements relative to carbon black mentioned in both legislation.

- ➤ MERCOSUR/GMC/ RES. Nº 15/10 Colorants
- ➤ MERCOSUR/GMC/RES. N°32/07 Positive list of additives

The purity requirements in both Mercosur legislation are identical to the ones mentioned in the European Directive 2007/19/EC (4th amendment of Dir. 2002/72/EC). These Mercosur regulations authorise and regulate the use/manufacture/importation of plastic materials and articles compliant with these legislation and **containing a maximum of 2.5 % carbon black**.

Switzerland

« Ordonnance du DFI sur les matériaux et objets destinés à entrer en contact avec les denrées alimentaires », SR 817.023.21 of 16/12/2016 updated version of 1/5/2017 (Annexe 2).

This grade is compliant and is specifically tested to ensure continuous compliance with carbon black (CAS 1333-86-4, Substance No 1194) purity requirements and specific restrictions/specifications mentioned in this Annex 2.

This Swiss regulation authorises and regulates the use/manufacture/importation of plastic materials and articles compliant with this legislation and **containing a maximum of 2.5 % carbon black**.

Anyway, we wish to point out that the responsibility of determining the suitability of Cabot carbon blacks for any particular use, and the way they are used, must rest with the customer. In particular some migration tests prescribed by the a.m. legislation have to be performed on the final commercialised item by the manufacturer of this item.

The information contained herein is based on the present state of our knowledge. The validity of this document is one year from the issue date.

Cabot Rue Vandervelde 131 4431 Ans / Loncin Belgium Page 2 of 2

2 of 2 M4750