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Declaration of Compliance

Business Operator: B S Teasdale & Son Ltd t/a BST Detectable Products

Unit 7, Delta Court, Sky Business Park, Robin Hood Airport, Doncaster, DN9 3GN

01302 775208

Product Name: BST Retractable Dry Wipe Fine Tip Pen

Product part Code: BSTRDWFT

Material: Polypropylene copolymer

EU Compliance

Regulation (EC) No 1935/2004

The raw materials used in the manufacturing process of the part above can be considered suitable for food contact applications in terms of compliance with European regulations. The raw materials used meet the relevant requirements of EU Framework Regulation 1935/2004 on materials and articles intended to come into contact with food.

Regulation (EC) No 2023/2006

Hereby we declare that the materials listed above are manufactured in line with the relevant requirements of 2023/2006/EC as amended by Commission Regulation (EC) 282/2008, on good manufacturing practice (GMP) for materials and articles intended to come into contact with food.

Regulation (EC) No 10/2011

The monomers, starting substances and additives used are listed in Annex I of the consolidated Commission Regulation No.10/2011 as amended by (EU) 321/2011, (EU) 1282/2011, (EU) 1183/2012, (EU) 202/2014, (EU) 2015/174, (EU) 2016/1416, (EU) 2017/752, (EU) 2018/79, (EU) 2018/213, (EU) 2018/831, (EU) 2019/37, and (EU)2019/1338, respectively, related to Plastic Materials and Articles intended to come into contact with foodstuffs. Colourants used are compliant with European Council Resolution AP(89) 1 on the use of colourants in plastic materials coming into contact with food, and also with German BfR Recommendations (IX).

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Migration Analysis:

Samples of the product, or a similar product made from identical plastic material, have been tested for overall migration according to the test conditions specified in (EU) 10/2011.

Food simulants used for overall migration were Overall migration by total immersion into simulants A, B and 95%v/v ethanol; exposure conditions 10 days at 40ºC. Overall migration by total immersion into iso-octane; exposure conditions 2 days at 20ºC.

Part complies with the overall migration requirements given in EU Regulation 10/2011, as amended, with regards to use with all non-fatty foods, aqueous foods and fatty foods that require a reduction factor of 2 (or greater), as given in EU regulation 10/2011, as amended.

Compliance with specific migration were carried out, part was exposed to simulant B under exposure conditions of 10 days at 60ºC

US FDA Compliance:

The polypropylene base resin used meets the FDA (Food and Drug Administration) requirements contained in the Code of Federal Regulations in 21 CFR 177.1520 (a) (3) (i) , (b) and (c) (3.1a). At the same time this base resin grade meets the FDA criteria in 21 CFR 177.1520 for food contact applications, excluding cooking, listed under conditions of use C through H in 21 CFR 176.170 (c), Table 2., and can be used in contact with all food types as listed in 21 CFR 176.170 (c), Table 1. Also the mineral additives and the pigments used are GRAS (Generally Recognized As Safe) or are FDA cleared under specific FDA citations.

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