



Declaration of Compliance Statement - 105 - Elephant

Applicable Products:

This statement refers to the following Detectamet Polypropylene based products.

Product Code:	Product Description:
105-C1**-I**-PA01	Elephant Stick Pen * Housing * WC
105-C1**-I**-PA02	Elephant Stick Pen * Housing * MC
105-C1**-I**-PA03	Elephant Stick Pen * Housing * LY

Pen Component	Colours Available
Housing	

Regulations and Standards

We confirm that the above mentioned products are suitable for use in contact with all food types and are in conformity with the applicable requirements of the following regulations and standards:

- Regulation (EC) no.1935/2004 on Materials and Articles intended to come into contact with food.
- Commission Regulation (EU) No.10/2011 on Plastic materials intended to come into contact with food including its updates Regulation 1282/2011 and Regulation 1183/2012.
- Regulation (EC) no. 2023/2006 on Good Manufacturing Practice for materials and articles intended to come into contact with food.
- Council of Europe Resolution AP 89/1 on the use of Colorants in Plastic Materials coming into contact with food.
- US FDA 21 CFR 177.1520 (Olefin polymers) with colorants and additives cleared for use through listing in 178.3297 (Colorants for polymers), 178.2010 (antioxidants and/or stabilisers for polymers, or other respective parts of the FDA regulations).

Migration test data obtained under short-term repeat use test conditions (6dm²/kg food) has demonstrated that levels of overall migration and specific migration of additives from these products will not exceed the legal limits with all food types.

Test Simulants	Food Types	Testing Condition
A-C, D1, D2 of Regulation No. 10,2011 for Plastic Materials and Articles in contact with food.	All dry, aqueous, acidic, alcoholic and fatty foods.	2 hours at 70C, Repeat use. Test OM3 of regulation 10/2011





Dual-use food additives may be present but any migration into food will be minimal.

This compliance statement is based on information supplied by the polymer and pigment manufacturers, migration testing according to Regulation 10/2011, migration modelling and quality control systems in place at Detectamet.

Supporting documents are available and can be disclosed to the competent authority on request.

REACH - No substances of very high concern (SVHC) above the 0.1% weight (w/w) threshold limit are present in the materials.

No warranty is given or implied with respect to this information or patent infringement. Detectamet Ltd do not accept liability for loss or damage arising from the use of this information. Results are based on a test sample, our general experience and information from our suppliers. Data and results must be confirmed by the buyer by testing for its intended conditions of use.

Jevan Medlock
Group Technical Director



FICHA TÉCNICA

BOLÍGRAFO DETECTABLE NO RETRÁCTIL SIN CLIP



DESCRIPCIÓN

Bolígrafo detectable especialmente diseñado y fabricado por PLÁSTICOS DETECTABLES S.L. para ser utilizado en las industrias del sector alimentario, farmacéutico y químico.

CARACTERÍSTICAS

- ✓ Mínimo número de partes divisibles
- ✓ Detectable por detector de metales
- ✓ Visible por equipo de rayos X
- ✓ Escritura de alta calidad
- ✓ Ergonómico y Antideslizante
- ✓ Robusto

DATOS TÉCNICOS

Longitud:	140 mm
Ancho:	10 mm
Peso:	9,77 g
Grado de inflamabilidad	UL 94 HB
Carcasa y mecanismo: material	Polipropileno
Carcasa y mecanismo: colores	Azul
Mina: tipo de tinta	Estándar
Mina: material del cuerpo	Latón
Tinta: colores	Azul y negro
Cantidad por caja	50 unidades
País de fabricación	España
Código arancelario	96081099

NORMATIVA

El polipropileno de las carcasas y mecanismos cumple con las normas EU 1935/2004, 2023/2006, 10/2011 y FDA 21. La mina cumple con la normativa ISO 12757-2:1998, EU 1907/2006 (REACH), Listado TSCA de Estados Unidos, Listado MITI de Japón y presentan un contenido inferior al 0,1% de sustancias SVHC y de sustancias CMR.

RECOMENDACIONES

Almacenar en lugar fresco y seco, protegido de la luz solar. No exponer a temperaturas superiores a 60 °C. Mantener las puntas lejos de otra superficie de contacto que no sea papel, se aconseja no llevar las puntas de los bolígrafos expuestas en los bolsillos.

VALIDEZ

Documento válido para los bolígrafos QU0021AA y QU0021AN.

Consulte la Declaración de conformidad para más información sobre el contacto con alimentos.

Los datos técnicos y normativa están basados en la información facilitada por los fabricantes de los componentes.

