

Detectable HD Retractable Pen W/O Refill - 101-I0

Document Number: HSE 705

Date Of Issue: 21/08/2018

Revision Number: 2

Date of Revision: 10/03/2023



This Declaration of Compliance Statement document is appropriate for the following products:

Product Name	Product Code	Description	Colour	Dimensions	Material Type
HD Pen WC	101-I0	Standard HD pen with clip	Housing and endcap Available in any of 9 Colours offered.	136x19x10mm	PP
HD Pen MC	101-I0	Standard HD pen minus clip	Housing and endcap Available in any of 9 Colours offered.	136x19x10mm	PP
HD Pen LY	101-I0	Standard HD pen lanyard	Housing and endcap Available in any of 9 Colours offered.	136x19x10mm	PP

HD Housing and End Cap:

Colour:	Blue
Carrier polymer:	PP
Addition Rate:	100%
Heat stability:	280 °C
Light Fastness:	7-8 ISO 4892 (Blue Wool scale)
Weather Stability:	4-5 ISO 4892 (ISO 105-A002)
Heavy Metals:	NO
Diarylide:	NO
Additive:	YES

The above is manufactured using pigments which are in accordance with: -

- European Resolution AP (89) 1
- Recommendation IX of the BfR for colouring plastics
- EN71-3 Toy regulation
- EU regulation EU No 2019/1381 amending Regulation EU No 1935/2004
- Is based on a polymer carrier that is compliant with: -
- EU regulation EU No 2020/1245 amending and correcting Regulation (EU) No 10/2011
- EU regulation EU No 2019/1381 amending Regulation EU No 1935/2004
- Has been produced according to Regulation 2023/2006/EC on good manufacturing practice for materials and articles intended to come into contact with food, applicable to plastic raw materials.

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.

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

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

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.

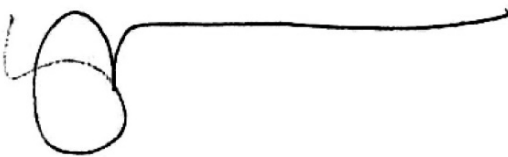
General Information:

Maximum use Temperature: 100 °c

Maximum wash Temperature: 121 °c

Maximum use Temperature: Do not store at deep freeze temperatures prior to use.

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.



Helen Morrison
Group Managing Director