



Detectamet Detectable Products Not Used In Direct Contact With Food Declaration of Compliance Statement

Retractable Pens - New heavy duty x-ray visible + detectable housing	with clip	black ink	DTM HD0020 WC
		blue ink	DTM HD0021 WC
		red ink	DTM HD0022 WC
		green ink	DTM HD0028 WC
	without clip	black ink	DTM HD0020 MC
		blue ink	DTM HD0021 MC
		red ink	DTM HD0022 MC
		green ink	DTM HD0028 MC
	with lanyard attachment	black ink	DTM HD0020 LY
		blue ink	DTM HD0021 LY
		red ink	DTM HD0022 LY
		green ink	DTM HD0028 LY

Materials used in the manufacture of these products 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 on the materials used 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 70°C, 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.

This Declaration is for the products specified above and is valid for two years. An updated statement will be provided if the information on which the declaration is based changes or regulatory requirements impact on its validity.

Signed (Approved Signatory):

Angela Musson
Quality Manager
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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.

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