

Declaration of compliance statement

Products not used in direct contact with food: Pens

1.- PRODUCT IDENTIFICATION

Detectable product – Pen

Product code	Product name	Photo	Temperature range (°C)	Housing Colour	Ink Colour
DP0009	Metal Detectable & X Ray Detectable retractable pen with clip		From 0 to 45	2	2 3 6

Materials used in the manufacture of these products are in conformity with the applicable requirements of the following regulations and standards:

Acetal resin – in which the basic polymer chemically consists of a polyoxymethylene, has the following status relative to food contact regulations in Europe.

We can confirm that the product plastic accordance with the Regulation (EC) No. 1935/2004 in term of specific measures for groups of materials – in case, plastics – in from of Regulation (EU) No. 10/2011 incl. amendments, the enclosed declaration of conformity and by having installed a traceability system. Furthermore, the product is in accordance with the Regulation (EC) No. 2023/2006 (Article 5, 6, und 7). The components and monomers of the product are listed in the Regulations (EU) No. 10/2011 and amendments.

The specific migration limits applies as follows:

Migration Limits:

- Formaldehyde (CAS 50-00-0): SML(T) = 15 mg/kg food
- 1,3-dioxolane (CAS 646-06-0): SML = 5 mg/kg food
- 1,3,5-trioxane (CAS 110-88-3): SML = 5 mg/kg food
- Triethyleneglycol-bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propionate] (CAS 36443-68-2): SML = 3 mg/kg food
- Melamine (CAS 108-78-1): SML = 2.5 mg/kg food

Statement of a raw material supplier for one component: ...*Listed (10/2011/EC) Iron Oxide has CAS 1332-37-2. This Iron Oxide has a molecular formula unspecified and hence includes any generic Iron Oxide material...* Therefore the used component can safely be added in plastics without restriction.

The product does not contain any dual-use additives.

The colorants fulfil the requirements of the European Resolution AP(89)1.

USA:

The components are listed e.g. FDA under 21 CFR §§ 177.2470, 178.2010, 178.3297, 186.1374 (GRAS)

The following restrictions apply for one component:

- Types of food except foods containing 15% or more alcohol.
- Conditions of use: Use temperature shall not exceed 120°C [per CFR177.2470]
- Application: Repeated use articles only per 21CFR177.2470

The suitability of the finished article for the intended use (food contact) must be checked by the manufacturer or seller.

Declaration on behalf of DETECTA PLASTICS, S.L.

Vilassar de Mar, January 8th, 2018.

DETECTA-PLASTICS, S.L.

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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.