

PRODUKTINFORMATIONEN

V 3.0 June 2023
Product Specification Sheet

Trace-It Detectable Pen |



The Trace-It Detectable Pen

These Trace-It pens are an economical alternative to our premium pens which feature a metal detectable and x-ray visible plastic body and insert which is made from our specially formulated xdetect Polypropylene compound. With a blue or red body for visual identification and blue, black and red ink options, as well as clipped and looped models available, these pens are designed to be the perfect addition to your food production areas. They are compliant with EU and FDA food contact legislation and the ink conforms with ISO 12757-2 for documentary use.

The Trace-It Detectable Pen Advantages

- ✓ Detectable by in-line metal detection systems & x-ray inspection systems
- ✓ Available in two body colours for easy visual identification (Varies per model)
- ✓ The ink conforms with ISO 12757-2
- ✓ Strong, durable, shatter resistant and chemically resistant
- ✓ Compliant with EU & FDA food contact legislation, including mandatory EU migration test standards
- ✓ Can be used as part of HACCP and BRC procedures
- ✓ Write out length of 9,000m +/- 30%
- ✓ Clipped and looped* versions are available and bespoke printing can be added if requested
- ✓ Displays due diligence in the prevention of foreign body contamination

*Looped models are only available in blue body

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Product and Packaging Information

With Pocket Clip:	8900372-, 8900376-
With Loop:	---
Pack Size:	50
Pack Weight:	0.55 kg
Body Colours:	B, R
Ink Colours:	B, K, R
Housing Material:	XDETECT
Cartridge Material:	Stainless Steel
Write Out Length:	9,000m +/- 30%
Detectability:	Dual Detectable
Commodity Code:	96081010

Ink Specification

Temperature Range 5 ~ 30°C
Unpressurised ink
MITI Listed (Japan)
ISO 12575 - 2 DOC G2
ISO 12575 - 2 DOC H
ISO 12575 - 2 G2
ISO 12575 - 2 DOC A2
TSCA Listed (USA)
ISO 12757 - 1
ISO 12575 - 2
Conforms to REACH standards

Safety Certificates / Approvals

FDA Approved
EU Compliant
BRC Compliant
ISO 9001:2015

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Food Contact Status (EU)

Hereby we declare that the material XDETECT® in various colours is 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.

The raw materials used in the manufacturing process of the above mentioned materials (XDETECT® in various colours) 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.

All monomers, starting substances and additives used to manufacture these grades are listed in Commission Regulation (EU) 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, (EU) 2019/1338, and (EU) 2020/1245 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)

We hereby declare that articles manufactured from XDETECT® are, according to EU regulations, authorised to come into direct contact with all types of foodstuffs at a maximum temperature of 40°C for a maximum time period of one hour.

Food Contact Status (FDA)

The polypropylene base resin used in HDPE meets the FDA (Food and Drug Administration) requirements contained in the Code of Federal Regulations in 1 CFR 177.1520. 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.

Food Contact Status (Japan)

The base resin (PP copolymer) used in the manufacturing process of the above mentioned compounds is listed in the Positive List of Base Polymers (Table 1). The additives used in the manufacturing process of the PP-C resin are listed in the Positive List of Additives (Table 2) authorised for use in this base resin.

Animal Derivatives

To the best of our knowledge there are no ingredients in the formulation of this material that is of animal origin. As such, this material should not pass on any animal derived disease like BSE (Bovine Spongiform Encephalopathy) or other TSE (Transmissible Spongiform Encephalopathy).

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Migration Testing

The following overall migration results for XDETECT® were obtained using a UKAS accredited laboratory, with overall migration simulants and conditions as detailed in EU Regulation No 10/2011 as amended, on plastic materials and articles intended to come into contact with food.

Sample: PP-C-2013/393

Test conditions: Simulants A, B and 95%v/v ethanol: 10 days at 40°C. Iso-octane: 2 days at 20°C

Method	EN-1186-3 Migration into 10 % v/v Ethanol (Simulant A)	EN-1186-3 Migration into 3% w/v Acetic Acid (Simulant B)	EN-1186-14§ Migration into Iso-octane (Substitute test)	EN-1186-14§ Migration into 95 % Ethanol (Substitute test)
Replicate #1	0.2 mg/dm ²	0.5 mg/dm ²	19.4 mg/dm ²	0.8 mg/dm ²
Replicate #2	0.3 mg/dm ²	0.5 mg/dm ²	21.0 mg/dm ²	0.9 mg/dm ²
Replicate #3	0.0 mg/dm ²	0.3 mg/dm ²	20.8 mg/dm ²	0.6 mg/dm ²
Mean Result	0.2 mg/dm ²	0.4 mg/dm ²	20.4 mg/dm ²	0.8 mg/dm ²
EU Limit	10.0 mg/dm ²	10.0 mg/dm ²	#20.0 mg/dm ²	10.0 mg/dm ²
Tolerance			#6.0 mg/dm ²	

#Limit and tolerance are quoted after the application of a fatty food reduction factor of 2 as quoted in EU Regulation 10/2011. To summarise the overall migration test results, the PP-C-2013/393 complies with the overall migration requirements given in EU Regulation 10/2011, as amended, with regard 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.

DetectaPen Metal Detectability

The DetectaBoards are made using XDETECT, an electromagnetically detectable and x-ray visible plastic compound. The metal detectability of this product will vary based on, but not limited to:

- Calibration Levels
- Product Type (E.g. Wet, Dry, Frozen, Liquid)
- Aperture Dimensions
- Orientation

Orientation is a highly influential factor for the metal detectability of a contaminant that is non spherical, i.e. it will be easier to detect the contaminant when passing in one orientation compared to another - this is known as the orientation effect.

For this reason Niebling recommend that all our products be thoroughly tested on your metal detection system / x-ray inspection system by a trained and certified professional. Your equipment may need to be re-calibrated in order to reliably detect this product. Such a professional should be available by contacting the manufacturer of your metal detection system.

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DetectaPen X-Ray Visibility

In contrast to metal detection, x-ray visibility is determined by material density. For this reason, XDETECT contains an additional, evenly dispersed, food safe, high density additive.

Based on our experience and testing, positive readings should be consistent both for whole pens and XDETECT fragments as small as 5mm. X-ray detection performance will be reduced when small fragments are buried in deeper, denser products – detection will depend on product type and density.

We highly recommend that all our products be thoroughly tested on your x-ray inspection systems by a trained and certified professional. It may be the case that your equipment needs to be recalibrated in order to reliably detect this product. Such a professional should be available by contacting the manufacturer of your x-ray inspection system.

The information provided in this product specification sheet is based on our experience and knowledge to date and we believe it to be true and reliable. This information is intended as a guide for your use of our products, the use of which is entirely at your own discretion and risk. We, Niebling Technische Bürsten GmbH, cannot guarantee favourable results and assume no liability in connection with the use of our products.