

PRODUKTINFORMATIONEN

Product Specifications

| January 2020



Product Name: Retractable Detecta-Lite-R **Highlighter Marker**

Product Description: The retractable highlighter marker features metal detectable and x-ray visible external and internal plastic components made from our specially formulated XDETECT Polypropylene compound.

Our retractable markers boast all the same properties as other pens in the range, including FDA, EU, and Japanese food contact approvals. They are shatter resistant, lanyard compatible, have colour co-ordinated retractable push inserts, sureflow ink and we are proud to say 'Made in Britain'.

The Highlighter features a polyester chiselled nib ideally shaped for highlighting text.

Product Code: 8900342-B, 8900344-B, 8900345-B, 8900347-B, 8900348-B

Ink Colours: Yellow, Blue, Orange, Pink & Green

Pack Size: Pack of 10

Pack Weight: 0.300 Kg

Product Advantages:

- ✓ Detectable by conventional metal and x-ray detection systems
- ✓ FDA, EU and Japanese Food Contact Approved
- ✓ Chiselled polyester style nib for easy highlighting
- ✓ Shatter resistant, lanyard compatible and feature Sureflow
- ✓ Highly visible bright blue body colour for easy visual identification
- ✓ Displays "All Due Diligence" in the prevention of foreign body contamination

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- Product Dimensions:** 146mm x 18mmØ
- Product Colour:** Blue
- Product Materials:** Marker body & internal parts manufactured from metal detectable and x-ray visible polypropylene, chiselled style nib manufactured from polyester.
- Handling / Storage:** Store at normal room temperature, keep away from direct heat and keep in original container.

Ink Properties:	<u>Property</u>	<u>Value</u>
	Hazard Identification:	With normal use, no known hazards
	Stability / Reactivity:	Product is stable
	Eco Toxicity:	No adverse ecological effects known
	Regulatory Information:	Not applicable

Ink Safety: Ink contact with skin is not considered hazardous when coming into contact with skin through normal use. In the event of abnormal use causing health problems please refer to the below information:

<u>Route</u>	<u>First Aid</u>
Oral:	Give plenty of water to drink if ingestion is suspected
Skin Contact:	Wash skin with soap and water
Eye Contact:	Irrigate with water for ten minutes - obtain medical attention
Inhalation:	Remove from exposure - in severe cases obtain medical attention

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 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) on plastic materials and articles intended to come into contact with food. Applicable restrictions on monomers, additives etc. (SML, QM) are available on request. The finished articles are required to meet the Overall Migration Limit (OML) of 10 mg/dm(sq) or 60 mg/kg food.

Colourants used are compliant with European Council Resolution AP(89) 1 on the use of colourants in plastic materials coming into contact with food.

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XDETECT (various colours) is compliant with Directive 1895/2005/EC on the restriction of use of certain epoxy derivatives (BADGE, BFDGE, NOGE), since the latter substances are not intentionally used in the manufacturing process of XDETECT.

Detectable Products 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.

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/dm²	0.4 mg/dm²	20.4 mg/dm²	0.8 mg/dm²
EU Limit	10.0 mg/dm²	10.0 mg/dm²	#20.0 mg/dm²	10.0 mg/dm²
Tolerance			#6.0 mg/dm²	

#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 regards 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.

Food Contact Status (FDA)

The polypropylene base resin used in XDETECT meets the FDA (Food and Drug Administration) requirements contained in the Code of Federal Regulations – latest revision (1/4-2011) - in 21 CFR 177.1520 (a) (3) (i) , (b) and (c) (3.1a).

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.

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Metal Detectability

The Retractable Markers 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 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 metal detection system.

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.

DISCLAIMER

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.