

450- Metal Detectable Vinyl Gloves

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This specification describes the Detectamet Detectaglove (Patented Product) Non-Medical, Powder Free, Phthalate free, Blue Vinyl Disposable Gloves.

Applicable Products:

Product Code	Product Description	Product Colour
450-A65-S089-X31	Vinyl Gloves Powder Free Detectable Small Box100	Blue
450-A65-S090-X31	Vinyl Gloves Powder Free Detectable Medium Box100	Blue
450-A65-S091-X31	Vinyl Gloves Powder Free Detectable Large Box100	Blue
450-A65-S092-X31	Vinyl Gloves Powder Free Detectable X Large Box100	Blue

Material: The Detectamet Detectaglove (Patented Product) is produced of vinyl resin, with a metal detectable additive dispersed evenly throughout. Powder free, phthalate free

Thickness: 0.05 inches - Tolerance+/-0.015 inches

Length: 9.0 inches - Tolerance+/-0.50 inches

Acceptances: All Detectamet components comply with the provisions of the Federal Food, Drug and Cosmetic Act 21 CFR 117.1520©3.2awhich allows repeated use in direct contact with food. Meets or exceeds USDA standards for use in food handling applications.

Size: Small (450-A65-S089-X31), Medium (450-A65-S090-X31), Large (450-A65-S091-X31) and X-Large(450-A65-S092-X31)

Packaging: 100 pieces per box, 10 boxes per case

European Standards:

Intended Food Contact Applications: Non-fatty foods(foods assigned to simulants A, B, C and E in Regulation 10/2011, Plastic Materials and articles in contact with food)

We confirm that Detectagloves 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 amendments 1282/2011 and 1183/2012

Regulation (EC) no.2023/2006 on Good manufacturing Practice for materials and articles intended to come into contact with food.

When used as intended, the overall migration and specific migration of substances subject to restriction do not exceed the legal limits (calculated as 6 dm² glove per 1kg of food)

Test Simulants	Food Types	Testing Condition
A-C, D1 of Regulation No. 10,2011 for Plastic Materials and Articles in contact with food	All Dry, aqueous, acidic, food, dairy products, and low alcoholic foods	2 hours at 70°, Test OM3 of Regulation 10/2011

The following substances subject to specific migration restrictions are associated with these gloves.

Substances	FCM Substance Number.	EU Reference Number	Restriction in food
Di-iso nonyl phthalate (DNIP)	728	75100	SML=9mg/kg
Vinyl chloride monomer	127	26050	Not detectable in food 1mg/kg in glove.

This compliance statement is based on information received from material suppliers, migration testing undertaken according to Regulation 82/711, and quality control systems in place.

REACH

No substances of very high concern (SVHC) above the 0.1% weight (w/w) threshold limit are present in the glove. These gloves do not contain phthalates.

FDA Regulatory Requirements

Detectagloves are in full compliance with FDA regulations for use in contact with food at temperatures up to 40°C. All ingredients are either the subject of an effective food contact notification, are permitted for use by their inclusion on chapter 21, Section 178.3740 (plasticiser in polymeric substances) or are listed as indirect additives.

Canada

A no objection certificate for direct food contact use of the vinyl gloves has been issued by the Canadian Food Inspection Agency.

CE Marking

Detectaglove are NQA certified for approval CE marking according to the Medical Device Directive 93/42/EEC.

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