Technical Data Sheet

450 – Metal Detectable Vinyl Gloves



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This Technical Data Sheet is applicable to the

450-A65-S090-X31	Vinyl Gloves Powder Free Detectable Medium Box 100
450-A65-S091-X31	Vinyl Gloves Powder Free Detectable Large Box 100
450-A65-S092-X31	Vinyl Gloves Powder Free Detectable X-Large Box 100

Industry Use

These patented metal detectable disposable blue food safe gloves, available in three sizes, are powder free, phthalate free and manufactured from food safe latex free vinyl

Features and Benefits

- Metal Detectable
- Manufactured from EU and FDA approved food contact material
- Phthalate free
- Disposable
- Powder free
- Latex Free
- Not suitable for use with fatty foods
- Suitable for use up to 40°c (104°F)
- Thickness: 100 +/- 3µm (4 +/- 0.1 MIL)
- Medium: Length 230mm (9.05"), Width 95mm (3.74")
- Large: Length 230mm (9.05"), Width 105mm (4.13")
- X-Large: Length 230mm (9.05"), Width 115mm (4.52")

Compliance information

These products comply with the provisions of the Federal Food, Drug and Cosmetic Act 21 CFR 117.1520©3.2 which allows repeated use in direct contact with food. Metts or exceed USDA standards for use in food handling applications.

Intended Food Contact Applications: Non-Fatty Foods (foods assigned too simulants A,B,C and E in Regulation EU 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 it's 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.

The below is further phthalate testing information

Phthalates	**CAS No.**	**Detection Limit**	**Result**	**Limit**
Dilsobutyl Phthalate (DIBP)	84-69-5	0.005%	ND	0.1%
Dibutyl Phthalate (DBP)	84-74-2	0.005%	ND	0.1%
Benzylbutyl Phthalate (BBP)	85-68-7	0.005%	ND	0.1%
Dicyclohexyl Phthalate (DCHP)	84-61-7	0.005%	ND	0.1%
Bis-(2-ethylhexyl) Phthalate (DEHP)	117-81-7	0.005%	ND	0.1%
Dilsononyl Phthalate (DINP)	28553-12-0/68515-48-0	0.005%	ND	0.1%
Di-n-hexyl phthalate (DHEXP)	84-75-3	0.005%	ND	0.1%
Di-n-pentyl Phthalate (DPENP)	131-18-0	0.005%	ND	0.1%
Di-n-octyl phthalate (DNOP)	117-84-0	0.005%	ND	0.1%**
Dilsodecyl Phthalate (DIDP)	26761-40-0/68515-49-1	0.005%	Nd	0.1%**

ND = Not Detected (< Detection Limit)
** = The requirement was supplied by client

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 of up to 40°c. All ingredients are either the subject of an effective food contact notification, are permitted for

use y their inclusion on chapter 21, Section 178.3740 (plasticizer 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 issues 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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