

SAFETY DATA SHEETS

This SDS packet was issued with item:

071300953

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

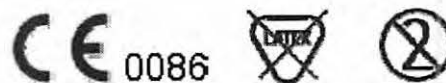
071300912 071300938 071300946 071300961

Manufactured by	Medline Industries, Inc.		
Made in	Malaysia		
Reference (Sizes 5.5 – 9.0)	MSG1055, MSG1060, MSG1065, MSG1070, MSG1075, MSG1080, MSG1085, MSG1090		
Product Description	Sterile Synthetic Powder-Free Surgical Gloves		
Primary Material	Isolex™ Polyisoprene Rubber (This product does not contain natural rubber latex.)		
Color	White		
Grip/Finish	Smooth		
Donning Lubricant	Synthetic Polyacrylate Resin		
Moisturizing Agent	Aloe Vera		
Chemical Accelerators	Zinc Diethyldithiocarbamate (ZDEC), Zinc Mercaptobenzothiazole (ZMBT)		
Former Design	Anatomical, curved design to replicate natural hand shape and reduce fatigue during use		
Cuff Design	Anti-rolldown, beaded design to reduce cuff-rolldown during use		
Thickness	<u>Single Wall</u>	<u>Mils</u>	<u>mm</u>
	Finger Tip	10.0	0.25
	Cuff	6.5	0.16



Packaging	100 pairs per case, 25 pairs per dispenser box
	100% Polyethylene Peel Pouch
	- Prevents tearing when opening product - Protects product from ozone degradation - Ensures product sterility during shelf life

Packaging Dimensions	Carton	Dispenser	Pouch
Length (mm)	290	290	290
Width (mm)	300	150	150
Height (mm)	260	130	1.5
Weight (g)	4780	1195	45



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AQL	1.0
Sterilization	Gamma Radiation
Expiration Date	3 years
Storage Conditions	Store at room temperature. Avoid excessive heat. Keep dry. Product should be shielded from direct sunlight, fluorescent lighting, x-rays, moisture, and ozone.
Regulations & Quality Standards	Manufacturing locations are certified to EN ISO 13485 Product meets requirements of the EU Medical Device Directive 93/42/EEC Product meets requirements of the European standards EN 455-1, EN455 -2, and EN 455-3
Viral Penetration	Tested and passed, in accordance with ASTM F 1671.
EN 455 Test Results	Testing performed by an ISO17025 accredited laboratory.

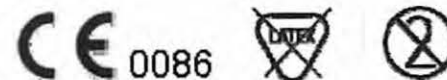
EN 455-1	Test Results	EN 455 Requirement
Freedom from Holes	Complies	AQL 1.5

EN 455-2	Test Results	EN 455 Requirement
Dimensions (Length)	298 mm (size 7.5)	270 mm (size 7.5)
Dimensions (Width)	95 mm (size 7.5)	95 ± 5 mm (size 7.5)
Force at break before accelerated aging	12.5 Newtons	≥ 9 Newtons
Force at break after accelerated aging (7 days at 70°C in an oven)	11.6 Newtons	≥ 6 Newtons

EN 455-3	Test Results	EN 455 Requirement
Powder Content	0.76 mg/glove	< 2.0 mg/glove
Protein Content	N/A	N/A

Manufacturer Information	US HEADQUARTERS Medline Industries, Inc. One Medline Place Mundelein, IL 60060	LOCAL CONTACT
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Website www.medline.com





Medline Industries, Inc.

Three Lakes Drive
Northfield, IL 60093

1.847.949.5500
1.800.MEDLINE (633.5463)

medline.com

Corporate Quality Assurance/Regulatory Affairs

September 7, 2017

Subject: Safety Data Sheets

Item Description: [SensiCare with Aloe Powder-Free Surgical Gloves](#)

Item: [MSG1055](#), [MSG1055H](#), [MSG1055G](#), [MSG1060](#), [MSG1060H](#), [MSG1060Z](#), [MSG1065](#), [MSG1065H](#), [MSG1065Z](#), [MSG1070](#), [MSG1070H](#), [MSG1070Z](#), [MSG1075](#), [MSG1075H](#), [MSG1075Z](#), [MSG1080](#), [MSG1080H](#), [MSG1080Z](#), [MSG1085](#), [MSG1085H](#), [MSG1085Z](#), [MSG1090](#), [MSG1090H](#), [MSG1090Z](#)

The item(s) referenced above for which you have requested a Safety Data Sheet are manufactured or distributed by Medline Industries, Inc. and are retailed as a medical device, drug, cosmetic or article. Products of this type are not subject to the Hazard Communication Standard (29 CFR 1910.1200). This exemption is set forth in the following sections:

Section b (6) This section does not apply to:

Section b (6) (v) Articles (as that term is defined in paragraph (c) of this section);

Section b (6) (vii) Any drug, as that term is defined in the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), when it is in solid, final form for direct administration to the patient (e.g., tablets or pills); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs); and drugs intended for personal consumption by employees while in the workplace (e.g., first aid supplies);

Section b (6) (viii) Cosmetics which are packaged for sale to consumers in a retail establishment, and cosmetics intended for personal consumption by employees while in the workplace;

Section b (6) (ix) Any consumer product or hazardous substance, as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 *et seq.*) and Federal Hazardous Substances Act (15 U.S.C. 1261 *et seq.*) respectively, where the employer can show that it is used in the workplace for the purpose intended by the chemical manufacturer or importer of the product, and the use results in a duration and frequency of exposure which is not greater than the range of exposures that could reasonably be experienced by consumers when used for the purpose intended;

Section b (6) (Xii) Biological hazards.

Section (c) *Definitions*. *Article* means a manufactured item other than a fluid or particle: (i) which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities, *e.g.*, minute or trace amounts of a hazardous chemical (as determined under paragraph (d) of this section), and does not pose a physical hazard or health risk to employees.

These products, in their marketed packaging, are generally not considered hazardous under normal conditions of use when used in accordance with labeling instructions.

Medline Corporate Quality
1-800-MEDLINE (1-800-633-5463)