PURPLE NITRILE* Max

Examination Glove – Non-sterile

TECHNICAL DOCUMENT

Description

47195 Purple Nitrile* Max - S
47196 Purple Nitrile* Max - M
47197 Purple Nitrile* Max - L
47198 Purple Nitrile* Max – XL

Non-powdered, textured fingertips, ambidextrous, single use. Color: Purple.

Dimensions:

	Palm width	Length
Extra Small (XS)	x	x
Small (S)	80 mm	419 mm
Medium (M)	100 mm	419 mm
Large (L)	111 mm	419 mm
Extra Large (XL)	121 mm	419 mm

Properties:	**HALYARD (Minimum Results/Specification Target)**	**EN/ ASTM requirement/Test Method**
Median force at break before aging (Newton)	**18 N**	EN 455-2: 6N
Median force at break after aging (Newton)	**24 N**	EN 455-2: 6N
Residual powder mg/glove	**2.0 mg (3x rinsed)**	EN 455-3/ ISO 21171/ASTM 6124: <2.0 mg
Material Thickness	**Thickness middle finger: 0.30 mm** **Thickness palm: 0.24 mm** **Thickness cuff: 0.14 mm**	--
Tensile Strength ASTM D6319	**24 MPa Before Aging (2.5 AQL)** **22 MPa After Aging (2.5 AQL)**	Test Method ASTM D412: 14 MPa (4.0 AQL)
Ultimate Elongation ASTM D6319	**550% Before Aging (2.5 AQL)** **450% After Aging (2.5 AQL)**	Test Method ASTM D412: 500% Before aging 400% After aging (4.0 AQL)
ASTM F 1342 Puncture Resistance	**0 punctures (14.9 N)**	Material resistance to puncture force, measured in Newtons (N).
Detection of Holes in Medical Gloves ASTM D5151 Freedom of pinholes	**1.0 AQL**	ASTM D5151: AQL 2.5 EN 455-1: 1.5 AQL

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Halyard gloves are tested by accredited independent laboratories: Akron Rubber & Development Lab (US), Eurofins Product Testing A/S (Belgium), Centexbel (Belgium). O&M Halyard is a global company that adheres to the regulatory rules and clearance requirements specific to each country where its products are registered and utilized.

Indication

To protect patient and user from cross-contamination.

Counter indication

Not intended for applications involving direct exposure to harsh chemicals, where heavy duty industrial gloves are required.

Main Materials

Base material: Nitrile Butadiene.
Accelerators: ZDBC (Zinc dibutyl dithiocarbamate)/ ZDEC (Zinc diethyl dithiocarbamate).with residual concentrations < 100 µg per gram**.**
Not intentionally formulated or treated with any of the following: Bisphenol A, colophony (rosin), natural rubber latex, brominated flame retardants, phthalates (DBP, BBP, DEHP, DMEP, DNOP, DPP, DIPP, DIDP, DINP), **thiurams, mercaptobenzothiazole, thiourea, 1,3-diphenylguanidine, cetylpyridinium chloride, casein, (p)-phenyl endiamines.**

Skin Friendly

Biocompatibility testing – Medical Devices	HALYARD
Biocompatibility testing in accordance with the ISO 10993-1 ▪ ISO 10993-11 (acute systemic toxicity) ▪ ISO 10993-10 (sensitization) ▪ ISO 10993-23 (irritation)	**Pass**

Residual Chemicals

High Pressure liquid Chromatography (HPLC)	HALYARD
Measure the type and amount of residual chemicals left on the glove. Lower levels of residual chemicals decrease the risk of developing irritant and Type IV reactions.	Rinsed 3x to reduce harmful chemicals to below detectable levels. ZDBC (Zinc dibutyl dithiocarbamate)/ ZDEC (Zinc diethyl dithiocarbamate) < 100 µg per gram.

Sterilization

Products are non-sterile.

Packaging

References 47195, 47196, 47197, 47198:
Shipping case of 400 units.
8 dispenser boxes of 50 units in each shipping case.

Bar coding: GS1-128 symbology, linear, on shipping case and dispenser box.

Dimensions	Length	Breadth	Height
Dispenser Box (mm)	400	127	61
Shipping Case (mm)	415	259	255

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EAN

Item	Description	AUn	EAN/UPC
47195	PURPLE NITRILE MAX Exam Gloves S	Sell Unit Package	30680651471957
47195	PURPLE NITRILE MAX Exam Gloves S	Inner Package	20680651471950
47196	PURPLE NITRILE MAX Exam Gloves M	Sell Unit Package	30680651471964
47196	PURPLE NITRILE MAX Exam Gloves M	Inner Package	20680651471967
47197	PURPLE NITRILE MAX Exam Gloves L	Sell Unit Package	30680651471971
47197	PURPLE NITRILE MAX Exam Gloves L	Inner Package	20680651471974
47198	PURPLE NITRILE MAX Exam Gloves XL	Sell Unit Package	30680651471988
47198	PURPLE NITRILE MAX Exam Gloves XL	Inner Package	20680651471981

Manufacturing

Products are manufactured in Thailand/Malaysia. The quality system of the manufacturing sites are ISO 13485 and ISO 9001 compliant.

Regulatory information

Medical Device Class I
CE 2797
(PPE Cat. III)
UK CA
0086

- Product CE marked as per Regulation (EU) 2017/745 on Medical Devices. Class of the device: I.
- Product CE marked as per (EU) 2016/425 regulation on Personal Protective Equipment. Class of the equipment: PPE Category III
- Comply with EN 455-1, EN 455-2, EN 455-3, EN 455-4
- Comply with EN ISO 21420
- Comply with EN ISO 374-1, EN ISO 374-2, EN ISO 374-4, EN ISO 374-5, EN 16523-1
- Comply with EN ISO 16604

AQL	HALYARD	EN 455-1 requirement
Freedom from pinholes	**1.0** **33% less defects per lot than EN 455 standard**	1.5

EN ISO 374-5 Microorganism risks	HALYARD
Resistance to bacteria and fungi	**Pass**
Resistance to virus	**Pass (ISO 16604 and ASTM F1671)**

- **EN 374-1 Type B (J K T) -** EN 16523-1

Chemical	Permeation Test EN 16523-1:2015+A1:2018		Degradation Test EN ISO 374-4:2019
	Minimum Breakthrough Time (min)	Performance Level	Degradation (%)
Formaldehyde, 37% (T)	>480	6	-22.1
n-Heptane, 99% (J)	148	4	26.5
Sodium hydroxide, 40% (K)	>480	6	6.7

Performance levels according to EN ISO 374-1:2016 +A1:2018	1	2	3	4	5	6
Measured breakthrough times (mins)	> 10	> 30	> 60	> 120	> 240	> 480

Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.
NOTE: Where the test specimens gave an increased puncture force after chemical exposure, the result is reported as a negative degradation.

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Storage

Store in a dry and cool place, away from intense sources of heat and sources of radiation.
Keep as much as practicably possible in its shipper box.

Shelf life

3 years, from the date of manufacture.

Chemotherapy/Chemicals

At O&M Halyard, we seek to constantly improve upon the quality of healthcare products and services available in the marketplace. We strive to deliver clinically superior products with remarkable service to improve the wellbeing of the people we touch every day. In accordance with this vision, we want to inform our customers of additional chemical and chemotherapy drug testing performed on our **PURPLE NITRILE* Max Powder-Free Exam Gloves**. In the US, the Food and Drug Administration requires submission and clearance of a premarket notification for medical exam gloves that are intended for use with chemotherapy drugs and requires glove products to be labeled with drugs tested and breakthrough times. Package labeling for Halyard exam gloves sold in the US meet this labeling requirement. Although additional chemotherapy drug and chemical testing is not required, Halyard believes the more informed our customers are, the better they will be able to understand the appropriate use of our products. The following chemotherapy drugs and chemicals have been tested according to EN374-1 (EN 16523-1 where applicable), ASTM D6978 (chemotherapy drugs) and ASTM F739 (chemicals). This data is provided for your information but is not intended to expand the intended use of the products beyond the scope of what has been cleared by the FDA or covered by the safety and performance requirements of the CE certification and European harmonized standards.

Chemotherapy Testing Information - Permeation testing per ASTM D6978

Chemotherapy Drugs Tested	Breakthrough time (minutes) Purple Nitrile* Max
Aresenic Trioxide (1 mg/ml)	>240
Azacitidine (25 mg/ml)	>240
Bendamustine (5 mg/ml)	>240
Bortezomib (1 mg/ml)	>240
Bleomycin sulfate (15 mg/ml)	>240
Busulfan (6 mg/ml)	>240
Carboplatin (10 mg/ml)	>240
Carfilzomib (10 mg/ml)	>240
Carmustine (3.3 mg/ml)	>80.4
Cetuximab (Erbitux) (2 mg/ml)	>240
Cisplatin (1 mg/ml)	>240
Cyclophosphamide (20 mg/ml)	>240
Cytarabine HCL (100 mg/ml)	>240
Cytovene (10 mg/ml)	>240
Dacarbazine (10 mg/ml)	>240
Daunorubicin HCL (5 mg/ml)	>240
Decitabine (5 mg/ml)	>240
Docetaxel (10 mg/ml)	>240
Doxorubicin HCL (2 mg/ml)	>240
Ellence (2 mg/ml)	>240
Eribulin Mesylate (0.5 mg/ml)	>240
Etoposide (20 mg/ml)	>240
Fludarabine (25 mg/ml)	>240
Fluorouracil (50 mg/ml)	>240
Fulvestrant (50 mg/ml)	>240
Gemcitabine (38 mg/ml)	>240
Idarubicin (1 mg/ml)	>240
Ifosfamide (50 mg/ml)	>240
Irinotecan (20 mg/ml)	>240
Mechlorethamine HCL (1 mg/ml)	>240

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Chemotherapy Drugs Tested	Breakthrough time (minutes) Purple Nitrile* Max
Melphalan (5 mg/ml)	>240
Methotrexate (25 mg/ml)	>240
Mitomycin (0.5 mg/ml)	>240
Mitoxantrone (2 mg/ml)	>240
Oxaliplatin (2 mg/ml)	>240
Paclitaxel (6 mg/ml)	>240
Paraplatin (10 mg/ml)	>240
Pemetrexed (25 mg/ml)	>240
Pertuzumab (30 mg/ml)	>240
Raltitrexed (0.5 mg/ml)	>240
Retrovir (10 mg/ml)	>240
Rituximab (10 mg/ml)	>240
Temsirolimus (25 mg/ml)	>240
ThioTEPA (10 mg/ml)	>240
Topotecan HCL (1 mg/ml)	>240
Trastuzumab (21 mg/ml)	>240
Triclosan (1 mg/ml)	>240
Trisenox (1 mg/ml)	>240
Vinblastine (1 mg/ml)	>240
Vincrinstine Sulfate (1 mg/ml)	>240
Vinorelbine (10 mg/ml)	>240
Zoledronic Acid (0.8 mg/ml)	>240

Additional Chemical Testing Information – ASTM F739/EN 374-1: EN 16523-1 (where applicable)

Chemical	Concentration/Contents	CAS Number	Test Method	Average Breakthrough Time (Minutes) Purple Nitrile *Max
Adhesive Tape Remover Pads	Isoparaffin (75%) Petroleum Naphtha (15%) Isopropyl Alcohol (5%)		ASTM F739	>480
Chlorhexidine gluconate	4%	18472-51-0	ASTM F739	>480
Cidex 14-Day (or equivalent)	Glutaraldehyde (2.4%)		ASTM F739	>480
Cidex OPA			ASTM F739	>480
Cidex OPA/Ortho-phthalaldehyde	n/a		ASTM F739	>480
Cidex OPA-C (ASP)	Ortho-phthalaldehyde Concentrate (7.5%)		ASTM F739	0
Ethydium bromide	0.40%	1239-45-8	EN 16523-1	>480
Formalin	10%	50-00-0	ASTM F739	>480
Formaldehyde	10%		ASTM F739	>480
Glutaraldehyde	4%	111-30-8	ASTM F739	>480
Hydrochloric Acid	37%	7647-01-0	ASTM F739	>480
Hydrochloric Acid	30%	7647-01-0	EN 16523-1	>480
Hydrogen peroxide	30%		ASTM F739	>480
Hydrogen Peroxide	Hydrogen Peroxide (3%)	7722-84-1	ASTM F739	>480
Isopropyl alcohol	70%	67-63-0	ASTM F739	159.3
Isopropyl Alcohol	Isopropyl alcohol (90%)	67-63-0	ASTM F739	18.7
Medivators Rapicide PA (Part A and Part B)	Hydrogen Peroxide (22%) Peracetic Acid (5%) Trisodium Phosphate (0.22%) Surfactant (0.20%)		ASTM F739	>480
Medline Instrument Lubricant	White Mineral Oil (10-13%)		ASTM F739	>480
Medline Instrument Stain Remover	Phosphoric Acid (13.5%)		ASTM F739	>480

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Chemical	Concentration/Contents	CAS Number	Test Method	Average Breakthrough Time (Minutes) Purple Nitrile *Max
Medline Low-Suds Liquid Detergent Concentrate	Octanoic Acid (1-5%) 1,2,3-Propanediol (5-10%)		ASTM F739	>480
n-Hexane	96.10%	110-54-3	ASTM F739	98.3
PDI Sani-Cloth Germicidal Wipes	Isopropyl Alcohol (55%) Alkyl dimethyl benzyl ammonium chlorides (0.25%) Alkyl ethylbenzyl ammonium chlorides (0.25%)		ASTM F739	>480
Povidone iodine	10%	25655-41-8	ASTM F739	>480
Quaternary Detergent			ASTM F739	>480
Resert XL HLD	2-Furnancarboxylic acid (3%), Hydrogen peroxide (3%), Potassium hydroxide (0.4%), Phosphoric acid (04%), 1-Hydroxyethane-1,1-diphosponhic aicd (0.3%)		ASTM F739	>480
Sodium hydroxide	40%	1310-73-2	EN 16523-1	>480
Sodium hypochlorite (bleach)	10-13%	7681-9	ASTM F739	>480
Steris Pre-Klenz Point of Use Transport Gel	-		ASTM F739	>480
Sulfuric acid	50%	7664-93-9	EN 16523-1	>480
Methanol		67-56-1	EN 16523-1	12
Acetone		67-64-1	EN 16523-1	<5
Ethyl Acetate		141-78-6	EN 16523-1	<5
Sulphuric Acid	96%	7664-93-9	EN 16523-1	20
Nitric acid	65%	7697-37-2	EN 16523-1	9
n-Heptane		142-82-5	EN 16523-1	224
Acetic acid	99%	64-19-7	EN 16523-1	19
Ammonium Hydroxide	25%	1336-21-6	EN 16523-1	53
Hydrogen Peroxide	30%	7722-84-1	EN 16523-1	>480
Formaldehyde	37%	50-00-0	EN 16523-1	>480
Ethanol	70%	64-17-5	EN 16523-1	116

Sustainability

ISO 14001:2015 - Environmental management systems	ISO
Patented nitrile exam glove dispensers and cartons, made with up to 95% recycled material.	PACKAGING MADE WITH UP TO 95% RECYCLED MATERIAL

Our Commitment to you

Better Infection Prevention

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