

TECHNICAL DOCUMENT

Description

52000M PURPLE NITRILE XS
52001M PURPLE NITRILE S
52002M PURPLE NITRILE M
52003M PURPLE NITRILE L
52004M PURPLE NITRILE XL

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

Dimensions:

	Palm width	Length
Extra Small (XS)	70 mm	> 240 mm
Small (S)	80 mm	> 240 mm
Medium (M)	95 mm	> 240 mm
Large (L)	110 mm	> 240 mm
Extra Large (XL)	120 mm	> 240 mm



Properties:	HALYARD (Minimum Results/Specification Target)	EN/ ASTM requirement/Test Method
Median force at break before aging (Newton)	12.0 N	EN 455-2: 6N
Median force at break after aging (Newton)	12.0 N	EN 455-2: 6N
Residual powder mg/glove	1.0 mg (3x rinsed)	EN 455-3/ ISO 21171/ASTM D6124: <2.0 mg
Material Thickness	Thickness middle finger: 0.15 mm Thickness palm: 0.12 mm Thickness cuff: 0.09 mm	--
Tensile Strength ASTM D6319	30 MPa Before Aging (2.5 AQL) 30 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) 500% After Aging (2.5 AQL)	Test Method ASTM D412: 500% Before aging 400% After aging (4.0 AQL)
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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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: ZDEC (ZINC DIETHYLDITHIOCARBAMATE) 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 <ul style="list-style-type: none">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. ZDEC (ZINC DIETHYLDITHIOCARBAMATE) with residual concentrations <100 µg per gram.

Sterilization

Products are non-sterile.

Packaging

References 52000M, 52001M, 52002M, 52003M:
Shipping case of 1000 units.
10 dispenser boxes of 100 units in each shipping case.

Reference 52004M: Shipping case of 900 units.
10 dispenser boxes of 90 units in each shipping case.

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

Dimensions	Length	Breadth	Height
Dispenser Box (mm)	245	128	80
Shipping Case (mm)	415	259	255

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EAN

Item	Description	AUn	EAN/UPC
52000M	PURPLE NITRILE Exam Glove XS	Sell Unit Package	30680651504860
52000M	PURPLE NITRILE Exam Glove XS	Inner Package	20680651504863
52001M	PURPLE NITRILE Exam Glove S	Sell Unit Package	30680651504877
52001M	PURPLE NITRILE Exam Glove S	Inner Package	20680651504870
52002M	PURPLE NITRILE Exam Glove M	Sell Unit Package	30680651504884
52002M	PURPLE NITRILE Exam Glove M	Inner Package	20680651504887
52003M	PURPLE NITRILE Exam Glove L	Sell Unit Package	30680651504891
52003M	PURPLE NITRILE Exam Glove L	Inner Package	20680651504894
52004M	PURPLE NITRILE Exam Glove XL	Sell Unit Package	30680651504907
52004M	PURPLE NITRILE Exam Glove XL	Inner Package	20680651504900

Manufacturing

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

Regulatory information

- 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 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		Degradation Test
	EN 16523-1:2015+A1:2018		EN ISO 374-4:2019
	Minimum Breakthrough Time (min)	Performance Level	Degradation (%)
Formaldehyde, 37% (T)	>480	6	20
n-Heptane, 99% (J)	31.2	2	54.9
Sodium hydroxide, 40% (K)	>480	6	-17.8

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

5 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* 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*
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
Capecitabine (26 mg/ml)	>240
Carboplatin (10 mg/ml)	>240
Carfilzomib (10 mg/ml)	>240
Cetuximab (2 mg/ml)	>240
Carmustine (3.3 mg/ml)	55.3
Cisplatin (1 mg/ml)	>240
Cladribine (1 mg/ml)	>240
Cyclophosphamide (20 mg/ml)	>240
Cyclosporin A (100 mg/ml)	>240
Cytarabine (Cytosine) (100 mg/ml)	>240
Cytovene (Ganciclovir) (10 mg/ml)	>240
Dacarbazine (DTIC) (10 mg/ml)	>240
Dactinomycin (0.5 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
Epirubicin HCL (Ellence) (2 mg/ml)	>240
Etoposide (Toposar) (20 mg/ml)	>240
Fludarabine (25 mg/ml)	>240
5-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

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Chemotherapy Drugs Tested	Breakthrough time (minutes) Purple Nitrile*
Irinotecan (20 mg/ml)	>240
Leuprolide Acetate Salt (5 mg/ml)	>240
Mechlorethamine HCL (1 mg/ml)	>240
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
Pemetrexed (25 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)	78.7
Topotecan HCL (1 mg/ml)	>240
Triclosan (2 mg/ml)	>240
Trisenox (1 mg/ml)	>240
Vinblastine Sulfate (1 mg/ml)	>240
Vincristine 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)

Chemicals Tested	CAS #	Test Method	Breakthrough time (minutes) Purple Nitrile*
Adhesive Tape Remover Pads		ASTM F739	132.7
Alcoholic Bouin's Fixative		ASTM F739	140.0
Alcoholic Eosin		ASTM F739	21.3
Bleach	7681-9	ASTM F739	> 480
Bouin's Fixative		ASTM F739	> 480
B-Plus Fixative		ASTM F739	> 480
CarNoy's Fluid		ASTM F739	0
Chlorhexidine Gluconate 4%		ASTM F739	240
Cidex 14-Day		ASTM F739	> 480
Cidex OPA		ASTM F739	213.3
Decalcifier I		ASTM F739	> 480
EM Fixative		ASTM F739	> 480
Eosin Stain		ASTM F739	80.0
Ethidium Bromide (1%)	1239-45-8	ASTM F739	>480
Ethyl Alcohol (95%)	64-17-5	ASTM F739	16.0
Formalin Alcohol (tested for Formaldehyde)		ASTM F739	22.0
Formalin Alcohol (tested for Reagent Alcohol)		ASTM F739	> 480
Formalin, 10% Buffered (tested for Formaldehyde)	50-00-0	ASTM F739	> 480
Formalin, 10% Buffered (tested for Methanol)	50-00-0	ASTM F739	> 480
Giemsa Stain Solution		ASTM F739	13.3
Glutaraldehyde 4%	111-30-8	ASTM F739	240
Haematoxylin Stain (Harris Solution)		ASTM F739	40.0
Hydrochloric Acid, 35.5%	7647-01-0	ASTM F739	214.3
Hydrogen Peroxide, 3%	7722-84-1	ASTM F739	> 480
Isopropyl Alcohol, 70%	67-63-0	ASTM F739	40.3
Methanol	67-56-1	ASTM F739	8.0
Methyl Methacrylate (Bone Cement)	80-62-6	ASTM F739	0
Monseil's Solution	1310-45-8	ASTM F739	> 480
OxyCide Concentrate		ASTM F739	146.7

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Chemicals Tested	CAS #	Test Method	Breakthrough time (minutes) Purple Nitrile*
OxyCide Ready to Use		ASTM F739	> 480
Permaslip Mounting Medium & Liquid Cover Slip		ASTM F739	0
Rapid Bone Decalcifier		ASTM F739	> 480
Reagent Alcohol	64-17-5	ASTM F739	13.3
Resert XL HLD		ASTM F739	266.7
Sodium Hydroxide (40%)	1310-73-2	ASTM F739	> 480
Sulfuric Acid (50%)	7664-93-9	ASTM F739	12.0
Trichloroacetic Acid, (10%)	76-03-9	ASTM F739	> 480
Xylene, (99%)	1330-20-7	ASTM F739	0
Acetone	67-64-1	EN 16523-1	< 5
Acetic acid (99%)	64-19-7	EN 16523-1	10
Ammonia (25%)	1336-21-6	EN 16523-1	32.6
Ethyl Acetate	141-78-6	EN 16523-1	< 5
Ethanol (70%)	64-17-5	EN 16523-1	54
Incidin Rapid (Isopropanol)	67-63-0	EN 16523-1	320
Incidin Foam (Isopropanol & Ethanol)	67-63-0 and 64-17-5	EN 16523-1	>480
Incidin Plus (Diethylene Glycol Butyl Ether & phenoxyethanol)	112-34-5 and 122-99-6	EN 16523-1	160
Hydrogen Peroxide (30%)	7722-84-1	EN 16523-1	283.3
n-Heptane (99%)	142-85-5	EN 16523-1	31.2
Formaldehyde (37%)	50-00-0	EN 16523-1	> 480
Fentanyl Citrate Injection, 100 µg/2ml	990-73-8	ASTM D6978	> 240
Sulphuric Acid (96%)	7664-93-9	EN 16523-1	10
Nitric acid (65%)	7697-37-2	EN 16523-1	< 5

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Sustainability

ISO 14001:2015 - Environmental management systems	
The HALYARD* manufacturing facility is purpose designed, using 92% renewable energy, from sustainable by-products of rubber tree plantations, instead of fossil fuels, as part of the manufacturing process.	<p>GLOVES MADE WITH 92% RENEWABLE ENERGY</p> 
Patented nitrile exam glove dispensers and cartons, made with up to 95% recycled material.	<p>PACKAGING MADE WITH UP TO 95% RECYCLED MATERIAL</p> 
<p>Thailand labor management excellence award</p> <p>This award is part of an initiative to recognize and encourage outstanding practices in labor management within Thai companies and organizations. The goal is to promote better working conditions, enhance the quality of life for workers, and increase productivity by highlighting organizations that demonstrate excellence in various aspects of labor management.</p>	<p>SAFESKIN* LABOR MANAGEMENT EXCELLENCE AWARD 2019-2023</p> 
Eco Factory Gold+ Award is a recognition under the "Eco Factory" program in Thailand, aimed at encouraging and honoring factories that achieve exceptional environmental performance. This award is part of a broader initiative by the Federation of Thai Industries (FTI) and the Ministry of Industry to promote sustainable industrial practices.	<p>SAFESKIN* ECO FACTORY GOLD+ AWARD 2020</p> 
The Green Industry Level 5 Award is the highest level of recognition in Thailand's Green Industry initiative, which is administered by the Ministry of Industry. This award is designed to honor companies that demonstrate the highest commitment to environmental sustainability and integrate eco-friendly practices across every aspect of their business operations.	<p>SAFESKIN* GREEN INDUSTRY LEVEL 5 AWARD 2023</p> 
<p>Economical packaging</p> <p>HALYARD* Nitrile Exam Gloves: Offer up to a 5 YEAR SHELF LIFE</p>	<p>IDEAL FOR STOCKPILING</p> 

**Our
Commitment
to you**

**Better
Infection
Prevention**

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