

HYGIPLAS

Food Safety Solutions

Instructions for Use - Keep for future reference



Manufactured by: Nisbets, Fourth Way, Avonmouth, Bristol, BS11 8TB United Kingdom

EU Type examination carried out by Notified Body No. 2777. SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin D15 YN2P, Ireland

SATRA Technology Europe Ltd are responsible for ongoing conformity

(EN) Vinyl Gloves - Powder free

This product's principle intended purpose is personal protection and as such complies with, and is CE marked under, the Personal Protective Equipment Regulation 2016/425.

The gloves offer protection against bacteria, fungi and viruses.

Cleaning: Gloves cannot be cleaned and reused. Before use, check gloves for physical damage. Do not use damaged gloves.

Fitting and Sizing: Only wear products of a suitable size. Products which are either too loose or tight will restrict movement and will not provide the optimum level of protection.

Allergy Advice: This product does not contain natural rubber latex but may contain low levels of residual chemical accelerators, which may cause allergic reactions.

(NL) Vinyl handschoenen – poedervrij

Het belangrijkste beoogde doel van dit product is persoonlijke bescherming en voldoet als zodanig aan, en is CE-gemarkeerd onder de persoonlijke beschermingsmiddelenverordening 2016/425.

De handschoenen bieden bescherming tegen bacteriën, schimmels en virussen.

Reiniging: Handschoenen kunnen niet worden schoongemaakt en hergebruikt. Controleer handschoenen voor gebruik op fysieke schade. Gebruik geen beschadigde handschoenen.

Pasvorm en maatvoering: draag alleen producten met een geschikte maat. Producten die te los of te strak zitten, beperken de beweging en bieden niet het optimale beschermingsniveau.

Allergeneninformatie: Dit product bevat geen natuurrubberlatex, maar kan een laag gehalte aan resterende chemische versnellers bevatten, die allergische reacties kunnen veroorzaken.

(FR) Gants en vinyle - sans poudre

Le principal objectif de ce produit est la protection des personnes et, en tant que tel, il est conforme au règlement 2016/425 sur les équipements de protection individuelle et porte le marquage CE.

Les gants offrent une protection contre les bactéries, les champignons et les virus.

Nettoyage : Les gants ne peuvent pas être nettoyés et réutilisés. Avant de les utiliser, vérifiez que les gants ne présentent pas de dommages physiques. N'utilisez pas de gants endommagés.

Ajustement et taille : Portez uniquement des produits d'une taille appropriée. Les produits trop lâches ou trop serrés restreignent les mouvements et n'offrent pas un niveau de protection optimal.

Conseils en cas d'allergie : Ce produit ne contient pas de latex de caoutchouc naturel mais peut contenir de faibles niveaux d'accélérateurs chimiques résiduels, qui peuvent provoquer des réactions allergiques.

(DE) Vinylhandschuhe - Puderfrei

Der Hauptzweck dieses Produkts ist der persönlichen Schutz und entspricht als solcher der Verordnung über die persönliche Schutzausrüstung 2016/425 und trägt die CE-Kennzeichnung.

Die Handschuhe bieten Schutz vor Bakterien, Pilzen und Viren.

Reinigung: Handschuhe können nicht gereinigt und wiederverwendet werden. Prüfen Sie die Handschuhe vor der Verwendung auf physische Schäden. Verwenden Sie keine beschädigten Handschuhe.

Passform und Größe: Tragen Sie nur Produkte in einer passenden Größe. Produkte, die entweder zu locker oder zu eng sitzen, schränken die Bewegungsfreiheit ein und bieten nicht den optimalen Schutz.

Hinweis für Allergie: Dieses Produkt enthält kein Gummilatax, aber kann geringe Mengen an restlichen chemischen Restbeschleunigern enthalten, die allergische Reaktionen auslösen können.



Guanti in vinile - Senza polvere

Questo è un dispositivo di protezione personale e come tale è conforme al regolamento per dispositivi di protezione individuale CE 2016/425, di cui reca la marcatura.

I guanti offrono protezione contro batteri, funghi e virus.

Pulizia: i guanti non possono essere puliti e riutilizzati. Prima dell'uso, verificare l'assenza di danni fisici sui guanti.

Misure e indossabilità: indossare solo la misura adatta. I prodotti troppo larghi o troppo stretti limitano i movimenti e non garantiscono un livello di protezione adeguato.

Avviso in merito alle allergie: questo prodotto non contiene lattice di gomma naturale ma può contenere residui limitati di acceleratori chimici che possono causare reazioni allergiche.



Guantes de Vinilo-Libre de polvo

El objetivo principal de este producto es la protección personal y, como tal, cumple con el Reglamento de Equipos de Protección Personal 20160/435 y bajo la marca CV.

Los guantes ofrecen protección contra bacterias, hongos y virus.

Limpieza: Los guantes no se pueden limpiar ni reutilizar. Antes de usarlos, compruebe si los guantes presentan daños físicos. No use guantes dañados.

Ajuste y tamaño: Use únicamente productos de un tamaño adecuado. Los productos que estén demasiado sueltos o apretados restringirán el movimiento y no brindarán el nivel óptimo de protección.

Aviso de alergia: Este producto no contiene látex de caucho natural, pero puede contener niveles bajos de aceleradores químicos residuales, que pueden causar reacciones alérgicas.

The Declaration of Conformity can be found at <http://productip.com/?f=16b217> or by scanning the following QR code.

Een conformiteitsverklaring kan worden gevonden op <http://productip.com/?f=16b217> of door de QR-code hieronder te scannen.

Une déclaration de conformité est disponible à l'adresse <http://productip.com/?f=16b217> Vous pouvez également accéder à la déclaration de conformité en scannant le code QR ci-dessous.

Eine Konformitätserklärung finden Sie unter <http://productip.com/?f=16b217> oder durch Scannen des folgenden QR-Codes.

È possibile trovare la dichiarazione di conformità collegandosi all'indirizzo <http://productip.com/?f=16b217> o scansionando il codice QR di seguito.

Puede encontrar una Declaración de Conformidad en <http://productip.com/?f=16b217> o escaneando el siguiente Código QR.



UK	+44 (0)845 146 2887	Fourth Way, Avonmouth, Bristol, BS11 8TB, UK
Eire		42 North Point Business Park, New Mallow Road, Cork, Ireland
NL	040 - 2628080	
FR	01 60 34 28 80	
BE-NL	0800 - 29129	
BE-FR	0800 - 29229	
DE	0800 - 1860806	
ES	901-100 133	

This product has passed all tests and meet the requirements of the following standards:

EN ISO 374-1: 2016; EN 374-2: 2014; EN 374-4: 2013;
EN ISO 374-5: 2016; EN 420:2003+A1:2009

Appendix I: Test results of Chemical Degradation as per EN 374-4: 2013

Sample description:	Disposable Vinyl Examination Gloves and Long cuff exam Vinyl Gloves		
Challenge chemical:	T=37% Formaldehyde (CAS: 50-00-0)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	13.0	2.8	7.9
Mean degradation (DR) / %:	7.9		
Standard deviation (σ_{DR}) / %:	5.1		
UoM \diamond / ± %:	49.2		
Appearance of samples after testing:	No change		

Sample description:	Disposable Vinyl Examination Gloves and Long cuff exam Vinyl Gloves		
Challenge chemical:	K= 40% Sodium hydroxide (CAS: 1310-73-2)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	-5.7	-2.4	9.2
Mean degradation (DR) / %:	0.4		
Standard deviation (σ_{DR}) / %:	7.8		
UoM \diamond / ± %:	51.9		
Appearance of samples after testing:	No change		

Sample description:	Disposable Vinyl Examination Gloves and Long cuff exam Vinyl Gloves		
Challenge chemical:	P=30% Hydrogen peroxide (CAS: 7722-84-1)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	4.5	-23.6	-18.2
Mean degradation (DR) / %:	-12.4		
Standard deviation (σ_{DR}) / %:	14.9		
UoM \diamond / ± %:	53.8		
Appearance of samples after testing:	No change		

\diamond Absolute measurement uncertainty of the mean degradation value; it is therefore inferred that the true degradation value, with 95% confidence, lies within the range (DR ± UoM) %.

NOTE: Where the test specimens gave an increased puncture force after chemical exposure, the result is reported as a negative degradation.

EN ISO 373-4: 2019 Degradation results indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

Appendix II: Test results for resistance to Permeation as per EN ISO 374-1: 2016

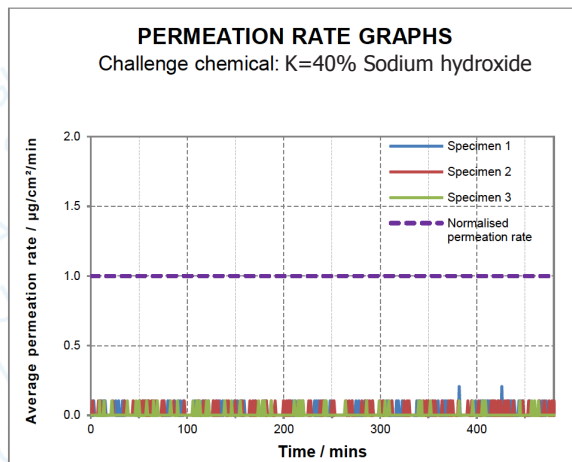
RESULTS AND REQUIREMENTS:

EN ISO 374-1:2016 - Protective gloves against dangerous chemicals and micro-organisms. Part 1: Terminology and performance requirements for chemical risks. Table 1: Permeation performance levels.

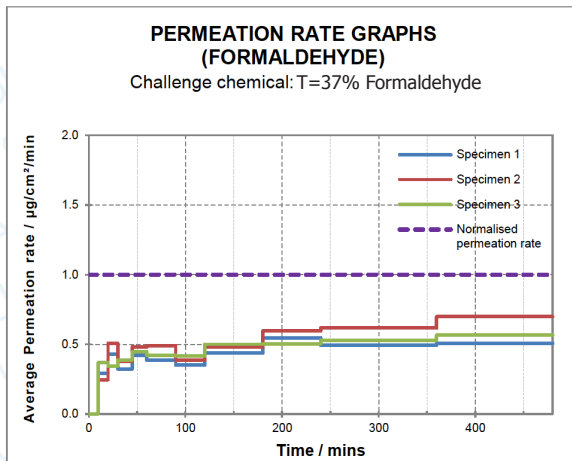
Permeation performance level	Measured breakthrough time (minutes)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

Performance levels are based on the lowest individual result achieved per chemical.

EN 16523-1:2015 in accordance with SATRA SOP CAT-009	Test information:	Chemical: K= 40% Sodium Hydroxide		Level 6
		Normalised permeation rate (NPR): 1 µg/cm ² /min		
		Detection technique: Conductimetry (continuous measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)		
		Test temperature: (23 ± 1) °C		
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)^Δ	Breakthrough time (mins)	
	1	0.07	>480	
	2	0.06	>480	
	3	0.06	>480	
	Test result:		>480	
UoM:		<1		
Visual appearance of specimens after testing:		No change		



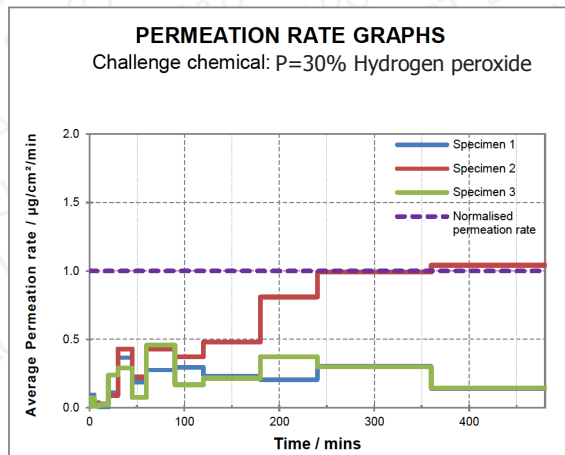
Test/Property	Sample reference:	Disposable Vinyl Examination Gloves and Long cuff exam Vinyl Gloves		Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-025	Test information:	Chemical: T=37% Formaldehyde		Level 6
		Normalised permeation rate (NPR): 1 µg/cm ² /min		
		Detection technique: Spectrophotometry (periodic measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: (each cell constant to within ± 10%) 45 – 65 ml/min		
		Test temperature: (23 ± 1) °C		
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)^Δ	Breakthrough time (mins)[▼]	
	1	0.08	>480	
	2	0.08	>480	
	3	0.07	>480	
		Test result:	>480	
	UoM:	<1		
Visual appearance of specimens after testing:		Discoloured		



Formaldehyde is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve.

Test/Property	Sample reference:	Disposable Vinyl Examination Gloves and Long cuff exam Vinyl Gloves		Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-025	Test information:	Chemical: P= 30% Hydrogen peroxide		Level 5
		Normalised permeation rate (NPR): 1 µg/cm ² /min		
		Detection technique: Electrochemical detector (periodic measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: (each cell constant to within ± 10%) 45 – 65 ml/min		
		Test temperature: (23 ± 1) °C		
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)^Δ	Breakthrough time (mins)[▼]	
	1	0.07	>480	
	2	0.06	Between 361 to 480	
	3	0.07	>480	
		Test result:	Between 361 to 480	
	UoM:	See below		
Visual appearance of specimens after testing:		Swollen and discoloured		

For SOP CAT-025, where both the P_1 and P_u are observed in the same sampling range, uncertainty is expressed as the time difference between the mid-point of the range and the previous sampling time. This uncertainty is included in the reported result.



Hydrogen peroxide is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve.

- EN 16523-1:2015 - Determination of material resistance to permeation by chemicals. Part 1: Permeation by liquid chemical under conditions of continuous contact
- △ EN 16523-1:2015 does not require the test specimen thicknesses to be reported, this information is indicative only.
- ▼ Breakthrough expressed as a range between discrete sampling points where the average permeation rate exceeds the NPR. Due to the complexity of the detection technique, the minimum sampling frequency as specified in table 1 of EN 16523-1:2015 is not possible.

Appendix III: Test results for resistance to penetration as per EN ISO 374-5:2016

The positive control sample showed the bacteriophages passed through a microporous film whilst the negative control samples showed no passage through the polyethylene film.

Test specimen	Result	Pass/Fail results
1	No penetration	Pass
2	No penetration	Pass
3	No penetration	Pass

Test specimens were selected from different colours and incorporated both powder-free and powdered variants.

APPENDICES:

Resistance to penetration by blood-borne pathogens-Test method using Phi-X174 bacteriophage

Standard used	ISO 16604 (2004)
Product standard	EN ISO 374-5 (2016)
Dimension of the test specimens	75mm x 75mm
Number of test specimens	3
Test procedure used	Procedure B
Used bacteriophage	<i>Bacteriophage Phi-X174 (ATCC 13706-B1 LOT CNCM 14812)</i>
Penetration survey method	Plaque-forming units (PFU)
Pre-test bacteriophage titre	3.8×10^8
Post-test bacteriophage titre	3.7×10^8

Appendix IV: Additional warnings

- This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.
- The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in cases where the glove is equal to or over 400mm - where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical is used in a mixture.
- It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation.
- When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves.
- The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.

HYGIPLAS

Food Safety Solutions

CF403-Y247_leaflet_ML_A5_v2_20211207