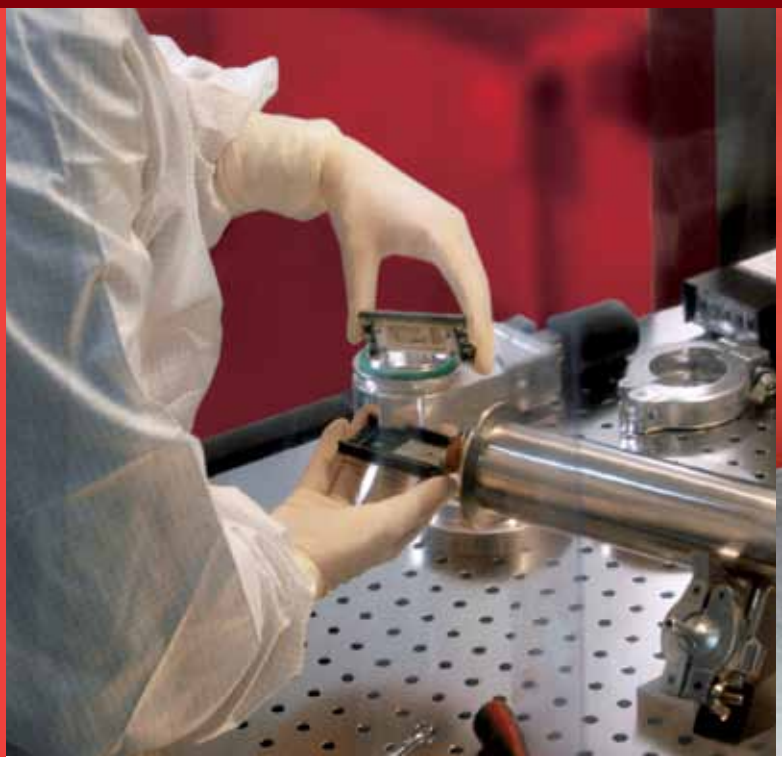
Hand Protection Solutions for Critical Environments



Touch N Tuff® 92-605

WWW.ANSELL.EU

Ansell

Validationpack

interactive menu

Touch N Tuff® 92-605
Production Location: Ansell Lanka, Biyagama, Sri Lanka
Ansell Thailand, Bangkok, Thailand

Contents:

Ansell Healthcare Europe N.V.
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http://www.ansell.eu E-mail info@ansell.eu

ISO 9001 Certificate
Number FM 40130

Touch N Tuff® 92-600 92-605

NBR **NITRILE** | **SPLASH** | **CHEMICAL & LIQUID PROTECTION**

STYLE #	LINER MATERIAL	CUFF STYLE	COLOUR	GRIP DESIGN	THICKNESS MM	POW-DER-FREE	EN SIZE	LENGTH MM	PACKAGING
92-600	Not applicable	Rolled Beaded	Green	Smooth	0.12	Yes	6½-7, 7½-8, 8½-9, 9½-10	240	100 gloves in a box, 10 boxes in a carton
92-605	Not applicable	Rolled Beaded	Green	Smooth	0.12	Yes	6½-7, 7½-8, 8½-9, 9½-10, 10½-11	300	100 gloves in a box, 10 boxes in a carton

Proven splash resistance against hazardous chemicals

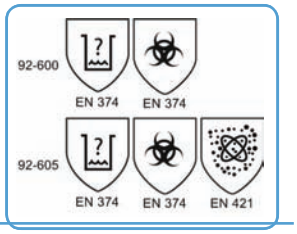
PRIMARY INDUSTRIES

IDEAL APPLICATIONS

- Chemical handling
- Laboratory analysis
- Pharmaceuticals
- Paint and spray shops
- Printing industry
- Electronics
- Light assembly tasks
- Light assembly of oil-coated pieces
- Glass manufacturing
- Handling of cytostatics
- Intricate parts handling

DESCRIPTION

- Further testing of the Touch N Tuff® by a certified body on an even wider range of chemicals confirms that it resists a greater variety of industrial chemicals for longer periods than any other nitrile disposable gloves (see page 76).
- Manufactured from nitrile, Touch N Tuff® offers up to four times the puncture resistance of comparable natural-latex gloves, and three times the resistance of similar neoprene gloves.
- It contains no natural rubber proteins, which means no risk of Type I allergies for the wearer. Primary skin irritation studies and Insult Patch tests have also shown no evidence of risk from irritation or allergic contact dermatitis.
- With a unique "Thin Nitrile Technology" formulation, this glove offers easy donning and strong grip in wet or dry conditions.
- The glove is highly versatile and suitable for many different uses.
- AQL 1.5 (EN374)



CATEGORY III

92-600: Fit for special purpose

Touch N Tuff® is anti-staticity tested (EN 1149-1 & 1149-3) and meets the requirements defined in EN 1149-5

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Ansell

Technical Datasheet

Touch N Tuff®

Product protection

Orig	06-07-2004
Rev	26-07-2010

Product description
Blue-green unlined nitrile rubber disposable gloves.
Thickness: min. 0.10 mm
Typical 0.12 mm

Glove material
Acrylonitrile-butadiene rubber

Possible Harmful ingredients
Sensitizers:

- Zinc mercaptobenzothiazole
- Zinc dibutyldithiocarbamate

Only a very small number of users may be sensitised to any of these ingredients and hence may develop irritant and/or allergic reactions.

No Substances of Very High Concern (as per REACH Regulation 1907/2006)

Properties
Excellent physical properties
Excellent comfort
Excellent puncture resistance
Free of silicone and plasticisers
No latex proteins: low risk for skin allergies.
Very good chemical protection against solvents: please contact Ansell Protective Products.

EN Test Data
Abrasion resistance: Performance level 0
Blade cut resistance:
Performance level 0 (index 1.1)
Tear resistance:
Performance level 0 (0.2 N)
Puncture resistance:
Performance level 0 (16.3 N)
Anti-staticity: -Surface resistance: 5.5×10^9 Ω
-Vertical resistance: 1.5×10^8 Ω
Liquidproofness: Acceptable Quality Level 1.5 or EN performance level 2
Chemical permeation: upon request

Type	Reference	(EN) Sizes	Length
Powder-free	92-600	$6^{1/2}$-7, $7^{1/2}$-8, $8^{1/2}$-9, $9^{1/2}$-10	240 mm
	92-605	$6^{1/2}$-7, $7^{1/2}$-8, $8^{1/2}$-9, $9^{1/2}$-10, $10^{1/2}$-11	300 mm

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BSI REGISTERED UKAS QUALITY MANAGEMENT 003
ISO 9001 Certificate Number FM 40130

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EC DECLARATION OF PRODUCT CONFORMITY

Category III

The manufacturer, established in the European Economic Community:

ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS

declares that the PPE described hereafter:

Touch N Tuff® 92-605

is in conformity with the provisions of the Council Directive 89/686/EEC and with the European harmonised standards EN420: 2003, EN421: 1994, EN374: 2003, and is identical to the PPE which is subject to the EC Type Examination certificate number 03210376 issued by the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 7
B-9052 ZWIJNAARDE

is subject to the procedure set out in Article 11 point A of Directive 89/686/EEC under the supervision of the Notified Body

CENTEXBEL (0493)
TECHNOLOGIEPARK 7
B-9052 ZWIJNAARDE

Wednesday, February 02, 2011
Guido VAN DUREN
Director Technical Services
ANSELL HEALTHCARE EUROPE N.V.

In application of the directive 89/686/EEG of 21 December 1989 concerning the harmonisation of the Member States legislation relative to personal protective equipment, Centexbel Notified body 0493 authorised by decree AV/OA235/ST dated 94-05-25 of the Ministry of Employment and Labour has issued

to: **Ansell Healthcare Europe nv Riverside Business Park - Spey House**

Internationale Laan 55

1070 Brussels

Belgium

CE TYPE EXAMINATION CERTIFICATE

Nr. 03208213

This CE Type examination certificate is valid until 12/07/2015

for: The gloves Touch N Tuff 92-500 and 92-600

The personal protective equipment above mentioned satisfies the applicable essential safety requirements of the Directive.

For the argumentation, the following standards are used:

EN 420:2003: Protective gloves - general requirements

EN 374-1:2003 (low): Protective gloves against chemicals and micro-organisms

This is PPE of category III, subject to regular checks in accordance with article 11 of the European PPE directive. In agreement with the manufacturer's choice random checks shall be carried out to assess the quality of the final product (art.11A). The manufacturer must be able, on request, to present the test report of this quality control check. A first quality control check shall be performed at the latest on 31.12.2011 and at least be repeated with intervals of one year.

The technical file is registered with number 2726

20 May 2008

Re-issued 12 July 2010

Inge De Witte
certification officer

Jan Laperre
general manager

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Annex to certificate 03208213

The gloves Touch N Tuff 92-500 and 92-600 fulfil the requirements of EN 374-1:2003 (low):

to use the following pictogram

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Ansell Healthcare Europe

c/o Mr Van Duren

Riverside Business Park, Spey House
Boulevard International 55
1070 Bruxelles
Belgique

your notice of	your ref.	our ref.	date
22/04/2008		YR/cr/08/250	Chaineux, 22 May 2008

Analysis Report Nr. 8248

Required test :

ISO 16604 – procedure B : 2004

Description of the samples :

Identification number	Information given by the customer	Date of receipt
V800374	Touch N Tuff 92-600/605	24/04/08
V800375	TNT Blue 92-670/665	24/04/08

Yvette Rogister
Order responsible

For further information please contact our sectorial adviser : Mark Croes.

ISO 17025
BELAC
056-TEST

VAT BE 459 218 289 **Fin. Acc. 210-0472965-45** **IBAN BE44 2100 4729 6545**

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e-mail chaineux@centexbel.be

CENTEXBEL-BRUSSELS
Montoyerstraat 24 B2
BE-1000 Brussels
Tel. + 32 2 287 08 30 • Fax + 32 2 230 68 15

Reference :

V800374	**Touch N Tuff 92-600/605**
V800375	**TNT Blue 92-670/665**

ISO 16604 : 2004

Clothing for protection against contact with blood and body fluids – Determination of the resistance of protective clothing materials to penetration by blood-borne pathogens – Test method using Phi-X174 bacteriophage

Date of ending the test : 22/05/2008

1. Method

ISO 16604 : 2004 : Clothing for protection against contact with blood and body fluids – Determination of the resistance of protective clothing materials to penetration by blood-borne pathogens – Test method using Phi-X174 bacteriophage

A specimen is subjected to a nutrient broth containing a virus for a specified time and pressure sequence. Visual detection of penetration is supplemented with an assay procedure that will detect viable viruses which penetrate the material even when liquid penetration is not visible. Any evidence of viral penetration for a sample constitutes failure.
In the method, the specimen is inserted in the penetration cell with the normal outside surface of the textile toward the cell reservoir which is further filled with the Phi-X174 bacteriophage challenge suspension.
The other face is, for procedures B and D, in contact with a retaining screen (which assures a good bearing of the textile during the pressure application).
The pressure application procedure depends on the type of material, and the applied pressure is chosen according to the result obtained with ISO 16603 (highest pressure with no visible penetration in ISO 16603 used for ISO 16604).

2. Results

General information

- *Sampling :* sampling in 3 gloves, in the palm and the back of hand.
- *Number of test specimens :* 3
- *Test specimen dimension :* 7.5 X 7.5 cm^2
- *Conditioning of the sample :* 24 hours at 21 ± 5°C and 60 ± 10 % relative humidity. The sample is not tested in conditioned atmosphere but directly after conditioning.
- *Sterilisation of the samples :* None
- *Side in contact with the bacteriophages suspension :* external side
- *Test procedure :* ***PROCEDURE*** *B* with the following pressure and time sequence : *- 0 kPa for 5 min,*
  - followed by 14 kPa for 1 min,
  - followed by 0 kPa for 4 min.
  Use of a metal square mesh screen (open area >50%, limiting deflection of the sample limited to ≤ 5.0mm).
- *Surface tension of the bacteriophages suspension:* 42 +/- 2 dynes/cm.
- *Used bacteriophage :* *Bacteriophage Phi-X 174* (ATCC 13706-B1)
- *Host bacteria :* *Escherichia coli* (ATCC 13706)

Centexbel reference of the sample	**V800374**					
Pressure	**14 kPa**					
Type of sample	Green Gloves					
Sample thickness	Not requested					
Sample weight	Not requested					
Paraffin-sealed edges	No					
Sterilisation type	None					
Procedure selected	B					
Inhibition test : ratio	1.6					
Number of plaques per settle plates during the different steps of the test (PFU)	Samp. 1	Samp.2	Samp.3	Contr.(1) conta.	Contr. -	Contr.+
During the filling of the cell	0	0	0	0	0	0
During the rinsing and the draining of the cell	0	0	0	0	0	0
During the test	0	0	0	0	0	0
During the initial titer determination	0	-	-	-	-	-
During the final titer determination	-	-	-	-	-	0
Titer of the initial bacteriophages suspension Titre (PFU/ml)	Before filling the first cell $2\ 10^8$ PFU/ml					
Titer of the bacteriophages suspension after the test (drained from the last cell) Titre (PFU/ml)	After the last cell $2.6\ 10^8$ PFU/ml					
Results	Sample 1	Sample 2	Sample 3	Contr.(1) conta.	Contr. -	Contr. +
Number of plaques 1	0	0	0	0	0	high
Number of plaques 2	0	0	0	0	0	high
Number of plaques 3	0	0	0	0	0	high

(1) : Control of contamination (only when the sample can't be sterilised)

Performed under accreditation in the microbiological lab under the responsibility of Yvette Rogister.

Centexbel reference of the sample	**V800375**					
Pressure	**14 kPa**					
Type of sample	Blue Gloves					
Sample thickness	Not requested					
Sample weight	Not requested					
Paraffin-sealed edges	No					
Sterilisation type	None					
Procedure selected	B					
Inhibition test : ratio	1.88					
Number of plaques per settle plates during the different steps of the test (PFU)	Samp. 1	Samp.2	Samp.3	Contr.(1) conta.	Contr. -	Contr.+
During the filling of the cell	0	0	0	0	0	0
During the rinsing and the draining of the cell	0	0	0	0	0	0
During the test	0	0	0	0	0	0
During the initial titer determination	0	-	-	-	-	-
During the final titer determination	-	-	-	-	-	0
Titer of the initial bacteriophages suspension	Before filling the first cell					
Titre (PFU/ml)	$2.4\ 10^8$ PFU/ml					
Titer of the bacteriophages suspension after the test (drained from the last cell)	After the last cell					
Titre (PFU/ml)	$2.3\ 10^8$ PFU/ml					
Results	Sample 1	Sample 2	Sample 3	Contr.(1) conta.	Contr. -	Contr. +
Number of plaques 1	0	0	0	0	0	18
Number of plaques 2	0	0	0	0	0	21
Number of plaques 3	0	0	0	0	0	17

Performed under accreditation in the microbiological lab under the responsibility of Yvette Rogister.

Summary : ISO 16604 – procedure B

Sample	Replicate	Results
V800374 14 kPa	1 2 3	Pass Pass Pass
V800375 14 kPa	1 2 3	Pass Pass Pass

Ansell Occupational Healthcare

c/o Mr. Guido Van Duren

Internationale Laan 55
B-1070 Brussels

your notice of	your ref.	our ref.	date
10/03/2006 25/09/2009		YR/sn/09/610	Chaineux, 28 September 2009

Analysis Report Nr. 6121/B

Modification of analysis report 6121, made on 4 May 2006

Required test :

ASTM F 1671 : 1997

Description of the samples :

Identification number	Information given by the customer	Date of receipt
V600127	Sol-Vex 37-675 - green rubber gloves	15/03/2006
V600128	Sol-Vex 37-645 - green rubber gloves	15/03/2006
V600129	Bi-Colour 87-900 lot 0504045509 - green and yellow rubber gloves	15/03/2006
V600130	Extra 87-950 lot 0410072309 - black rubber gloves	15/03/2006
V600131	Profil Plus 87-850 lot 0310046909 - yellow rubber gloves	15/03/2006

Yvette Rogister
Order responsible

For further information please contact our sectorial adviser : Marc Croes.

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Identification number	Information given by the customer	Date of receipt
V600132	Universal Plus 87-660 lot 0507618028 – red rubber gloves	15/03/2006
V600133	Touch N Tuff 92-600.605 lot 0408106728 - green rubber gloves	15/03/2006
V600134	Conform + 69-150 lot 05070322 EP – beige latex gloves	15/03/2006
V600135	Micro-Touch Ultra PF lot 05092423EP – beige latex gloves	15/03/2006
V600136	BN45L – black apron	15/03/2006
V600137	PVC45G – green apron	15/03/2006
V600138	VSB-8-HS – white "arm or leg" protective cover	15/03/2006

Yvette Rogister
Order responsible

For further information please contact our sectorial adviser : Marc Croes.

References :

V600127 Sol-Vex 37-675 - green rubber gloves
V600128 Sol-Vex 37-645 - green rubber gloves
V600129 Bi-Colour 87-900 lot 0504045509 - green and yellow rubber gloves
V600130 Extra 87-950 lot 0410072309 - black rubber gloves
V600131 Profil Plus 87-850 lot 0310046909 - yellow rubber gloves
V600132 Universal Plus 87-660 lot 0507618028 – red rubber gloves
V600133 Touch N Tuff 92-600 lot 0408106728 – green latex gloves
V600134 Conform + 69-150 lot 05070322 EP – beige latex gloves
V600135 Micro-Touch Ultra PF lot 05092423EP – beige latex gloves
V600136 BN45L – black apron
V600137 PVC45G – green apron
V600138 VSB-8-HS – white "arm or leg" protective cover

ASTM F 1671 – 97 Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System Specimen Exposure Procedure B

Date of ending the test : 02/05/2006

1. Method

- **ASTM F1671-97 : Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System - Specimen Exposure Procedure B**

  In the method, the textile is put into the cell test. One side of the textile is directly in contact with a bacteriophages suspension (phi-X174) (textile side to be tested), the other side is in contact with a retaining screen (which ensures a good bearing of the textile during the pressure application). After assembly, the cell is placed in the ASTM equipment and the pressure is applied. The bacteriophage penetration through the textile is induced by this pressure application. The application procedure is the following one : 5 minutes of contact without pressure application, 1 minute of contact at 13.8 kPa, 54 minutes of contact without pressure application.
  A the end of the test, the sample surface which has not been in contact with the bacteriophages suspension is rinsed. The liquid of rinsing is then put on an agar plate previously inoculated with *Escherichia coli* (host bacteria of the used bacteriophage).
  The plates are incubated during 24 hours at 37°C and the presence of plaques (lysis of the bacteria cells) on the agar surface signified that the bacteriophage is passed through the sample.

The detection of only one plaque constitutes a failure of the textile. Results are expressed in the form : PASS or FAIL Test .

2. Results

Sampling method

- For the gloves, we have cut the samples from the inside and the back of the hand. We have cut in the centre a sample of 7.5 cm x 7.5 cm

- For the other samples, we have cut samples of 7.5 cm x 7.5 cm at random

General information

- Sterilization of the sample : Ethylene oxide
- Pressure at which the sample is submitted : 13.8 KPa 1 minute
- Used bacteriophage : Bacteriophage Phi-X 174 (ATCC 13706-B1)
- Host bacteria : *Escherichia coli* (ATCC 13706)
- Surface tension of the bacteriophage suspension : 42 +/- 2 dynes/cm.
- Test is repeated three times
- Tested side : outer side

Centexbel reference of the sample	**V600133**					
Type of sample	Green rubber gloves					
Sample thickness	Not asked					
Sample weight	Not asked					
Paraffin-sealed edges	No					
Sterilization type	Ethylene oxide					
Inhibition test : ratio	3					
Number of plaques per settle plates during the different steps of the test (PFU)	Samp. 1	Samp.2	Samp.3	Contr.(1) conta.	Contr. -	Contr.+
During the filling of the cell	0	0	0	/	0	0
During the rinsing and the draining of the cell	0	0	0	/	0	0
During the test	0	0	0	/	0	0
During the initial titer determination	0	-	-	-	-	-
During the final titer determination	-	-	-	-	-	0
Titer of the initial bacteriophages suspension Titer (PFU/ml)	Before filling the first cell $1.1\ 10^8$ PFU/ml					
Titer of the bacteriophages suspension drained from the last cell after the test Titer (PFU/ml)	After the last cell $1.5\ 10^8$ PFU/ml					
Results	Samp. 1	Sampl. 2	Sampl. 3	Contr.(1) conta.	Contr. -	Contr. +
Number of plaques 1	0	0	0	/	0	A lot
Number of plaques 2	0	0	0	/	0	A lot
Number of plaques 3	0	0	0	/	0	A lot
Retaining screen specifications	Metallic screen					

(1) : Control of contamination (only when the sample can't be sterilized)

Sample	Replicate	Results
V600133	1	Pass
	2	Pass
	3	Pass
V600134	1	Pass
	2	Pass
	3	Pass
V600135	1	Pass
	2	Pass
	3	Pass
V600136	1	Pass
	2	Pass
	3	Pass
V600137	1	Pass
	2	Pass
	3	Pass
V600138	1	Pass
	2	Pass
	3	Pass

Ansell

Technical Glove Xperts

Touch N Tuff® 92 -600.605

Herewith, I confirm that the Ansell Touch N Tuff® 92 -600.605 gloves are made from nitrile. They do not contain natural rubber and hence are free from any latex proteins which are known to cause allergens to sensitized people.

Ann Van den Borre
Technical Manager
Ansell Healthcare Europe

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ISO 9001 Certificate Number FM 40130

Permeation breaktrough times according to EN374-3:2003 (minutes)

Glove :

Touch N Tuff® 92-605

	Chemical Agent	Breakthrough Time	Protection Index	CAS Number	Notified Body	EN Standard
	1,1,1-trichloro-2-methyl-2-popyl alcohol in Peanut oil	> 480	6		Centexbel	374-3:2003
	1,2-dichloroethane	< 20	0	107-06-2	Centexbel	374-3:2003
	1-Iododecane	> 60	3	2050-77-3	Force Technology	374-3:2003
	1-Methoxy-2-Propanol	14	1	107-98-2	Centexbel	374-3:2003
	Acetic Acid, Glacial	7	0	64-19-7	Centexbel	374-3:2003
	Acetone	0.5	0	67-64-1	Force Technology	374-3:2003
	Acetonitrile	< 5	0	75-05-8	Centexbel	374-3:2003
	Acetonitrile 73% + Methyl Alcohol 25% + Ammonia 2%	1	0		Centexbel	374-3:2003
	Acrylamide, 40%	> 480	6	79-06-1	Force Technology	374-3:2003
	Acrylic Acid	< 5	0	79-10-7	Centexbel	374-3:2003
	Allylchloride	70	3	107-05-1	Centexbel	374-3:2003
	Ammonium Hydroxide, 25%	29	1	1336-21-6	Centexbel	374-3:2003
	Anioxyde 1000	> 480	6		Force Technology	374-3:2003
	Benzyl Alcohol	10	0	100-51-6	Centexbel	374-3:2003
	Bromochloromethane	88	3	74-97-5	Centexbel	374-3:2003
	Butyl Alcohol	> 480	6	71-36-3	Centexbel	374-3:2003
	Cacodylic acid Sodium salt buffer 0,1M	> 480	6		Centexbel	
	Caffeine 1.6%	> 480	6	58-08-2	Centexbel	374-3:2003
	Carbon disulfide	< 5	0	75-15-0	Centexbel	374-3:2003

Permeation breaktrough times according to EN374-3:2003 (minutes)						
0	1	2	3	4	5	6
< 10	10-30	30-60	60-120	120-240	240-480	> 480
Not recommended	Splash protection		Medium protection		High protection	

Data given in the table above are based on results of laboratory tests performed on the palm area of the glove or are based on extrapolations from the results of laboratory tests. These tests were run using standard test methods that may not adequately replicate any specific conditions of end use. Because Ansell has no detailed knowledge or control over the conditions of end use, any of these data must be advisory only, and Ansell must decline any liability.

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Permeation Breakthrough Times

Material & Thickness	Polychloroprene (0,12mm)	Nitrile (0,12 mm)	Latex (0,12 mm)
Productname	NeoTouch®	Touch N Tuff®	Conform®+
Permeation breakthrough time (minutes)			
70% Isopropanol (CAS 67-63-0)	>60	>60	<10
70% Methanol (CAS 67-56-1)	<10	<10	<10
70% Ethanol (CAS 64-17-5)	14	27	<10
Disinfectants based on quaternary ammonium compounds	>480	>480	>480
70% Ethanol with 0,125% H2O2	>10	>10	<10

Permeation breakthrough times according to EN374 (minutes)

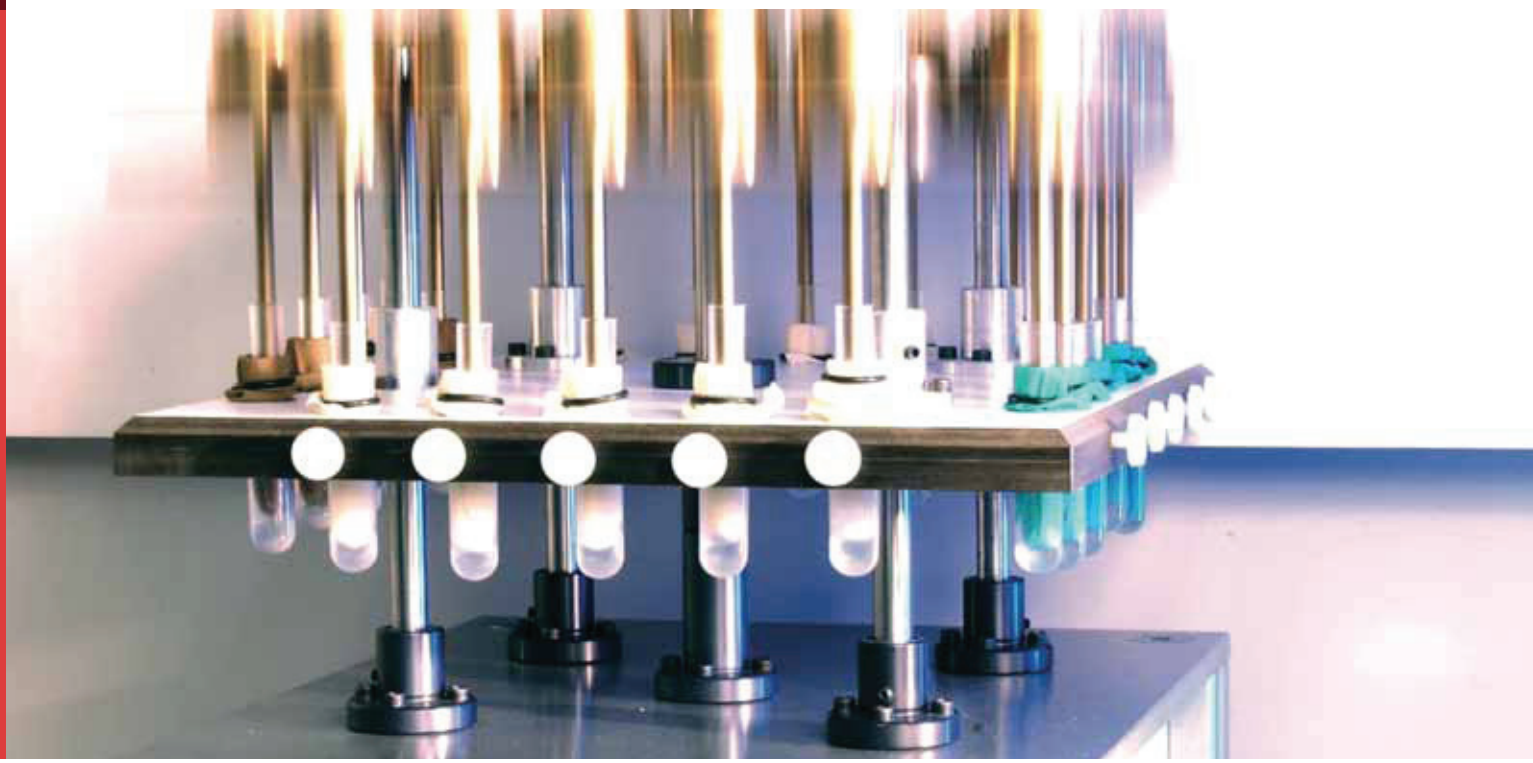
0	1	2	3	4	5	6
< 10	**10-30**	**30-60**	**60-120**	**120-240**	**240-480**	**> 480**
Not recommended	Splash protection		Medium protection		High protection	

Data given in this recommendation are based on results of laboratory tests performed on the palm area of the glove or are based on extrapolations from the results of laboratory tests. These tests were run using standard test methods that may not adequately replicate any specific conditions of end use. Because Ansell has no detailed knowledge or control over the conditions of end use, any of these data must be advisory only, and Ansell must decline any liability.

Style	Size	Product Name	ASPN	Tariff Code	UOM	Alt. UOM	Quantity per Case	Cases per pallet	Case Length (cm)	Case Width (cm)	Case height (cm)	Case weight (kg)	Bar code for the smallest packaging unit	Bar code for the inner polybag or the shipper
92-605	6.5-7	Touch N Tuff® Long Cuff	588954	4015190000	Case	Piece	1000		47	26	30		0076490483463	20076490483467
92-605	7.5-8	Touch N Tuff® Long Cuff	588955	4015190000	Case	Piece	1000		47	26	30		0076490483456	20076490483450
92-605	8.5-9	Touch N Tuff® Long Cuff	588956	4015190000	Case	Piece	1000		47	26	30		0076490483449	20076490483443
92-605	9.5-10	Touch N Tuff® Long Cuff	588957	4015190000	Case	Piece	1000		47	26	30		0076490483432	20076490483436
92-605	10.5-11	Touch N Tuff® Long Cuff	588958	4015190000	Case	Piece	1000		47	26	30		0076490482671	20076490482675

ACPP: Ansell Chemical Permeation Program

Ansell invests for your protection and information



In partnership with the
Université Catholique de Louvain
Brussels - Belgium

Ansell

Why the ACPP?

According to the World Health Organization, between now and 2020 the cancer rate is going to increase by 50 % to about 15 million new cases a year worldwide.

This predicted sharp increase in new cases will mainly be due to the existence of steadily ageing populations in both developed and developing countries, but also to the current prevalence of smoking and the rise in numbers of those adopting unhealthy lifestyles.

One of the most frequently used treatments for cancer is chemotherapy.
Unfortunately it is well known that cytostatic agents are potentially hazardous for the manipulator (pharmacist, assistant, nurse, surgeon (HIPEC technique) etc.).

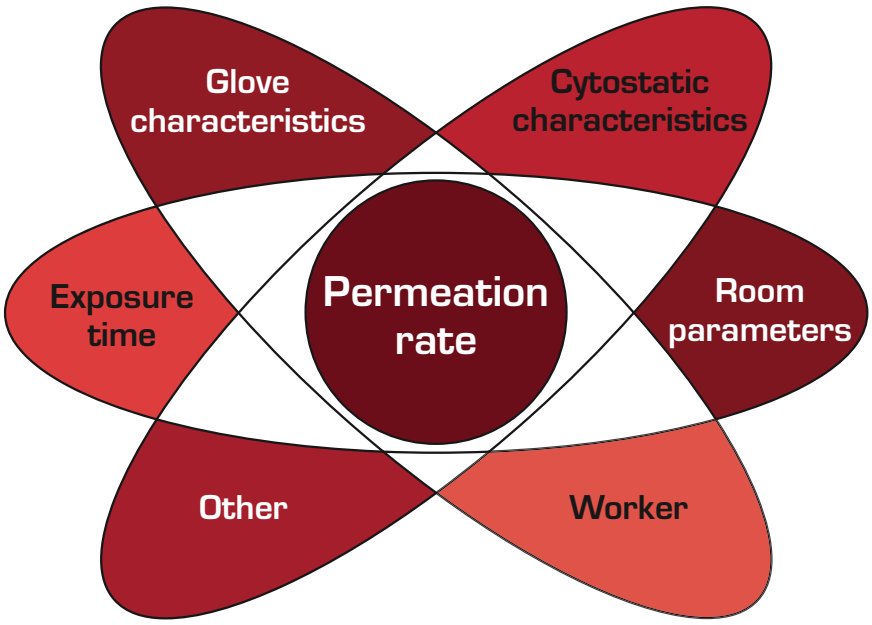
Cytostatics are known to be:
- Mutagenic
- Carcinogenic
- Teratogenic.

Some of the other potential effects are:
- Decrease in fertility
- Foetal malformation
- Abortion
- Extra uterine pregnancy
- High toxicity for certain organs.

ACPP project goals:

- To contribute to better protection for healthcare personnel handling cytostatics
- To present results corresponding to real life conditions or, better still, to worst case scenarios (dynamic treatment & cytostatic concentration)
- To be innovative & bring very practical answers to our customers

Permeation: a very complex process



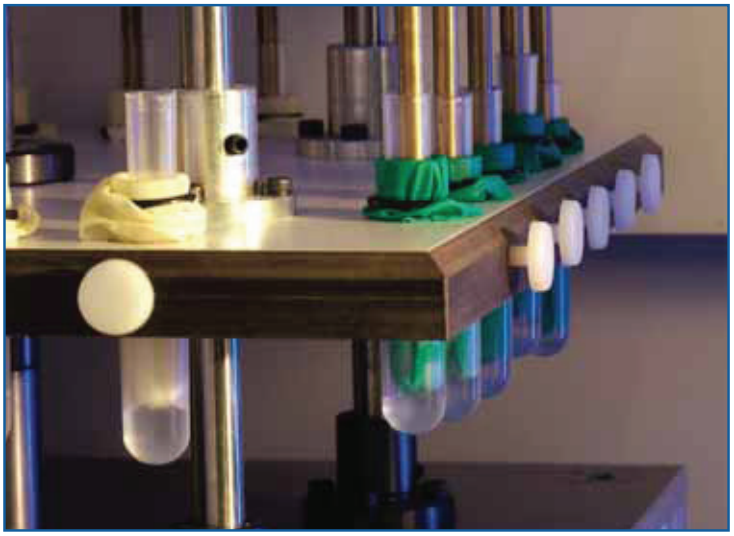
Permeation depends on many parameters and therefore the results obtained cannot be extended to any other material, brand or competitive product.

Dynamic Permeation Device

In order to ensure your maximum protection when handling cytostatics, Ansell has invested in a totally new permeation assessment protocol.

Because gloves are made to be used under dynamic physical conditions (stretching, tension, rubbing etc.) we thought at Ansell that it was our duty to test some of our products for cytostatic permeation under the same constraints.

In partnership with the Université Catholique de Louvain, Brussels, Belgium, we have developed a UNIQUE dynamic permeation device. After dynamic permeation simulation, aliquots of the collecting medium are analysed by LC-MS/MS* or HPLC-DAD*



Dynamic permeation device

The molecules tested are the following

	Cytostatic	Brand name	Company	Analytical method	Concentration	LOD (Detection limit)	LOQ (Quantification limit)	Mol. Weight	Log P
1	Carmustine (25°C)	Nutrimon BICNU	Almirall-Prodesfarma	HPLC-DAD	3.0 mg/ml	59.02 ng/ml	196.73 ng/ml	214.0	1.50
2	Cisplatin (25°C)	Platinol	Bristol-Myers Squibb	HPLC-DAD	1.0 mg/ml	49.70 ng/ml	165.67 ng/ml	300.1	300.1
3	Cyclophosphamide (25°C)	Endoxan	AstaMedica	LCMS/MS	20.0 mg/ml	1.95 ng/ml	31.60 ng/ml	261.1	0.60
4	Cytarabine (25°C)	Cytosar	Pharmacia & UpJohn	LCMS/MS	100.0 mg/ml	0.97 ng/ml	4.93 ng/ml	243.2	- 2.50
5	Docetaxel (25°C)	Taxotere	Aventis Pharma	LCMS/MS	10.0 mg/ml	3.11 ng/ml	17.32 ng/ml	807.8	NA
6	Doxorubicin (25°C)	Adriblastina	Pharmacia	LCMS/MS	2.0 mg/ml	35.26 ng/ml	55.10 ng/ml	543.5	1.30
7	Etoposide (25°C)	Vepesid	Bristol-Myers Squibb	HPLC-DAD	20.0 mg/ml	63.06 ng/ml	210.19 ng/ml	588.5	0.60
8	5-Fluorouracil (25°C)	Fluoroblastine	Pharmacia & UpJohn	HPLC-DAD	50.0 mg/ml	37.47 ng/ml	124.92 ng/ml	130.1	- 1.00
9	Ifosfamide (25°C)	Holoxan	AstaMedica	LCMS/MS	100.0 mg/ml	4.11 ng/ml	45.11 ng/ml	261.1	NA
10	Irinotecan (25°C)	Campto	Aventis Pharma	LCMS/MS	20.0 mg/ml	16.32 ng/ml	30.73 ng/ml	586.6	NA
11	Methotrexate (25°C)	Ledertrexate	Wyeth Lederle	LCMS/MS	25.0 mg/ml	1.41 ng/ml	12.85 ng/ml	454.4	- 1.80
12	Thiotepa (25°C)	Ledertepa	AstaMedica	LCMS/MS	10.0 mg/ml	3.06 ng/ml	17.36 ng/ml	189.2	0.50
13	Vinorelbine (25°C)	Navelbine	Pierre Fabre	LCMS/MS	10.0 mg/ml	6.48 ng/ml	43.72 ng/ml	779.9	16.00
14	Mitomycin C (43°C)	Mitomycin C	Nycomed Belgium	HPLC-DAD	0.4 mg/ml	12.80 ng/ml	42.50 ng/ml	318.0	NA
15	Oxaliplatin (43°C)	Eloxatin	Sanofi-Synthelabo	HPLC-DAD	5.0 mg/ml	19.00 ng/ml	64.00 ng/ml	397.3	NA
16	Paclitaxel (37°C) *	Taxol	Bristol-Myers Squibb	HPLC-DAD	6.0 mg/ml	37.50 ng/ml	125.00 ng/ml	853.9	NA
17	Ganciclovir (37°C)	Cymevene	Roche	LCMS/MS	50.0 mg/ml	6.00 ng/ml	20.00 ng/ml	255.2	- 1.60

** LC-MS/MS: Liquid Chromatography Tandem Mass Spectrometry*

** HPLC -DAD: High Pressure Liquid Chromatography - Diode Array Detection*

Ansell Gloves Cytostatics permeation chart

Contact time		CE Gloves				Lab Gloves		
		DermaShield® 73-701 (Neopr.)	AccuTech® Sterile UltraClean 91-210	AccuTech® Sterile Coated 91-250	AccuTech® Gammex® 91-225 (NRL)	NeoTouch® (Neopr.)	Touch N Tuff® (Nitrile)	Nitrilite® 93-311
15 min	Carmustine	4	4	3	6	6	2	3
	Cisplatine	6	6	6	6	6	3	6
	Cyclophosphamide	6	6	4	4	5	4	6
	Cytarabine	6	5	6	6	6	6	6
	Docetaxel	6	4	6	6	5	6	6
	Doxorubicin	6	4	6	6	6	6	5
	Etoposide	6	6	3	3	6	6	6
	5-Fluorouracil	6	5	3	2	6	3	6
	Ifosfamide	6	4	4	4	4	4	6
	Irinotecan	4	4	4	5	4	4	5
	Methotrexate	6	6	6	6	6	4	6
	Mitomycin C	6	5	4				6
	Oxaliplatin	6	6	6				6
	Paclitaxel	6	6	6				6
	Thiotepa	6	5	6	5	4	5	6
	Vinorelbine	4	6	6	6	4	6	4
	Ganciclovir	6	6	6				6
30 min	Carmustine	3	4	2	2	6	2	3
	Cisplatine	6	3	3	6	6	3	6
	Cyclophosphamide	5	6	4	4	5	4	5
	Cytarabine	4	6	6	6	6	6	6
	Docetaxel	5	4	5	5	5	5	5
	Doxorubicin	6	4	5	6	6	4	5
	Etoposide	6	4	3	2	6	2	4
	5-Fluorouracil	6	5	3	2	6	3	4
	Ifosfamide	4	4	4	4	4	4	5
	Irinotecan	4	4	4	4	4	4	5
	Methotrexate	5	5	5	6	5	4	6
	Mitomycin C	4	5	4				5
	Oxaliplatin	6	5	5				5
	Paclitaxel	4	4	4				4
	Thiotepa	5	4	4	5	4	5	6
	Vinorelbine	4	6	6	6	4	6	4
	Ganciclovir	5	5	5				5
60 min	Carmustine	3	2	1	2	6	2	3
	Cisplatine	6	3	3	6	6	3	6
	Cyclophosphamide	5	5	4	3	4	4	3
	Cytarabine	4	6	6	6	6	6	5
	Docetaxel	5	4	5	5	5	4	5
	Doxorubicin	6	4	5	6	6	4	5
	Etoposide	4	4	3	2	6	2	4
	5-Fluorouracil	6	5	3	2	4	3	4
	Ifosfamide	4	4	4	4	3	4	5
	Irinotecan	4	4	4	4	4	3	4
	Methotrexate	5	5	5	6	5	4	6
	Mitomycin C	4	5	4				5
	Oxaliplatin	4	5	5				5
	Paclitaxel	4	4	4				4
	Thiotepa	5	4	4	5	4	5	5
	Vinorelbine	4	4	5	6	4	5	4
	Ganciclovir	4	5	5				5

Key to Protection level

- Level 1 : Permeation detected above to 10 times below EN374-3 limit requirement
- Level 2 : Permeation detected 10 to 100 times below EN374-3 limit requirement
- Level 3 : Permeation detected 100 to 1.000 times below EN374-3 limit requirement
- Level 4 : Permeation detected 1.000 to 10.000 times below EN374-3 limit requirement
- Level 5 : Permeation detected 10.000 to 100.000 times below EN374-3 limit requirement
- Level 6 : > Permeation detected at least 100.000 times below EN374-3 limit requirement or no permeation measured

Permeation temperature indicator:
25°C 37°C 43°C

Results obtained at room temperature. These results are ONLY and SOLELY valid or the glove tested. Any extrapolation to other materials, brands or competitive products would be erroneous and NOT supported by Ansell.

European norm is EN374-3

Ansell Ansell Limited is a global leader in barrier protective products. With operations in the Americas, Europe and Asia, Ansell employs more than 11,000 people worldwide and holds leading positions in the natural latex and synthetic polymer glove and condom markets. Ansell operates in three main business segments: Occupational Healthcare, supplying hand protection to the industrial market; Professional Healthcare, supplying surgical and examination gloves to healthcare professionals; and Consumer Healthcare, supplying condoms and consumer hand protection.

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Fax Customer Service +32 (0) 2 528 74 03
http://www.ansell.eu - E-mail: info@ansell.eu

ZACPPOHCEN/ACPP leaflet OHC EN/3.000/05-08/Connexion

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2008

This is to certify that:

Ansell Lanka (Pvt) Limited
Biyagama Export Processing Zone
Biyagama
Sri Lanka

Holds Certificate No: **FM 11521**
and operates a Quality Management System which complies with the requirements of ISO 9001:2008 for the following scope:

The design and manufacture of sterile and non sterile natural latex and synthetic surgeons gloves.
The provision of a sterilisation service.
The design and manufacture of Industrial gloves.

For and on behalf of BSI:

Managing Director, Pharithacha Petchrungruengphol

Originally registered: **01/02/1991** Latest Issue: **17/09/2010** Expiry Date: **27/09/2013**

Certificate No: **FM 11521**

Location	***Registered Activities***
Ansell Lanka (Pvt) Limited Biyagama Export Processing Zone Biyagama Sri Lanka	The design and manufacture of sterile and non sterile natural latex and synthetic surgeons gloves. The provision of a sterilisation service. The design and manufacture of Industrial gloves.

Originally registered: **01/02/1991** Latest Issue: **17/09/2010** Expiry Date: **27/09/2013**

Ansell

Technical Glove Xperts

Touch N Tuff® EN455

Herewith, I confirm that the Touch N Tuff® 92-605 gloves are in conformity with the requirements of the European harmonised standard EN455-1:2000 part 1.

Ann van den Borre
Technical Manager
Ansell Healthcare Europe

Ansell Healthcare Europe N.V.
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BSI REGISTERED UKAS QUALITY MANAGEMENT 003

ISO 9001 Certificate Number FM 40130

Ansell Healthcare Europe N.V.
Riverside Business Park | Block J | Tel. 32 (0)2-528 74 00
Boulevard International 55 | B-1070 Brussels | Fax 32 (0)2-528 74 01

EC DECLARATION OF PRODUCT CONFORMITY

The manufacturer, established in the European Economic Community:

ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS

declares that the PPE described hereafter:

Touch N Tuff®

92-605

Testing performed in accordance to the worst foreseeable conditions of end-use (2 hours, 40°c).

is in conformity with the provisions of the EC-Regulation 1935/2004 and with the EC-Regulation 2023/2006 related to Good Manufacturing Practices (GMP) for Materials and Articles intended to come in contact with Foodstuffs.

Guido VAN DUREN

Director Technical Services

ANSELL HEALTHCARE EUROPE N.V.

Technical Department

Declaration of Conformity

Good Manufacturing Practices for Ansell's materials and articles intended to come in contact with food

Herewith, the undersigned declares that all Ansell gloves, that are intended for contact with Food products, are manufactured in accordance to the following requirements :

1. **Regulation 1935/2004**

- Gloves are sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties.

- Gloves are made with only legally acceptable Food-contact ingredients and do not exceed any legal migration levels based on the intended use of the product.
Raw materials used in the production of the gloves are specified safe for food contact, have GRAS (Generally Recognized As Safe) status, and are procured from an approved supplier.

2. **Regulation 2023/2006:**

- Gloves are made as per 'Good manufacturing practice (GMP)' meaning they are consistently produced and controlled to ensure conformity with the applicable rules and applicable quality standards.
This applies to all activities ; from procurement through approved suppliers of materials and all aspects of manufacturing, processing, handling, storage, transport and distribution of the finished article.

- The manufacturing plant has a documented and effective quality assurance system with the purpose of ensuring that materials and articles are of the quality required to ensure conformity with the rules applicable to them and the quality standards necessary for their intended use.

- The qualifications and training of personnel at manufacturing is documented. As well, the manufacturing facility and equipment is designed, cleaned, and maintained as necessary to ensure that in process materials and finished glove products comply with their specifications. Inherent in these requirements are personnel hygiene, pest control, contamination control, prevention of material damage from the environment, etc., etc.

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ISO 9001 Certificate
Number FM 40130

Ansell

Technical Department

- The manufacturing plant has conducted a formal risk analysis according to an established procedure (ISO 22000 employs HAACP Hazard Analysis Critical Control Points), and evaluate each proposed change to the documented system for its impact on risk to the user of the finished article.

- The manufacturing plant has an effective quality control system and a documented system of tests, inspections, document reviews and formal dispositions on raw materials, in process materials and finished articles. This system include clear decision criteria on materials and articles not meeting specifications.

- The manufacturing's quality control system monitors compliance to Good Manufacturing Practices and correct any failure to comply with GMP without delay. These corrective measures will be made available to competent authorities when relevant.
Ansell shall ensure adherence to the effective implementation of GMP through review of the supplier's internal audit system as described in the ISO 9001 Quality Management System.

- The manufacturing site maintains electronic or paper documents of specifications, manufacturing formulae, and processing necessary to achieve regulatory compliance and product safety.

- Finished articles must be labeled with a unique control number, which relates to specific records held by the manufacturer.

- When requested, the above documents are made available to both Ansell auditors and competent external authorities.

- Restrictions on printing inks, where relevant, are being considered in product formulation and design, and must be applied from the time of printing until final article distribution.

Guido VAN DUREN
Technical Services Director
ANSELL HEALTHCARE EUROPE

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BSI REGISTERED UKAS QUALITY MANAGEMENT 003
ISO 9001 Certificate Number FM 40130

Ansell

Technical Glove Xperts

Touch N Tuff® 92-600.605

Herewith, I confirm that the Ansell Touch N Tuff® 92-600.605 gloves are in compliance with the essential safety & health requirements as outlined by the European Directive 89/686/EEC and relevant EN standards and, as such, can be considered as harmless when the gloves are used according to their intended purpose (= mechanical protection).

This also means that these gloves are compliant to the requirements outlined in EN 420:2003; i.e.

1. pH = close to neutral
2. The ingredients and materials inside the gloves do not adversely affect the users health.

In addition, we can also confirm that these above mentioned gloves are:

- Free from Chromium VI and Nickel
- Free from any ingredients which are considered as Substances of High Concern as per the REACH Regulation 1907/2006
- Free from any releasable Carcinogenic, Mutagenic and Reprotoxic substances
- Free from any heavy metals
- Free from any azo-or carcinogenic colorants
- Free from any DMF or other releasable solvents

Please consult the technical data sheet of this glove for further details.

Ann Van den Borre
Technical Manager
Ansell Healthcare Europe

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BSI REGISTERED UKAS QUALITY MANAGEMENT 003
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INSTRUCTIONS FOR USE
CATEGORY III / COMPLEX DESIGN

EN

ANSELL DISPOSABLE AND CRITICAL ENVIRONMENT GLOVES

A. Use
This Instruction for Use note is to be used in combination with the specific information that is mentioned on or inside each packaging enclosure.
These gloves are designed as single use gloves and should be disposed of after use. The gloves are liquid proof, and can therefore be used for splash protection against certain chemicals.
They are in conformity with, and are marked per the requirements of the European Directive 89/686/EEC and its amendments. They also comply with the applicable European Standards.
Gloves which are accompanied with the pictogram which designates contact with foodstuffs, are also in conformity with the European Regulations 1935/2004 and 2023/2006 as well as with all applicable National Regulations for Food-contact materials.
Please ensure the gloves are used only for the designated purposes.

Explanation of pictograms:

A B C D EN 388: 2003 Protection from mechanical risks	A: Abrasion resistance B: Cut resistance C: Tear resistance D: Puncture resistance	A B C D E FGHIJKL EN 374: 2003 Chemical breakthrough time > 30 minutes against :	A = methanol B = acetone C = acetonitrile D = dichloromethane E = carbon disulfide F = toluene G = diethylamine H = tetrahydrofurane I = ethyl acetate J = n-heptane K = sodium hydroxide, 40% L = sulphuric acid, 96%
EN 374: 2003 Protection against micro-organisms (AQL ≤ 1.5)	EN 374: 2003 Liquidproof gloves. Chemical resistance data available upon request.	EN 421 Protection against radio-active contamination	Suitable for contact with foodstuffs

Warning! The information given in the pictograms or data provided on chemical resistant breakthrough times is based on lab tests and is therefore advisory only since it does not necessarily reflect the actual duration in the workplace.
EC-Type examination certificate from Centexbel Belgium (I.D. 0493), Technologiepark 7, B-9052 Zwijnaarde.
For more detailed information on the glove's performance and to obtain a copy of the Conformity Declaration, please consult Ansell.

B. Precautions for use
1. Before usage, inspect the gloves for any defects or imperfections. If the gloves are ripped or punctured during use, dispose of them immediately. If in doubt, do not use the gloves, get a new pair.
2. If the gloves are used against chemicals, it is essential to keep all chemicals from the skin, even if they are thought to be harmless. Therefore use gloves which are rated with a protection index of 6 or with an excellent degradation resistance rating. In all other cases, the gloves should be used for splash protection or short contact only. Ensure that chemicals cannot enter via the cuff. For more details regarding chemical suitability, please contact the Ansell Technical department.
3. Avoid wearing gloves which are dirty on the inside – they may irritate the skin causing dermatitis or worse.
4. Contaminated gloves should be cleaned or washed before removal.
5. The gloves should not be used in applications requiring thermal protection.
6. Disposable glove type versions with a glove length below 260 mm are 'Fit for Special Purpose gloves' because they are to be used to protect the hand ONLY from chemical splashes when handling chemicals. Do not use the gloves when protection in the cuff area is needed.
7. Gloves shall not be used for protection against ionising radiation nor for use in containment enclosures.
8. Not all gloves that are suitable for contact with foodstuffs can be used against all foodstuffs. Some gloves may show excessive migration towards certain types of foodstuffs. To know which restrictions apply and for which specific foodstuffs the gloves can be used, please obtain advise from the Ansell technical department or consult the Ansell Food Conformity declaration.
9. If gloves are marked, the printed surfaces shall not come in contact with food.

C. Ingredients / Hazardous ingredients
Some gloves might contain ingredients which are known to be a possible cause of allergies in sensitised persons, who may develop irritant and/or allergic contact reactions. If allergic reactions should occur, obtain medical advice immediately.
For more information, please contact Ansell's Technical department.

D. Care instructions
Storage: Keep away from direct sunlight; store in a cool dry place.
Keep away from ozone sources or naked flame.
Cleaning: The gloves are not designed to be laundered.

E. Disposal
Used gloves may be contaminated with infectious or other hazardous materials.
Dispose of according to Local Authority Regulations.
Landfill or incinerate under controlled conditions.

09/2009

Ansell

Ansell

Ansell's **pharmaceutical** range for **laboratory** and **cleanroom** environments

For laboratory environments requiring safety and consistent product quality

For applications such as non-sterile drug manufacturing, medical device manufacturing that requires the use of a personal protective glove, bio-technology, laboratory analysis and laboratory work we offer:

Latex	69-150 Conform®+ powder-free
Nitrile	92-600 & 92-605 Touch N Tuff® powder-free
	92-670 & 92-665 TNT® Blue
Neoprene	25-101 NeoTouch®
	25-201 NeoTouch® Long

These gloves are ambidextrous, and packed in lots of 100pcs in cardboard dispensers.
We maintain relevant product information on these gloves, such as:
- Technical information
- Lot traceability

For controlled and critical environments that require a low tolerance level of airborne particles

For pharmaceutical and medical device manufacturing, and drug manufacturing applications that do not require sterile conditions, and that require the use of a personal protective glove, we offer:

Latex	91-104 AccuTech® Ambi UltraGrip (2)
	91-325 AccuTech® Gammex®
	91-250 AccuTech® Sterile Coated
Nitrile	93-311 Nitrilite® (2)
	93-401 Nitrilite® Silky Ultra-Clean (2)
Neoprene	73-701, 73-711 & 73-721 DermaShield®

We make technical data and certification information available online, via the Internet, on:
- Lot numbers
- Certificates of analysis
- Historical trend data
- (2) Particle count and extractables Packaging
- No paper contamination
- PE packaging
- IPA-resistant

For sterile environments ISO 5 (Class 100) required for aseptic drug manufacturing

For these applications we offer gloves that are both sterile and clean:

Latex	91-225 AccuTech® Gammex® Sterile
	91-250 AccuTech® Sterile Coated
Neoprene	73-701 & 73-711 DermaShield®

In compliance with the relevant ASTM* standards, we can provide you with the following, on request:
- Gamma Irradiation certificates
- Certificates of analysis
- (2) Particle count and extractables

* ASTM is the American equivalent of EN standards, which we refer to when we do not have an EN equivalent.

For more details about Ansell's pharmaceutical industry product range, please contact:

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