HYGISUN®

by INTCO

Untersuchungshandschuhe
Disposable Nitrile Exam Gloves

CE MD

EN 455 EN 374 EN 420

EN ISO:374-5: 2016 VIRUS

EN ISO:374-1: 2016 Type B KPT

Not for acidic food

AQL 1.5

Nitril / Puderfrei / Unsteril

Nitrile / Powder free / Non sterile

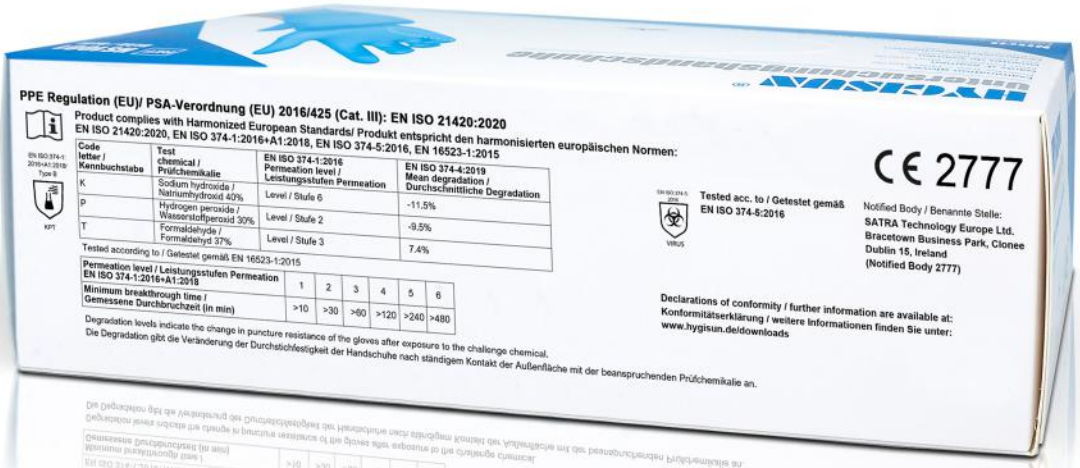
REF

S	M	L	XL
Größe	Größe	Größe	Größe
SNVE10014	SNVE10015	SNVE10016	SNVE10017


HYGISUN®
Untersuchungshandschuhe
Examination gloves
Powder free / Non sterile
Gants d' examen
Non poudrés / Non stérile
Guantes de examen
Sin polvo / No estériles
Onderzoekshandschoenen
Poedervrij / Niet steril
OPEN HERE
REF SNVE10015
BLAU / BLUE
Nitril
Puderfrei / Unsteril
Medizin- & Schutzhandschuh
Beachten Sie vor der Verwendung die Anweisungen und Vorsichtsmaßnahmen auf der Verpackungsunterseite.
Consult the instructions and cautions on the bottom of the box before using.
HYGISUN®
Untersuchungshandschuhe
Quatified acc. to
EN 374 & EN 455
100 Stk.
CE
MD
AQL 1.5
EN 455
EN 374
Beachten Sie vor der Verwendung die Anweisungen und Vorsichtsmaßnahmen auf der Verpackungsunterseite.
Medical Device


HYGISUN®
Untersuchungshandschuhe
Nitril / Puderfrei / Unsteril
Medizin- & Schutzhandschuh
100 Stk.
EN 455
EN 374
Beachten Sie vor der Verwendung die Anweisungen und Vorsichtsmaßnahmen auf der Verpackungsunterseite.
Medical Device
6 972940 817137


HYGISUN®
Untersuchungshandschuhe
Nitril / Puderfrei / Unsteril
Medizin- & Schutzhandschuh
100 Stk.
INTCO
Shandong INTCO Medical Products Co., Ltd.
www.intcomedical.com
Qiwang Road, Naoshan Industrial Park,
Qingzhou, Shandong, P.R. China
EC REP
Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
peter@lotusnl.com
Importeur
Sunbeam International GmbH
Schumanstr. 12, 52146 Würselen,
Germany
Tel: 0049-2405-603980
Mail: info@sunbeam-international.de
www.hygisun.de
M
Größe



PPE Regulation (EU)/ PSA-Verordnung (EU) 2016/425 (Cat. III): EN ISO 21420:2020

Product complies with Harmonized European Standards/ Produkt entspricht den harmonisierten europäischen Normen:
EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016, EN 16523-1:2015

EN ISO 374-1:2016+A1:2018/ Type B

KPT

Code letter / Kennbuchstabe	Test chemical / Prüfchemikalie	EN ISO 374-1:2016 Permeation level / Leistungsstufen Permeation	EN ISO 374-4:2019 Mean degradation / Durchschnittliche Degradation
K	Sodium hydroxide / Natriumhydroxid 40%	Level / Stufe 6	-11.5%
P	Hydrogen peroxide / Wasserstoffperoxid 30%	Level / Stufe 2	-9.5%
T	Formaldehyde / Formaldehyd 37%	Level / Stufe 3	7.4%

Tested according to / Getestet gemäß EN 16523-1:2015

Permeation level / Leistungsstufen Permeation EN ISO 374-1:2016+A1:2018	1	2	3	4	5	6
Minimum breakthrough time / Gemessene Durchbruchzeit (in min)	>10	>30	>60	>120	>240	>480

Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.
Die Degradation gibt die Veränderung der Durchstichfestigkeit der Handschuhe nach ständigem Kontakt der Außenfläche mit der beanspruchenden Prüfchemikalie an.

EN ISO 374-5 2016 VIRUS

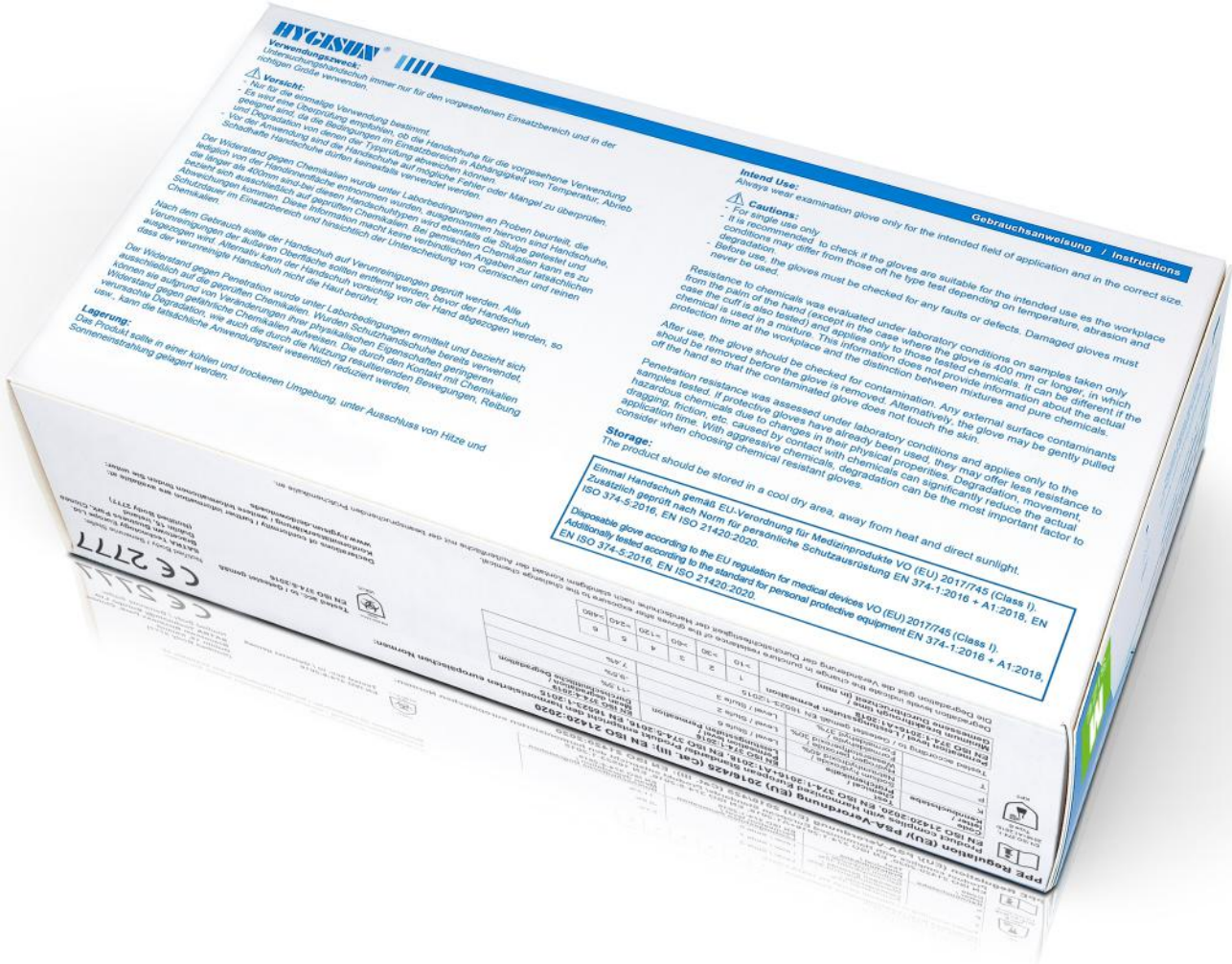
Tested acc. to / Getestet gemäß EN ISO 374-5:2016

CE 2777

Notified Body / Benannte Stelle:
SATRA Technology Europe Ltd.
Bracetown Business Park, Clonee
Dublin 15, Ireland
(Notified Body 2777)

Declarations of conformity / further information are available at:
Konformitätserklärung / weitere Informationen finden Sie unter:
www.hygisun.de/downloads


HYGISUN®
Disposable Nitrile Exam Gloves
Nitrile / Powder free / Non sterile
Medical & Personal Protective
M
SIZE
LOT XXXXXX
2021-0X
202X-0X
100 Pcs
CE


HYGISUN
Gebrauchsanweisung / Instructions
Verwendungszweck:
Untersuchungshandschuh immer nur für den vorgesehenen Einsatzbereich und in der richtigen Größe verwenden.
Vorsicht:
- Nur für die einmalige Verwendung bestimmt.
- Es wird eine Überprüfung empfohlen, ob die Handschuhe für die vorgesehene Verwendung geeignet sind. Dies ist Typprüfung abweichen können.
- Vor der Anwendung sind die Bedingungen im Einsatzbereich in Abhängigkeit von Temperatur, Abrieb und Degradation die Bedingungen, unter denen der Handschuhtyp wird ausgenommen hervor sind Handschuhe, Schadhafte Handschuhe dürfen keinesfalls verwendet werden.
Der Widerstand gegen Chemikalien wurde unter Laborbedingungen an Proben beurteilt, die lediglich von der Handinnenfläche entnommen wurden. Bei gemischten Chemikalien kann es zu Abweichungen kommen. Dieser geprüften Handschuhtypen wird ebenfalls die Stulpe getestet und die länger als 400mm sind bei diesen Handschuhtypen nicht die Haut berührt.
Nach dem Gebrauch sollte der Handschuh auf Verunreinigungen geprüft werden. Alle Verunreinigungen der äußeren Oberfläche sollten entfernt werden, bevor der Handschuh ausgezogen wird. Alternativ kann der Handschuh verschärft von der Hand abgezogen werden, so dass der verunreinigte Handschuh nicht die Haut berührt.
Der Widerstand gegen Penetration wurde unter Laborbedingungen ermittelt und bezieht sich ausschließlich auf die geprüften Chemikalien. Würden Schutzhandschuhe bereits verwendet, können sie aufgrund von Veränderungen ihrer physikalischen Eigenschaften geringeren Widerstand gegen gefährliche Chemikalien aufweisen. Die durch den Kontakt mit Chemikalien verursachte Degradation, wie auch die durch die Nutzung resultierenden Bewegungen, Reibung usw. kann die tatsächliche Anwendungszeit wesentlich reduziert werden.
Lagerung:
Das Produkt sollte in einer kühlen und trockenen Umgebung, unter Ausschluss von Hitze und Sonneneinstrahlung gelagert werden.
Intend Use:
Always wear examination glove only for the intended field of application and in the correct size.
Cautions:
- For single use only
- It is recommended, to check if the gloves are suitable for the intended use es the workplace conditions may differ from those off he type test depending on temperature, abrasion and degradation.
- Before use, the gloves must be checked for any faults or defects. Damaged gloves must never be used.
Resistance to chemicals was evaluated under laboratory conditions on samples taken only from the palm of the hand (except in the case where the glove is 400 mm or longer, in which case the cuff is also tested) and applies only to those tested chemicals. It can be different if the chemical is used in a mixture. This information does not provide information about the actual protection time at the workplace and the distinction between mixtures and pure chemicals.
After use, the glove should be checked for contamination. Any external surface contaminants should be removed before the glove is removed. Alternatively, the glove may be gently pulled off the hand so that the contaminated glove does not touch the skin.
Penetration resistance was assessed under laboratory conditions and applies only to the samples tested. If protective gloves have already been used, they may offer less resistance to hazardous chemicals due to changes in their physical properties. Degradation, movement, dragging, friction, etc. caused by contact with physical properties. Degradation, movement, application time. With aggressive chemicals, degradation can be the most important factor to consider when choosing chemical resistant gloves.
Storage:
The product should be stored in a cool dry area, away from heat and direct sunlight.
Einmal Handschuh gemäß EU-Verordnung für Medizinprodukte VO (EU) 2017/745 (Class I).
Zusätzlich geprüft nach Norm für persönliche Schutzausrüstung EN 374-1:2016 + A1:2018, EN ISO 374-5:2016, EN ISO 21420:2020.
Disposable glove according to the EU regulation for medical devices VO (EU) 2017/745 (Class I).
Additionally tested according to the standard for personal protective equipment EN 374-1:2016 + A1:2018, EN ISO 374-5:2016, EN ISO 21420:2020.
PPE regulation (EU) PSA-Verordnung (EU) 2016/425 (Cat. III): EN ISO 21420:2020
Produkt conform mit EN ISO 21420, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016, EN 16523-1:2015
Produkt conform mit EN ISO 21420, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016, EN 16523-1:2015
CE 2777


HYGISUN®
Untersuchungshandschuhe
Examination gloves
Powder free / Non sterile
Gants d' examen
Non poudrés / Non stérile
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Sin polvo / No estériles
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REF SNVE10015
BLAU / BLUE
Nitril
Puderfrei / Unsteril
Medizin- & Schutzhandschuh
Beachten Sie vor der Verwendung die Anweisungen und Vorsichtsmaßnahmen auf der Verpackungsunterseite.
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HYGISUN®
Untersuchungshandschuhe
Quatified acc. to
EN 374 & EN 455
100 Stk.
CE
EN 455
EN 374
Medical Device


HYGISUN®
Untersuchungshandschuhe
Nitril / Puderfrei / Unsteril
Medizin- & Schutzhandschuh
REF SNVE10015
CE
M
Größe
MD
NON STERILE
Not for acidic food
EN 455
EN 374
AQL 1.5
LATEX
BLAU
PPE Regulation (EU)/ PSA-Verordnung (EU) 2016/425 (Cat. III): EN ISO 21420:2020
Product complies with Harmonized European Standards/ Produkt entspricht den harmonisierten europäischen Normen:
EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016, EN 16523-1:2015
Tested acc. to / Getestet gemäß EN ISO 374-5:2016
VIRUS
Notified Body / Benannte Stelle:
SATRA Technology Europe Ltd.
Bracetown Business Park, Clonee
Dublin 15, Ireland
(Notified Body 2777)
CE 2777
Declarations of conformity / further information are available at:
Konformitätserklärung / weitere Informationen finden Sie unter:
www.hygisun.de/downloads
Mass: 335mm X 260mm X 250mm
Menge: 100 Packungen (100Stk./ Packung)
EAN (Box):
6 972940 817137
INTCO
Shandong INTCO Medical Products Co., Ltd.
www.intcomedical.com
Qinang Road, Nanshan Industrial Park,
Qingdao, Shandong, P.R. China
EC REP
Lotus NL B.V.
Noriksa fullstraulan 10, 1e Verd, 2595AK, The Hague, Netherlands
peter@lotusbl.com
Importeur
Sunbeam International GmbH
Schanzenstr. 12, 52068 Aachen, Germany
Tel. 0049-2405-802990
info@sunbeam-international.de
www.hygisun.de
M
Größe
LOT XXXXXX
2021-0X
202X-0X

INTCO
英科医疗

Document Number ：INTCO-CE-DC-NBR-001 Version: A/4

EU DECLARATION OF CONFORMITY

Manufacturer

Name: **Shandong Intco Medical Products Co., Ltd.**
Address: **Qiwang Road, Naoshan Industrial Park. Qingzhou, Shandong, China**

Authorized Representative

Name: **Lotus NL B.V.**

Address: **Koningin Julianaplein 10, le Verd, 2595AA， The Hague，Netherlands**

Declares that the MDR described hereafter

Product name and model:

Disposable Nitrile（NBR）Gloves

UMDNS code：11882

Model: XS /S /M /L /XL/XXL

UDI-DI:

Meet the provisions of the Council Regulation EU 2017/745 and Annex I which apply to them.

The medical device has been assigned to Class I, based on rule 1 of Annex VIII Chapter III of the Regulation EU 2017/745 MDR. It bears the mark

CE

This Declaration of conformity is valid for five years: 7 / May / 2020 to 6 / May / 2025. If there is a change in the declaration information, this declaration is invalid.

The above mentioned declaration of conformity is exclusively under the responsibility of
Company: Shandong Intco Medical Products Co., Ltd.
Address: Qiwang Road, Naoshan Industrial Park. Qingzhou, Shandong, China.

Shandong 2020-05-07

Place , date

Cui Zhongqiang Quality Manager

Legally binding signature, Function

INTCO
英科医疗

Document Number ：INTCO-CE-DC-NBR-001 Version: A/5

EU DECLARATION OF CONFORMITY

Manufacturer

Name: **Shandong Intco Medical Products Co., Ltd.**
Address: Qiwang Road NO.9888, Naoshan Industrial Park, Qingzhou, Shandong, China

Authorized Representative

Name: **Lotus NL B.V.**

Address: **Koningin Julianaplein 10, 1e Verd, 2595AA， The Hague，Netherlands**

Declares that the MDR described hereafter

Product name and model:

Disposable Nitrile Exam Gloves

EMDN code：T01020204

Model: XS /S /M /L /XL/XXL

Product Code: NGV/B/H/PEM 10013-10018, NGV/B/H/PEM 10023-10028, NGV/B/H/PEM 10033-10038, NGV/B/H/PEM 10043-10048, NGV/B/H/PEM 10053-10058.

Basic UDI-DI: 697024575Nitrile7G

SRN: CN-MF-000002100

This Declaration of Conformity is issued under the sole responsibility of the manufacturer: Shandong Intco Medical Products Co., Ltd.

Conformity Assessment Route：Annex II and Annex III according to EU 2017/745.

Applicable Standard:

EN ISO 13485:2016; EN 14971:2019; EN 1041:2008; EN 15223-1:2016;
EN 455-1:2020; EN 455-2:2015; EN 455-3:2015; EN 455-4:2009;
ISO 10993-1:2018; ISO 10993-10:2010. ISO 10993-11:2017.

Meet the provisions of the Council Regulation EU 2017/745 and Annex I which apply to them,

The medical device has been assigned to Class I, based on rule 1 & rule 5 of Annex VIII Chapter III of the Regulation EU 2017/745 MDR. It bears the mark

CE

We agree to develop, implement and maintain a documented post-production monitoring process.

Rick cheng

Shandong 2021-04-12 Rick Cheng Quality Manager

Place , date *Legally binding signature, Function*

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Shandong Intco Medical Products Co., Ltd.

Main Site: Qiwang Road No.9888, Naoshan Industrial Park, Qingzhou City, Shandong Province, 262500, P. R. China

has been registered by Intertek as conforming to the requirements of:

ISO 13485:2016

The management system is applicable to:

Manufacture of non-sterile NBR (Nitrile Butadiene Rubber) and PVC (Poly Vinyl Chloride) medical examination gloves.

Certificate Number:
0086238-01

Initial Certification Date:
28 April 2014

Date of Certification Decision:
9 January 2021

Issuing Date:
9 January 2021

Valid Until:
31 December 2021

ISO 13485:2016 CERTIFICATION ™
Intertek

SCC Accredited CB-MS
OCSM Accrédité CCN ™

Calin Moldovean
President, Business Assurance

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T 3J1,
Canada

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Shandong Intco Medical Products Co., Ltd

No.9888, Qiwang Road, Naoshan Industrial Park, Qingzhou City, Shandong Province, P. R. China

has been registered by Intertek as conforming to the requirements of:

ISO 9001:2015

The management system is applicable to:

Manufacturing of disposable non sterile NBR (Nitrile Butadiene Rubber) and PVC (Poly Vinyl Chloride) gloves and disposable face masks（Non-medical）.

(Organization was certified by another Certification Body before 2019/01/03)

Unified Social Credit Identifier:
91370781561439654L
Certificate Number:
111812005
Initial Certification Date:
27 January 2013
Date of Certification Decision:
23 December 2020
Certified by Intertek since:
03 January 2019
Issuing Date:
23 December 2020
Valid Until:
27 January 2022

014

Calin Moldovean
President, Business Assurance

Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom

Intertek Certification Limited is a UKAS accredited body under schedule of accreditation no. 014.

Issued to:

Shandong Intco Medical Products Co Ltd
Qiwang Road, Naoshan Industrial Park
Qingzhou
Shandong
262506
China

Notified Body: 2777

SATRA customer number: P1720

EU Type-Examination Certificate

Certificate number: 2777/17447-02/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

NGV/B/H/P/XE100
NGV/B/H/P/XE200
SNV/B/H/PE100
SNV/B/H/PE200

Description:

Disposable Nitrile Gloves/ SYNGUARD® Nitrile Exam Gloves

Blue	Black
NGV/B/H/P/XE100 13-18	NGV/B/H/P/XE100 43-48
NGV/B/H/P/XE200 13-18	NGV/B/H/P/XE200 43-48
SNV/B/H/PE100 13-18	SNV/B/H/PE100 43-48
SNV/B/H/PE200 13-18	SNV/B/H/PE200 43-48

White	Violet
NGV/B/H/P/XE100 23-28	NGV/B/H/P/XE100 33-38
NGV/B/H/P/XE200 23-28	NGV/B/H/P/XE200 33-88
SNV/B/H/PE100 23-28	SNV/B/H/PE100 33-38
SNV/B/H/PE200 23-28	SNV/B/H/PE200 33-38

Sizes:
6-11(XS-XXL)

Classification:

EN ISO 374-1:2016+A1:2018/Type B	**Level**	**EN ISO 374-4:2019 Degradation %**
(K) Sodium hydroxide 40%	6	-11.5
(P) Hydrogen peroxide 30%	2	-9.5
(T) Formaldehyde 37%	3	7.4

EN ISO 374-5:2016	**Level**
Protection against Bacterial and Fungi	Pass
Protection against Viruses	Pass

Standards/Technical specifications applied:
EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHT0291374/1944, CHM0291937/1946/JH, CHT0301241/2033
SGS: CH:TX:9420026599-1, CH:TX:9420026316-1, CH:TX:9420020333, CH:TX:9420029243
CTC: S200908976_2
TUV: 721655656

Signed on behalf of SATRA: Geoff Graham

Date first issued: 15/07/2021
Date of issue: 20/07/2021
Expiry date: 15/07/2026

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement. This certificate has been issued in accordance with Annex V (Module B) of the applicable legislation (see note 11).

Please note:

1. Where the product is classified as category III then CE or UKCA Marking of production is reliant on current compliance with module C2 or Module D of the applicable legislation (See note 11). (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturer's technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate and an EU declaration of product conformity shall be made available in accordance with the applicable legislation (See note 11)
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state, or UK government.
9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of the applicable legislation (See note 11).
11. These terms and conditions shall apply to the requirements set out in Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment or to UK legislation relating to UKCA Marking as defined within the issued certificate.

Test Report No. 7191205302-EEC19-WBH
dated 01 Mar 2019

PSB Singapore

Add value.
Inspire trust.

Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

SUBJECT:

Testing of Disposable Nitrile Glove submitted by
Shandong Intco Medical Products Co., Ltd. on 18 Feb 2019.

TESTED FOR:

Shandong Intco Medical Products Co., Ltd
No. 9888 Qiwang Road
Naoshan Industry Park, Qingzhou, Shandong, China

TEST DATE:

25 Feb 2019

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Nitrile Glove	Blue	/	M	217	Shandong Intco Medical Products Co., Ltd

Lot size as specified by client: 35,001 to 150,000 pieces

METHOD OF TEST:

EN 455-1:2000 Medical gloves for single use
Part 1: Requirements and testing for freedom from holes

TÜV SÜD PSB

Laboratory:
TÜV SÜD PSB Pte. Ltd.
No.1 Science Park Drive
Singapore 118221

Phone : +65-6885 1333
Fax : +65-6776 8670
E-mail: enquiries@tuv-sud-psb.sg
www.tuv-sud-psb.sg
Co. Reg : 199002667R

Regional Head Office:
TÜV SÜD Asia Pacific Pte. Ltd.
1 Science Park Drive, #02-01
Singapore 118221

PSB Singapore

RESULTS:

Sample: Disposable Nitrile Glove, Size M

Table: Results for EN 455-1:2000

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	7	200	0	Passed

REMARKS:

1. The manufacturing lot no. was not provided by the client.

Yeo Poh Kwang
Higher Associate Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

Photo : Disposable Nitrile Glove, Size M

PSB Singapore

Please note that this Report is issued under the following terms :

1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.

2. The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.

3. Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.

4. This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SÜD PSB or to the report or results furnished by TÜV SÜD PSB in any advertisements or sales promotion.

5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.

July 2011

Test Report No. 7191255592-EEC21-WBH
dated 31 Mar 2021

PSB Singapore

Add value.
Inspire trust.

Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

SUBJECT:

Testing of Examination Gloves submitted by
Shandong Intco Medical Products Co., Ltd. on 10 Mar 2021

TESTED FOR:

Shandong Intco Medical Products Co., Ltd.
No. 9888 Qiwang Road,
Naoshan Industry Park,
Qingzhou, Shandong,
China

TEST DATE:

12 Mar 2021 to 31 Mar 2021

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/ Model	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Nitrile Examination Gloves	Nil	Blue	Nil	S	15	Shandong Intco Medical Products Co., Ltd.
2				Nil	M	32	
3				Nil	L	15	
4				Nil	XL	15	

METHOD OF TEST:

EN 455-2:2015 Medical gloves for single use
Part 2: Requirements and testing for physical properties
-Clause 4 Dimensions
-Clause 5 Strength

TÜV SÜD PSB

Laboratory:
TÜV SÜD PSB Pte. Ltd.
15 International Business Park
TÜV SÜD @ IBP
Singapore 609937

Phone : +65-6778 7777
E-mail: info.sg@tuvsud.com
https://www.tuvsud.com/sg
Co. Reg : 199002667R

Regional Head Office:
TÜV SÜD Asia Pacific Pte. Ltd.
15 International Business Park
TÜV SÜD @ IBP
Singapore 609937

RESULTS:

Sample: Disposable Nitrile Examination Gloves

Table: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Size	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	S	≥ 240	13	248	Passed
		M		13	243	Passed
		L		13	248	Passed
		XL		13	250	Passed
	b) Width (mm)	S	80 ± 10	13	83	Passed
		M	95 ± 10	13	98	Passed
		L	110 ± 10	13	105	Passed
		XL	≥ 110	13	110	Passed
5	Strength a) Force at break (N)	M	For nitrile examination gloves: ≥ 6.0	13	6.5	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	M	For nitrile examination gloves: ≥ 6.0	13	6.3	Passed

REMARKS:

1. Brand/ Model and Lot No. were not provided by client.

Yeo Poh Kwang
Associate Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

Photo: Disposable Nitrile Examination Gloves

PSB Singapore

Please note that this Report is issued under the following terms :

1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.

2. The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.

3. Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.

4. This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SÜD PSB or to the report or results furnished by TÜV SÜD PSB in any advertisements or sales promotion.

5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, 15 International Business Park TÜV SÜD @ IBP Singapore 609937.

6. The tests carried out by TÜV SÜD PSB and this report are subject to TÜV SÜD PSB's General Terms and Conditions of Business and the Testing and Certification Regulations of the TÜV SÜD Group.

Effective 26 January 2021

Test Report No. 7191256089-EEC21-WBH
dated 31 Mar 2021

PSB Singapore

Add value.
Inspire trust.

Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

SUBJECT:

Testing of Examination Gloves submitted by
Shandong Intco Medical Products Co., Ltd. on 15 Mar 2021

TESTED FOR:

Shandong Intco Medical Products Co., Ltd.
No. 9888 Qiwang Road,
Naoshan Industry Park,
Qingzhou, Shandong,
China

TEST DATE:

17 Mar 2021 to 31 Mar 2021

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/ Model	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Nitrile Examination Gloves	Nil	Blue	Nil	S	34	Shandong Intco Medical Products Co., Ltd.
2				Nil	L	35	
3				Nil	XL	34	

METHOD OF TEST:

EN 455-2:2015 Medical gloves for single use
Part 2: Requirements and testing for physical properties
-Clause 4 Dimensions
-Clause 5 Strength

PSB Singapore

RESULTS:

Sample: Disposable Nitrile Examination Gloves

Table: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Size	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	S	≥ 240	13	248	Passed
		L		13	252	Passed
		XL		13	246	Passed
	b) Width (mm)	S	80 ± 10	13	84	Passed
		L	110 ± 10	13	104	Passed
		XL	≥ 110	13	115	Passed
5	Strength a) Force at break (N)	S	For nitrile examination gloves: ≥ 6.0	13	6.1	Passed
		L		13	6.4	Passed
		XL		13	6.3	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	S	For nitrile examination gloves: ≥ 6.0	13	7.0	Passed
		L		13	6.9	Passed
		XL		13	6.6	Passed

REMARKS:

1. Brand/ Model and Lot No. were not provided by client.

Yeo Poh Kwang
Associate Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

Photo: Disposable Nitrile Examination Gloves

PSB Singapore

Please note that this Report is issued under the following terms :

1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.

2. The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.

3. Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.

4. This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SÜD PSB or to the report or results furnished by TÜV SÜD PSB in any advertisements or sales promotion.

5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, 15 International Business Park TÜV SÜD @ IBP Singapore 609937.

6. The tests carried out by TÜV SÜD PSB and this report are subject to TÜV SÜD PSB's General Terms and Conditions of Business and the Testing and Certification Regulations of the TÜV SÜD Group.

Effective 26 January 2021

Material and Engineering Laboratory-Kaohsiung

Test Report

Report No. : KV-18-11251
Page No. : 1 OF 2
Date of Report : Dec. 25, 2018

Shandong Intco Medical Products Co., Ltd.
No.9888, Qiwang Road, Naoshan Industry Park, Qingzhou, Shandong, China

Product Name	Disposable Nitrile Glove (QDHL1811025521OT)
Date of Sample Received	Dec. 10, 2018
Date of Testing	Dec. 10, 2018~Dec. 25, 2018
Remark	The information mentioned in the above section is provided by Client(Exclude Date of Sample Received and Date of Testing)

==========

The laboratory tests according to the test requests and samples provided by client, and the results are as follows:

Test Request : Aqueous Extractable Protein

Test Method : Refer to BS EN 455-3:2015 Medical gloves for single use — Part 3 : Requirements and testing for biological evaluation

Test Result : Please see attached pages

----- 1 -----

The required specification(s) offered in this test report is/are for reference only.
The conformity judgment is at the Applicant's final verdict.

Signed for and on behalf of
SGS Taiwan Ltd.

Material and Engineering Laboratory-Kaohsiung

Test Report

Report No. : KV-18-11251
Page No. : 2 OF 2
Date of Report : Dec. 25, 2018

Test Equipment :

Name	Brand	Model
UV-VISIBLE Spectrophotometer	SHIMADZU	UV-1700

Lab. Environmental Conditions:

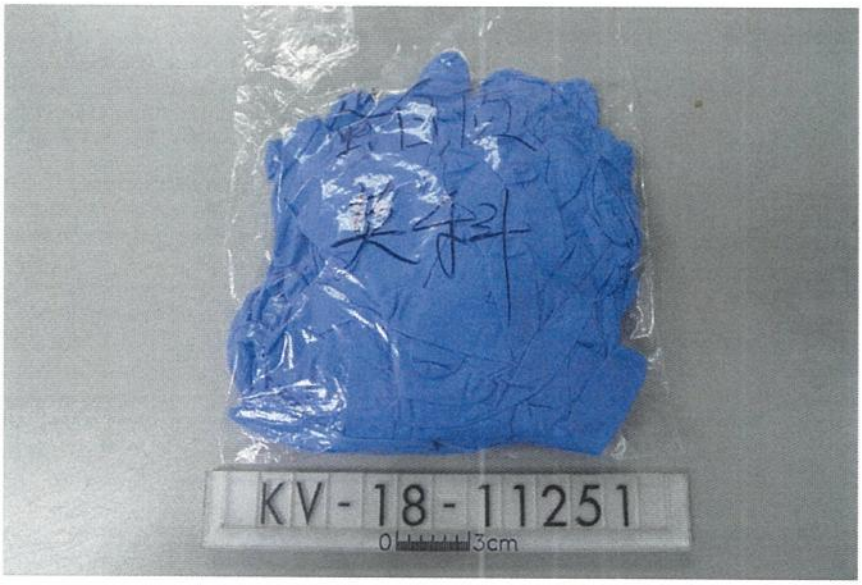
Ambient Temperature : (25 ± 2) ℃
Relative humidity : (50 ± 10) %

Test Result :

INSPECTION ITEM	TEST RESULT
Aqueous Extractable Protein (ppm)	n.d.

Note: 1. n.d. = not detected.
2. MDL (METHOD DETECTION LIMIT):0.2ppm.

Sample Photo :



----- oOo -----

The required specification(s) offered in this test report is/are for reference only.
The conformity judgment is at the Applicant's final verdict.

SGS Taiwan Ltd. 台灣檢驗科技股份有限公司 | No.61, Kai –Fa Road, Nanzih Export Processing Zone, Kaohsiung, Taiwan /高雄市楠梓加工出口區開發路61號
t (886-7) 301-2121 f (886-7) 301-1165 www.sgs.tw
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检测
TESTING
CNAS L0604

scan to see the report

QDHL2103500009MD

Test Report

Report No.: QDHL2103500009MD

Sample Description: DISPOSABLE NITRILE EXAM GLOVES

Applicant: SHANDONG INTCO MEDICAL PRODUCTS CO., LTD

Test Type: SUBMITTED BY CLIENT

Report No.: QDHL2103500009MD

Test Report

Sample information	Sample Description	DISPOSABLE NITRILE EXAM GLOVES	Color	NOT PROVIDED
	Received sample quantity/ Tested sample quantity	10PCS/ 5PCS	Type/ Specifications	S
	Lot No.	NOT PROVIDED	Lot Quantity	NOT PROVIDED
	Manufacture Date	NOT PROVIDED	Expiration Date	NOT PROVIDED
	Material/Appearance	NOT PROVIDED	Storage Condition	NOT PROVIDED
	Manufacturer	NOT PROVIDED		
	Others	NOT PROVIDED		
Client information	Applicant	SHANDONG INTCO MEDICAL PRODUCTS CO., LTD		
	Applicant address	NO.9888,QIWANG ROAD,NAOSHAN INDUSTRY PARK,QINGZHOU,SHANDONG,CHINA		

Report No.: QDHL2103500009MD

Test information	Sample Receiving Date	MAR.01,2021	Test Period Date	MAR.01,2021 TO MAR.05,2021
	Sample No.	QDHL2103500009MD	Test environment	Meet requirement
	Test items	Removable surface powder		
	Testing Accordance	EN 455-3:2015 Medical Gloves for Single Use–Part 3: Requirements and Testing for Biological Evaluation clause 4.4		
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: MAR.05,2021			
Remark	/			

Approver: Auditor: Compiler:

Date: 2021.03.05 Date: 2021.03.05 Date: 2021.03.05

SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, Shandong, China 266101 t (86-532) 68999888 www.sgsgroup.com.cn sgs.china@sgs.com

Report No.: QDHL2103500009MD

Sample Photo

Report No.: QDHL2103500009MD

Test Results

Test Items	Unit	Test Method	Requirement	Test Result	Assessment
Removable surface powder	mg	EN 455-3: 2015 Clause 5.2 EN ISO 21171: 2006	≤2	0.22	Pass

Remarks:

1. Finish of gloves: Powdered-free gloves (As per client's requirement).
2. The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

End of Report

Statement

1. The report is considered invalidated in one or more of the following conditions: no approval signature; no testing seal of SGS; no cross-page seal; altered;a copy without the red testing seal of SGS.

2. Above information and sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.

3. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. This document cannot be used for publicity, without prior written approval of the SGS.

4. The test report cannot be reproduced in any way, except in full content, without prior approval in writing by the laboratory.

5. Should you have any queries or objection to the test report, please contact us whthin 15 days after receiving the report.

Address:
SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, China.

Tel: 0532-68999187 Zip: 266101
Fax: 0532-80991952

E-mail: Emily.Zhang@sgs.com

"NABL ACCREDITED
Certificate No. TC-6176"

Revised report.

TEST REPORT

Report No. : CH:TX:9420026599-1 **DATE : 19/12/2018**

SHANDONG INTCO MEDICAL PRODUCTS CO., LTD
9888, QIWANG ROAD, NAOSHAN INDUSTRY PARK,
QINGZHOU, SHANGDONG,
CHINA
A/C F615001 SGS CSTC STANDARDS TECHNICAL SERVICES CO. LTD
CONTACT PERSON : --

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED AND IDENTIFIED BY/ON BEHALF OF THE CUSTOMER AS :

SAMPLE DESCRIPTION GLOVES
DISPOSABLE NITRILE GLOVE
COLOUR BLUE
PRODUCT CODE 69702457560
PHOTO APPENDIX.

SAMPLE RECD ON 22/05/2018 **TESTING PERIOD :** 22/05/2018 - 29/05/2018

Summary of Test Results/Conclusion		
Test Method / Standard	**Clause/Test Name**	**Status / Performance Level**
EN 16523-1:2015	**Permeation by Liquid chemical under conditions of continuous contact.**	
	Formaldehyde 37%	Level - 3

Per pro SGS India Private Ltd.

K. Pachaiyappan

K. PACHAIYAPPAN
ASST. MANAGER
Email your Test Report Related Enquiries at Feedback.SLT@sgs.com

Test report revised to add product code & reporting details as per customer request.

This Report cancels and supersedes the Report No 9420026599 Dated 30/05/2018 issued by SGS India.

SGS India Pvt. Ltd. **Consumer & Retail, 28 B/1 (SP), 28 B/2 (SP), Second Main Road, Ambattur Industrial Estate, Ambattur, Chennai – 600 058. Phone : 91-44-66081600,Fax :91-44-66081700**
Regd & Corp. Off : SGS House, 4B, A.S. Marg, Vikhroli (West), Mumbai-400083. Tel : (022) 66408888 Fax : (022) 66408829 www.sgs.com
Member of the SGS Group (SGS SA)

"NABL ACCREDITED
Certificate No. TC-6176"

Revised report.

TEST REPORT

Report No. : CH:TX:9420026599-1 **DATE : 19/12/2018**

R E S U L T S

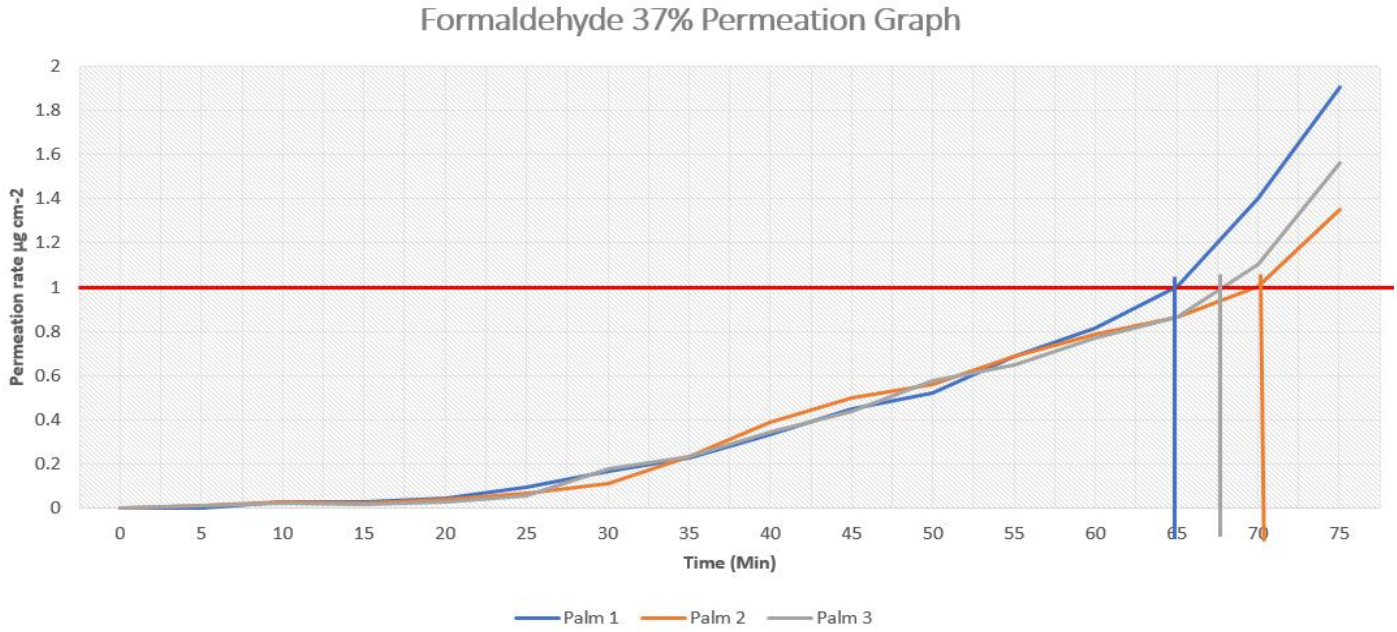
EN 16523-1:2015 Determination of material resistance to permeation by chemicals – Part-1: Permeation by Liquid chemical under conditions of Continuous contact.

Chemical CAS NO	Loop system/collection medium	Analytical technique used	Mean thickness (mm)	NBT at NPR 1.0 µg cm^{-2} min^{-1} (minutes)	Performance level accordance to EN ISO 374-1: 2016 Table 1	Observation
Formaldehyde 37% 50-00-0	Closed loop/ Grade 3 water	Periodic measurement with HPLC	0.11 0.10 0.10	65 70 68	Level - 3	Moderate Swelling

EN ISO 374-1:2016 – Protective gloves against dangerous chemicals and micro-organisms.
Part 1: Terminology and performance requirments 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 results achived per chemical



***** End of Report*****

SGS India Pvt. Ltd. **Consumer & Retail, 28 B/1 (SP), 28 B/2 (SP), Second Main Road, Ambattur Industrial Estate, Ambattur, Chennai – 600 058. Phone : 91-44-66081600,Fax :91-44-66081700**
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Member of the SGS Group (SGS SA)

"NABL ACCREDITED
Certificate No. TC-6176"

Revised report.

TEST REPORT

Report No. : CH:TX:9420026316-1 **DATE : 19/12/2018**

SHANDONG INTCO MEDICAL PRODUCTS CO., LTD
9888, QIWANG ROAD, NAOSHAN INDUSTRY PARK,
QINGZHOU, SHANGDONG,
CHINA
A/C F615001 SGS CSTC STANDARDS TECHNICAL SERVICES CO. LTD
CONTACT PERSON : --

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED AND IDENTIFIED BY/ON BEHALF OF THE CUSTOMER AS :

SAMPLE DESCRIPTION GLOVES
DISPOSABLE NITRILE GLOVE
COLOUR BLUE
PRODUCT CODE 69702457560
PHOTO APPENDIX.

SAMPLE RECD ON 22/05/2018 **TESTING PERIOD :** 22/05/2018 - 29/05/2018

Summary of Test Results/Conclusion		
Test Method / Standard	**Clause/Test Name**	**Status / Performance Level**
EN 16523-1:2015	**Permeation by Liquid chemical under conditions of continuous contact.**	
	Hydrogen peroxide 30%	Level - 2

Per pro SGS India Private Ltd.

K. Pachaiyappan

K. PACHAIYAPPAN
ASST. MANAGER
Email your Test Report Related Enquiries at Feedback.SLT@sgs.com

Test report revised to add product code & reporting details as per customer request.

This Report cancels and supersedes the Report No 9420026316 Dated 29/05/2018 issued by SGS India.

SGS India Pvt. Ltd. **Consumer & Retail, 28 B/1 (SP), 28 B/2 (SP), Second Main Road, Ambattur Industrial Estate, Ambattur, Chennai – 600 058. Phone : 91-44-66081600,Fax :91-44-66081700**
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"NABL ACCREDITED
Certificate No. TC-6176"

Revised report.

TEST REPORT

Report No. : CH:TX:9420026316-1 **DATE : 19/12/2018**

RESULTS

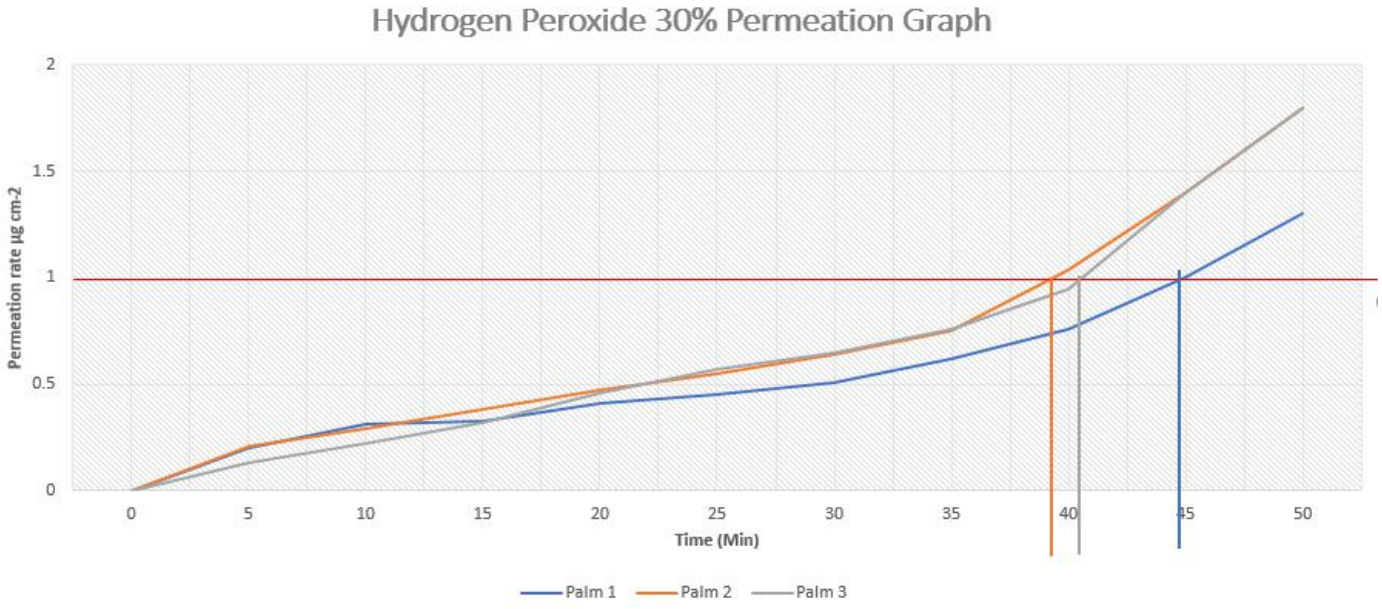
EN 16523-1:2015 Determination of material resistance to permeation by chemicals – Part-1: Permeation by Liquid chemical under conditions of Continuous contact.

Chemical CAS NO	Loop system/collection medium	Analytical technique used	Mean thickness (mm)	NBT at NPR 1.0 µg cm^{-2} min^{-1} (minutes)	Performance level accordance to EN ISO 374-1: 2016 Table 1	Observation
Hydrogen Peroxide 30% 7722-84-1	Closed loop/ Grade 3 water	Continuous measurement with Redox Electrode	0.10 0.09 0.09	45 39 41	Level - 2	Moderate Swelling

EN ISO 374-1:2016 – Protective gloves against dangerous chemicals and micro-organisms.
Part 1: Terminology and performance requirments 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 results achived per chemical.



***** End of Report*****

SGS India Pvt. Ltd. **Consumer & Retail, 28 B/1 (SP), 28 B/2 (SP), Second Main Road, Ambattur Industrial Estate, Ambattur, Chennai – 600 058. Phone : 91-44-66081600,Fax :91-44-66081700**
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Member of the SGS Group (SGS SA)

SATRA Technology Centre Ltd
Wyndham Way, Telford Way, Kettering,
Northamptonshire, NN16 8SD United Kingdom
Tel: +44 (0) 1536 410000
Fax +44 (0) 1536 410626
email: info@satra.com
www.satra.com

0248

Customer details: SATRA Technology Europe Ltd
Bracetown Business Park
Clonee
County Meath
Dublin 15
Eire

SATRA reference: CHM0295494/2009/JH

Your reference: STE0293607

Date of report: 4th March 2020

Samples received: 24th February 2020

Date(s) work carried out: 25th to 27th February 2020

TECHNICAL REPORT

SATRA Technology Europe Ltd: Certificate Number: 2777/11804-01/E00-00

Customer: Shandong Intco Medical Products Co Ltd
Qiwang Road, Naoshan Industrial Park
Qingzhou
Shandong
China
262506

Subject: Regulation 2016/425 Module C2 testing of gloves described as 697024575 Disposable Nitrile Non-Sterile Glove in accordance with EN 16523-1:2015+A1:2018 resistance to permeation by chemicals against 40% Sodium hydroxide .

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

Tests marked ≠ fall outside the UKAS Accreditation Schedule for SATRA. All interpretations of results of such tests and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor k=2, which provides a coverage probability of approximately 95%.

Report signed by: Jade Hurley
Position: Technologist
Department: Chemical & Analytical Technology

WORK REQUESTED:

Samples of gloves described as 697024575 Disposable Nitrile Non-Sterile Glove were obtained by SATRA Technology Europe Ltd from Shandong Intco Medical Products Co Ltd via SATRA Technology Services (Dongguan) Ltd on the 21st February 2020, in glove size Medium. The gloves were received by SATRA Technology UK on the 24th February 2020 for testing in accordance with EN 16523-1:2015+A1:2018 and with the performance requirements of EN ISO 374-1:2016+A1:2018 to demonstrate ongoing production compliance with Module C2 of Regulation (EU) 2016/425. These gloves are certified by certificate number 2777/11804-01/E00-00

SAMPLES SUBMITTED:

Samples described as 697024575
Disposable Nitrile Non-Sterile Glove

CONCLUSION:

When assessed in accordance with the requirements of EN ISO 374-1:2016+A1:2018 the samples of gloves described as 697024575 Disposable Nitrile Non-Sterile Glove achieved the following performance levels:

Chemical	Performance level
40% Sodium hydroxide (CAS: 1310-73-2)	6

Full results are reported in the following tables.

TESTING REQUIRED:

- EN 16523-1:2015+A1:2018 - Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact

RESULTS AND REQUIREMENTS:

EN ISO 374-1:2016+A1:2018 - Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks. Table 1: Permeation performance levels.

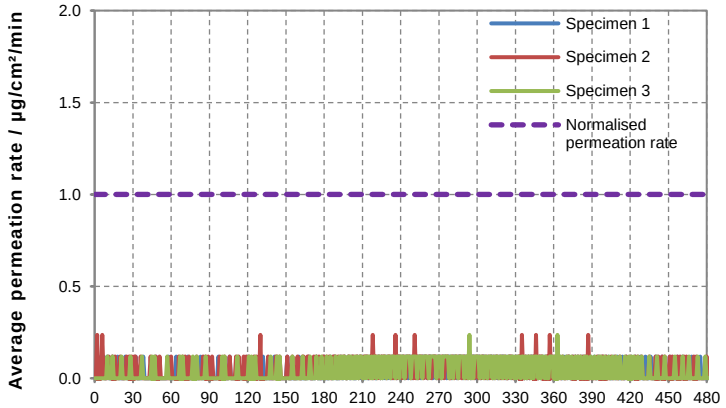
Permeation performance level	Measured breakthrough time (minutes)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

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

Test/Property	Sample reference:	697024575 Disposable Nitrile Non-Sterile Glove		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-009 Using PTFE permeation cells with standardised dimensions	Test information:	Chemical: 40% Sodium hydroxide		Level 6
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: Conductimetry (continuous 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		
	Specimen	**Thickness (mm)⌂**	**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:		Discoloured		

PERMEATION RATE GRAPHS

Challenge chemical: 40% Sodium Hydroxide.



⌂ EN 16523-1:2015+A1:2018 does not require the test specimen thicknesses to be reported, this information is indicative only.

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

1. GENERAL

1.1 Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are hereby excluded.

1.2 SATRA Technology Centre Limited, its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for or supply Goods to persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as Parties.

1.3 These terms and conditions will apply to the Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealing

1.4 Unless otherwise agreed in writing no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or certificates.

1.5 All references in these terms and conditions to:

(a) the "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and
(b) "Services" are the work or services to be supplied or performed under the Contract (including where relevant the supply of software, components and consumables); and
(c) "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment).

1.6 All drawings, descriptive matter, specifications and advertising material (including brochures and catalogues) are issued or published with the sole purpose of giving an indication of the goods or services being described and shall not form part of the Contract.

1.7 Where SATRA and the Client agree that the sale of Goods shall be governed by Incoterms 2010 (or any subsequent revision thereto) then the sale shall be governed by the relevant Incoterms mode of transport which is agreed by SATRA and the Client.

2. FEES AND PAYMENT

2.1 Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are net 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client failing to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is received.

2.2 Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA.

2.3 SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try and provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control.

2.4 Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client.

2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in writing.

2.6 Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA shall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued rights.

2.7 All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts.

2.8 The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA.

2.9 SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related costs.

2.10 Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and expenses.

3. INTELLECTUAL PROPERTY RIGHTS

3.1 All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other.

3.2 In the event of certification services the use of certification marks by the Client may be subject to national and international laws and regulations. The responsibility for the use of these certification marks lies solely with the Client.

3.3 All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract.

3.4 The Client agrees and acknowledges that SATRA retains any and all propriety rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client.

3.5 All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors. With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionstitch, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software and receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.

3.6 SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 2018 and the EU General Data Protection Regulation (GDPR) Regulation (EU) 2016/679. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

4. SUSPENSION OR TERMINATION OF SERVICES

4.1 Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made.

4.2 SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client any fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services not yet supplied unless the cancellation is due to the Clients failure to comply with its obligations under the Contract.

5. LIABILITY AND INDEMNIFICATION

5.1 Reports are issued on the basis of information, documents and or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.

5.2 Nothing in these terms and conditions shall limit or exclude SATRA's liability for:

(a) death or personal injury caused by its negligence or the negligence of its employees or agents;
(b) fraud or fraudulent misrepresentation;
(c) breach of the terms implied by Section 12 of the Sale of Goods Act 1979;
(d) defective products under the Consumer Protection Act 1987; or
(e) any other liability which cannot be limited or excluded by applicable law.

5.3 Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.

5.4 Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or £100,000 whichever is the lower figure.

6. MISCELLANEOUS

6.1 If any one or more provisions of these conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

6.2 During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.

6.3 The use of SATRAs corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation.

6.4 All reports and documentation which are supplied to the Client under the Contract remain the property of SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause.

6.5 The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other party before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.

6.6 All provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA, and being a company limited by guarantee and incorporated in England and Wales with company number 00153475), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

7. CONFIDENTIALITY

7.1 Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data or other forms of media.

7.2 Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA.

7.3 Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes testing, reporting and advising. The Client shall indemnify SATRA for any failure to do so.

7.4 The service deliverables referred to in clause 7.1 are submitted to the Client as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which has come into the public domain through no breach of this Contract by the Client.

7.5 The Client shall not disassemble, remove parts or carry out any form of analysis on goods or materials sold by SATRA for the purposes of reverse engineering or obtaining information on the construction, content or composition of the item without the consent of SATRA.

8. AMENDMENT

8.1 No amendment to this Contract shall be effective unless it is in writing, expressly stated to amend this Contract and signed by an authorised signatory of both Parties.

9. DISPUTE RESOLUTION

9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.

9.2 Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for resolution. The parties shall attempt to agree upon the appointment of a mediator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, either party, upon giving written notice, may apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a mediator.

9.3 Should the mediation fail, in whole or in part, either party may, upon giving written notice, and within twenty-eight days thereof, apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a single arbitrator, for final resolution. The arbitrator shall have no connection with the mediator or the mediation proceedings, unless both parties have consented in writing. The arbitration shall be governed by both the Arbitration Act 1996 and the Controlled Cost Rules of the

Signed:

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

Chartered Institute of Arbitrators (2000 Edition), or any amendments thereof, which Rules are deemed to be incorporated by reference into this clause. The seat of the arbitration shall be England and Wales.

9.4 The laws of England shall govern the interpretation of this Contract. Subject to clauses 9.1, 9.2 and 9.3 any dispute arising out of or in connection with the Contract shall be subject to the exclusive jurisdiction of the courts of England. However, the Party obtaining a judgement in such courts shall be entitled to enforce it in any court it chooses.

10. PROVISION OF SERVICES

10.1 SATRA shall provide Services using reasonable care and skill and in accordance with the Clients specific instructions and as confirmed by SATRA as part of the Contract review process.

10.2 Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the Services.

10.3 Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested.

10.4 SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.

10.5 Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRAs sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA.

10.6 Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such samples.

Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client. Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.

Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an "as new" condition.

10.7 Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Client from any or all obligations to SATRA.

10.8 SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are complied with.

10.9 The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations.

11. CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES

11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.

11.2 Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel.

11.3 The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA.

11.4 Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.

12. DELIVERY AND NON-DELIVERY OF GOODS

12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.

12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.

12.3 Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary.

12.4 SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered.

12.5 Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.

12.6 If for any reason the Client fails to accept delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance).

13. RISK/TITLE OF GOODS

13.1 Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.

13.2 The Company shall not accept responsibility for loss or damage in transit unless:

a) In the case of sales where delivery of Goods is made in the United Kingdom SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or

b) In all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.

13.3 Title to the Goods shall not pass to the Client until the earlier of when: -

a) SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums; and

b) the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.

13.4 Until ownership of Goods has passed to the Client, the Client shall:

a) hold the Goods as SATRA's bailee;

b) store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);

c) not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and

d) maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.

13.5 The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.

13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:

a) the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and

b) SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and

c) if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.

13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.

13.8 On termination of the Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause 13 shall remain in effect.

14. PATENTS

14.1 SATRA gives no indemnity against any claim of infringement of Letters Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of Letters Patent, Registered Design, Trade Mark or Copyright published at the date of the contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Letters Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order.

15. WARRANTY OF GOODS

15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship.

16. DEFECTIVE GOODS

16.1 Subject to clauses 16.6 and 16.7 if:

a) the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and

b) SATRA is given a reasonable opportunity of examining such Goods; and

c) the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.

16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.

16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.

16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.

16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.

16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:

a) the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or

b) the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or

c) the Client has breached any of the terms of the Contract under which the Goods were supplied; or

d) the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information;

16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:

a) SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;

b) nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.

16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

TEST REPORT

C.C: SHANDONG INTCO MEDICAL PRODUCTS CO LTD
ADDRESS: NO. 9888 QIWANG ROAD, NAOSHAN INDUSTRY PARK, QINGZHOU, SHANDONG, CHINA

LAB NO.: (9021)060-0218
DATE IN: MAR. 01, 2020
DATE MODIFIED: /
DATE OUT: MAR. 09, 2020
NO. OF WORKING DAYS: 7

OVERALL RATING

SATISFACTORY	**X**
UNSATISFACTORY	
DATA	

Vendor:	SHANDONG INTCO MEDICAL PRODUCTS CO LTD	**Agent:**	/
Raw Material Supplier:	/	**Factory/Manufacturer:**	/
P.O. No.:	/	**Style No.:**	/
Sample Description:	DISPOSABLE NITRILE GLOVES (NBR)	**SKU#:**	/
Color:	/	**Country of Origin:**	/
Buyer Name:	/	**Submitted Size:**	/
Submitted Amount:	/	**End Use:**	/
Country of Distribution	/	**Others:**	/

Product Category:	/
Test Requested:	SEE BELOW
Previous Report No.:	/

TEST PROPERTY	PASS	FAIL	DATA	COMMENTS
Candidate List of Substances of Very High Concern for authorization published by European Chemicals Agency (ECHA) Regarding Regulation (EC) No. 1907/2006 concerning REACH	X			

Remark:

The client specifies the test method and requirement.

BVCPS (SHANGHAI)-QINGDAO BRANCH CONTACT INFORMATION FOR THIS REPORT

Enquiry and invoicing:

Wendy Huang 86-533-7868187 wendy.huang@ bureauveritas.com
Sunnee Li 86-533-7868185 sunnee.li@bureauveritas.com

Bureau Veritas
Consumer Products Services (Shanghai)-Qingdao Branch

Anderson Zhang
Qingdao Hardline Reporting Manager

Note:

1. The limit of 0.1% (w/w) applies to an article. The results were calculated according to Guidance on requirements for substances in articles Version 4.0 – June 2017,reference to the judgement of the European Court of Justice of 10 September 2015 in case C-106/142 .However, the results may not be applicable if the intended use of the sample is a substance or mixture. According to REACH, definition of an article, substance and mixture are:
   i. Article - An object during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition
   ii Substance - A chemical element and its compound in the natural state or obtained by any manufacturing process
   iii Mixture (Previously known as "Preparation") - A mixture or solution composed of two or more substances
2. In accordance of Article 7 of Regulation (EC) No. 1907/2006 (REACH regulation) – Registration and notification of substances in articles, any producer or importer of articles shall notify ECHA, if a substance meets in criteria in Article 57 and is identified in accordance with Article 59(1), if both (1) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year & (2) the substance is present in those articles above a concentration of 0.1% weight by weight (w/w) are met. The information to be notified shall include (a) identity and contact details of the producer or importer, (b) the registration numbers, (c) the identity of the substance and (d) the classification of the substance, (e) a brief description of the use of the substance and (f) the tonnage range of the substance.
3 In accordance of Article 33 of Regulation (EC) No. 1907/2006 (REACH regulation) – Duty to communicate information on substances in articles, any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in concentration above 0.1% weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance. On request by a consumer the relevant information shall be provided by any supplier of an article free of charge, within 45 days of receipt of the request.
4 If SVHC was detected exceeding 0,1% (w/w) in test group, client is suggested to perform the further separate testing to identify the exact concentration of test items.

Bureau Veritas Consumer Products Services, Inc. (Shanghai), Qingdao Branch
No.3 building, GNDC Tech Base, No.192 Zhuzhou Road, Laoshan District, Qingdao,China,266101
Tel: 86-532-58827999 Fax: 86-532-88706839
Email: bvcpsinfor.qd@cn.bureauveritas.com
Website: cps.bureauveritas.com

TEST RESULT

Candidate List of Substances of Very High Concern for authorization published by European Chemicals Agency (ECHA) Regarding Regulation (EC) No. 1907/2006 concerning REACH

Method: Analysis is based on GC, LC, IC, ICP and UV, with various detection techniques.

Maximum Allowable Limit:	**0.1% (Each of listed)**

Test Item1:	Blue Plastic

Result		**Conclusion**
Detected Analyte(s)	**Conc. (%)**	
ND	ND	PASS

Remark:

ND = Not Detected Conc. = Concentration
mg/kg = milligram per kilogram % = percentage 1 mg/kg = 0.0001%
Detection Limit (%): See Appendix.
The detected SVHC and its value will be shown in above table, the else SVHC not shown in the table will be regarded as ND. When all SVHC for test are not detected, it will be shown ND.

APPENDIX

Candidate List of Substances of Very High Concern for authorization published by European Chemicals Agency (ECHA) Regarding Regulation (EC) No. 1907/2006 concerning REACH

No.	Substance name	CAS No.	EC No.	Detection Limit, %	Basis for identification as a SVHC
1	Triethyl arsenate*	15606-95-8	427-700-2	0.01	Carcinogenic
2	Anthracene	120-12-7	204-371-1	0.005	PBT
3	4,4'-Diaminodiphenyl methane (MDA)	101-77-9	202-974-4	0.005	Carcinogenic
4	Dibutyl phthalate (DBP)	84-74-2	201-557-4	0.005	Toxic for reproduction
5	Cobalt dichloride*	7646-79-9	231-589-4	0.01	Carcinogenic
6	Diarsenic pentaoxide*	1303-28-2	215-116-9	0.01	Carcinogenic
7	Diarsenic trioxide*	1327-53-3	215-481-4	0.01	Carcinogenic
8	Sodium dichromate*	7789-12-0(1), 10588-01-9(2)	234-190-3	0.01	Carcinogenic; Mutagenic; Toxic for reproduction
9	5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	81-15-2	201-329-4	0.005	vPvB
10	Bis (2-ethylhexyl) phthalate (DEHP)	117-81-7	204-211-0	0.005	Toxic for reproduction
11	Hexabromo cyclododecane (HBCDD) and all major diastereoisomers identified: α - HBCDD β - HBCDD γ - HBCDD	3194-55-6(3), 25637-99-4(4) 134237-50-6 134237-51-7 134237-52-8	247-148-4, 221-695-9	0.005	PBT
12	Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins) (SCCP)	85535-84-8	287-476-5	0.01	PBT, vPvB

13	Bis(tributyltin)oxide (TBTO)**	56-35-9	200-268-0	0.005	PBT
14	Lead hydrogen arsenate*	7784-40-9	232-064-2	0.01	Carcinogenic; Toxic for reproduction
15	Benzyl butyl phthalate (BBP)	85-68-7	201-622-7	0.005	Toxic for reproduction
16	2,4-Dinitrotoluene	121-14-2	204-450-0	0.005	Carcinogenic
17	Anthracene oil	90640-80-5	292-602-7	0.01	Carcinogenic, PBT, vPvB
18	Anthracene oil, anthracene paste, distn. Lights	91995-17-4	295-278-5	0.01	Carcinogenic; Mutagenic, PBT, vPvB
19	Anthracene oil, anthracene paste, anthracene fraction	91995-15-2	295-275-9	0.01	Carcinogenic; Mutagenic, PBT, vPvB
20	Anthracene oil, anthracene-low	90640-82-7	292-604-8	0.01	Carcinogenic; Mutagenic, PBT, vPvB
21	Anthracene oil, anthracene paste	90640-81-6	292-603-2	0.01	Carcinogenic; Mutagenic, PBT, vPvB
22	Diisobutyl phthalate	84-69-5	201-553-2	0.005	Toxic for reproduction
23	Aluminosilicate, Refractory Ceramic Fibres*[a]	Index no. 650-017-00-8		0.01	Carcinogenic
24	Zirconia Aluminosilicate, Refractory Ceramic Fibres*b	Index no. 650-017-00-8		0.01	Carcinogenic
25	Lead chromate*	7758-97-6	231-846-0	0.01	Carcinogenic; Toxic for reproduction
26	Lead chromate molybdate sulfate red (C.I. Pigment Red 104)*	12656-85-8	235-759-9	0.01	Carcinogenic; Toxic for reproduction
27	Lead sulfochromate yellow (C.I. Pigment Yellow 34)*	1344-37-2	215-693-7	0.01	Carcinogenic; Toxic for reproduction
28	Tris(2-chloroethyl) phosphate (TCEP)	115-96-8	204-118-5	0.005	Toxic for reproduction
29	Coal tar pitch, high temperature	65996-93-2	266-028-2	0.01	Carcinogenic, PBT, vPvB
30	Acrylamide	79-06-1	201-173-7	0.005	Carcinogenic; Mutagenic
31	Trichloroethylene	79-01-6	201-167-4	0.005	Carcinogenic
32	Boric acid*	10043-35-3, 11113-50-1	233-139-2 / 234-343-4	0.01	Toxic for reproduction
33	Disodium tetraborate, anhydrous*	1330-43-3(5), 12179-04-3(6), 1303-96-4(7)	215-540-4	0.01	Toxic for reproduction
34	Tetraboron disodium heptaoxide, hydrate*	12267-73-1	235-541-3	0.01	Toxic for reproduction
35	Sodium chromate*	7775-11-3	231-889-5	0.01	Carcinogenic; Mutagenic; Toxic for reproduction
36	Potassium chromate*	7789-00-6	232-140-5	0.01	Carcinogenic; Mutagenic
37	Ammonium dichromate*	7789-09-5	232-143-1	0.01	Carcinogenic; Mutagenic; Toxic for reproduction
38	Potassium dichromate*	7778-50-9	231-906-6	0.01	Carcinogenic; Mutagenic; Toxic for reproduction
39	Cobalt(II) sulphate*	10124-43-3	233-334-2	0.01	Carcinogenic; Toxic for reproduction
40	Cobalt(II) dinitrate*	10141-05-6	233-402-1	0.01	Carcinogenic; Toxic for reproduction
41	Cobalt(II) carbonate*	513-79-1	208-169-4	0.01	Carcinogenic; Toxic for reproduction
42	Cobalt(II) diacetate*	71-48-7	200-755-8	0.01	Carcinogenic;

					Toxic for reproduction
43	2-Methoxyethanol	109-86-4	203-713-7	0.005	Toxic for reproduction
44	2-Ethoxyethanol	110-80-5	203-804-1	0.005	Toxic for reproduction
45	Chromium trioxide*	1333-82-0	215-607-8	0.01	Carcinogenic; Mutagenic
46	Acid generated from chromium trioxide and their oligomers: Chromic acid* Dichromic acid* Oligomers of chromic acid and dichromic acid*	 7738-94-5 13530-68-2 -	 231-801-5 236-881-5 -	0.01	Carcinogenic
47	2-Ethoxyethyl acetate	111-15-9	203-839-2	0.005	Toxic for reproduction
48	Strontium Chromate*	7789-06-2	232-142-6	0.01	Carcinogenic
49	1,2-benzenedicarboxylic acid, di-C7-11 branched alkyl ester and linear alkyl ester	68515-42-4	271-084-6	0.005	Toxic for reproduction
50	Hydrazine	302-01-2 7803-57-8	206-114-9	0.005	Carcinogenic
51	1-Methyl-2-pyrrolidone	872-50-4	212-828-1	0.005	Toxic for reproduction
52	1,2,3-trichloropropane	96-18-4	202-486-1	0.005	Toxic for reproduction
53	1,2-benzenedicarboxylic acid, di-C6-8-branched alkyl ester, C7-rich (DIHP)	71888-89-6	276-158-1	0.005	Toxic for reproduction
54	Dichromium tris(chromate)*	24613-89-6	246-356-2	0.01	Carcinogenic
55	Potassium hydroxyoctaoxodizincatedi-chromate*	11103-86-9	234-329-8	0.01	Carcinogenic
56	Pentazinc chromate octahydroxide*	49663-84-5	256-418-0	0.01	Carcinogenic
57	Formaldehyde, oligomeric reaction products with aniline (technical MDA)	25214-70-4	500-036-1	0.005	Carcinogenic
58	Bis(2-methoxyethyl) phthalate	117-82-8	204-212-6	0.005	Toxic for reproduction
59	2-Methoxyaniline; o-Anisidine	90-04-0	201-963-1	0.005	Carcinogenic
60	4-(1,1,3,3-tetramethylbutyl)phenol, (4-tert-Octylphenol)	140-66-9	205-426-2	0.005	Equivalent level of concern
61	1,2-Dichloroethane	107-06-2	203-458-1	0.005	Carcinogenic
62	Bis(2-methoxyethyl) ether	111-96-6	203-924-4	0.005	Toxic for reproduction
63	Arsenic acid*	7778-39-4	231-901-9	0.01	Carcinogenic
64	Calcium arsenate*	7778-44-1	231-904-5	0.01	Carcinogenic
65	Trilead diarsenate*	3687-31-8	222-979-5	0.01	Carcinogenic; Toxic for reproduction
66	N,N-dimethylacetamide (DMAC)	127-19-5	204-826-4	0.005	Toxic for reproduction
67	2,2'-dichloro-4,4'-methylenedianiline (MOCA)	101-14-4	202-918-9	0.005	Carcinogenic
68	Phenolphthalein	77-09-8	201-004-7	0.005	Carcinogenic
69	Lead azide, Lead diazide*	13424-46-9	236-542-1	0.01	Toxic for reproduction
70	Lead styphnate*	15245-44-0	239-290-0	0.01	Toxic for reproduction
71	Lead dipicrate*	6477-64-1	229-335-2	0.01	Toxic for reproduction
72	1,2-bis(2-methoxyethoxy)ethane (TEGDME; triglyme)	112-49-2	203-977-3	0.005	Toxic for reproduction
73	1,2-dimethoxyethane; ethylene glycol dimethyl ether (EGDME)	110-71-4	203-794-9	0.005	Toxic for reproduction
74	Diboron trioxide*	1303-86-2	215-125-8	0.01	Toxic for reproduction
75	Formamide	75-12-7	200-842-0	0.01	Toxic for reproduction
76	Lead(II) bis(methanesulfonate)*	17570-76-2	401-750-5	0.01	Toxic for reproduction

77	TGIC (1,3,5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione) §	2451-62-9	219-514-3	0.005	Mutagenic
78	β-TGIC (1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione) §	59653-74-6	423-400-0	0.005	Mutagenic
79	4,4'-bis(dimethylamino)benzophenone (Michler's ketone)	90-94-8	202-027-5	0.005	Carcinogenic
80	N,N,N',N'-tetramethyl-4,4'-methylenedianiline (Michler's base)	101-61-1	202-959-2	0.005	Carcinogenic
81	[4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3)	548-62-9	208-953-6	0.005	Carcinogenic
82	[4-[[4-anilino-1-naphthyl][4-(dimethylamino) phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26)	2580-56-5	219-943-6	0.005	Carcinogenic
83	α,α-Bis[4-(dimethylamino)phenyl]-4 (phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4)	6786-83-0	229-851-8	0.01	Carcinogenic
84	4,4'-bis(dimethylamino)-4"-(methylamino)trityl alcohol	561-41-1	209-218-2	0.005	Carcinogenic
85	Bis(pentabromophenyl) ether (DecaBDE)	1163-19-5	214-604-9	0.005	Persistent, bioaccumulative and toxic; very persistent and very bioaccumulative
86	N,N-dimethylformamide; dimethyl formamide	68-12-2	200-679-5	0.005	Toxic for reproduction
87	Methoxy acetic acid	625-45-6	210-894-6	0.005	Toxic for reproduction ; equivalent level of concern
88	Dibutyltin dichloride (DBT)*	683-18-1	211-670-0	0.01	Toxic for reproduction
89	1,2-Diethoxyethane	629-14-1	211-076-1	0.005	Toxic for reproduction
90	Hexahydro-2-benzofuran-1,3-dione (HHPA), cis-cyclohexane-1,2-dicarboxylic anhydride, trans-cyclohexane-1,2-dicarboxylic anhydride	85-42-7, 13149-00-3, 14166-21-3	201-604-9, 236-086-3, 238-009-9	0.01	Equivalent level of concern having probable serious effects to human health
91	Hexahydromethylphathalic anhydride, Hexahydro-4-methylphathalic anhydride, Hexahydro-1-methylphathalic anhydride, Hexahydro-3-methylphathalic anhydride	25550-51-0, 19438-60-9, 48122-14-1, 57110-29-9	247-094-1, 243-072-0, 256-356-4, 260-566-1	0.01	Equivalent level of concern having probable serious effects to human health
92	4-Nonylphenol, branched and linear - substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in	-	-	0.005	Equivalent level of concern having probable serious effects to human health

	position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof				
93	Heptacosafluorotetradecanoic acid	376-06-7	206-803-4	0.005	Very persistent and very bioaccumulative
94	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear+	84777-06-0	284-032-2	0.005	Toxic for reproduction
95	Henicosafluoroundecanoic acid	2058-94-8	218-165-4	0.005	Very persistent and very bioaccumulative
96	N-pentyl-isopentylphtalate (iPnPP)+	776297-69-9	-	0.005	Toxic for reproduction
97	Pentacosafluorotridecanoic acid	72629-94-8	276-745-2	0.005	Very persistent and very bioaccumulative
98	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated - covering well-defined substances and UVCB substances, polymers and homologues	-	-	0.005	Equivalent level of concern
99	Tricosafluorododecanoic acid	307-55-1	206-203-2	0.005	Very persistent and very bioaccumulative
100	Lead bis(tetrafluoroborate)*	13814-96-5	237-486-0	0.01	Toxic for reproduction
101	Lead tetroxide (orange lead)*	1314-41-6	215-235-6	0.01	Toxic for reproduction
102	Diethyl sulphate	64-67-5	200-589-6	0.005	Carcinogenic; Mutagenic
103	Dinoseb	88-85-7	201-861-7	0.005	Toxic for reproduction
104	Lead Titanium Zirconium Oxide*	12626-81-2	235-727-4	0.01	Toxic for reproduction
105	Acetic acid, lead salt, basic*	51404-69-4	257-175-3	0.01	Toxic for reproduction
106	Furan	110-00-9	203-727-3	0.01	Carcinogenic
107	N-methylacetamide	79-16-3	201-182-6	0.005	Toxic for reproduction
108	o-Toluidine; 2-Aminotoluene	95-53-4	202-429-0	0.005	Carcinogenic
109	3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	143860-04-2	421-150-7	0.01	Toxic for reproduction
110	4,4'-oxydianiline and its salts	101-80-4	202-977-0	0.005	Carcinogenic; Mutagenic
111	[Phthalato(2-)]dioxotrilead (Dibasic lead phthalate)*	69011-06-9	273-688-5	0.01	Toxic for reproduction
112	Lead titanium trioxide*	12060-00-3	235-038-9	0.01	Toxic for reproduction
113	Lead oxide sulphate*	12036-76-9	234-853-7	0.01	Toxic for reproduction
114	Lead dinitrate*	10099-74-8	233-245-9	0.01	Toxic for reproduction
115	4-Aminoazobenzene; 4-Phenylazoaniline	60-09-3	200-453-6	0.005	Carcinogenic
116	Lead cyanamidate*	20837-86-9	244-073-9	0.01	Toxic for reproduction
117	Tetralead trioxide sulphate*	12202-17-4	235-380-9	0.01	Toxic for reproduction
118	4-methyl-m-phenylenediamine (2,4-toluene-diamine)	95-80-7	202-453-1	0.005	Carcinogenic
119	Pyrochlore, antimony lead yellow*	8012-00-8	232-382-1	0.01	Toxic for reproduction
120	Trilead bis(carbonate)dihydroxide (basic lead carbonate)*	1319-46-6	215-290-6	0.01	Toxic for reproduction
121	Dimethyl sulphate	77-78-1	201-058-1	0.005	Carcinogenic
122	Dioxobis(stearato)trilead*	12578-12-0	235-702-8	0.01	Toxic for reproduction
123	Silicic acid, barium salt, lead-doped*	68784-75-8	272-271-5	0.01	Toxic for reproduction
124	Biphenyl-4-ylamine	92-67-1	202-177-1	0.005	Carcinogenic
125	Lead oxide (lead monoxide)*	1317-36-8	215-267-0	0.01	Toxic for reproduction
126	Pentalead tetraoxide sulphate*	12065-90-6	235-067-7	0.01	Toxic for reproduction
127	Propylene oxide; 1,2-epoxypropane; methyloxirane	75-56-9	200-879-2	0.01	Carcinogenic; Mutagenic
128	Silicic acid, lead salt*	11120-22-2	234-363-3	0.01	Toxic for reproduction

129	Trilead dioxide phosphonate*	12141-20-7	235-252-2	0.01	Toxic for reproduction
130	o-aminoazotoluene	97-56-3	202-591-2	0.005	Carcinogenic
131	1-bromopropane	106-94-5	203-445-0	0.01	Toxic for reproduction
132	6-methoxy-m-toluidine (p-cresidine)	120-71-8	204-419-1	0.005	Carcinogenic
133	4,4'-methylenedi-o-toluidine	838-88-0	212-658-8	0.005	Carcinogenic
134	Tetraethyllead*	78-00-2	201-075-4	0.01	Toxic for reproduction
135	Sulfurous acid, lead salt, dibasic*	62229-08-7	263-467-1	0.01	Toxic for reproduction
136	Fatty acids, C16-18, lead salts*	91031-62-8	292-966-7	0.01	Toxic for reproduction
137	Diisopentylphthalate+	605-50-5	210-088-4	0.005	Toxic for reproduction
138	Diazene-1,2-dicarboxamide (C,C'-azodi(formamide))	123-77-3	204-650-8	0.01	Equivalent level of concern having probable serious effects to human health
139	Cadmium*	7440-43-9	231-152-8	0.01	Carcinogenic; Equivalent level of concern
140	Cadmium oxide*	1306-19-0	215-146-2	0.01	Carcinogenic; Equivalent level of concern
141	Dipentyl phthalate (DPP) +	131-18-0	205-017-9	0.005	Toxic for reproduction
142	4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]	-	-	0.005	Equivalent level of concern
143	Ammonium pentadecafluorooctanoate (APFO) ≠	3825-26-1	223-320-4	0.005	Toxic for reproduction; PBT
144	Pentadecafluorooctanoic acid (PFOA) ≠	335-67-1	206-397-9	0.005	Toxic for reproduction; PBT
145	Cadmium sulphide	1306-23-6	215-147-8	0.01	Carcinogenic; Equivalent level of concern
146	Dihexyl phthalate	84-75-3	201-559-5	0.005	Toxic for reproduction
147	Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	573-58-0	209-358-4	0.005	Carcinogenic
148	Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo] -5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)	1937-37-7	217-710-3	0.005	Carcinogenic
149	Imidazolidine-2-thione (2-imidazoline-2-thiol)	96-45-7	202-506-9	0.005	Toxic for reproduction
150	Lead diacetate	301-04-2	206-104-4	0.01	Toxic for reproduction
151	Trixylyl phosphate	25155-23-1	246-677-8	0.005	Toxic for reproduction
152	Cadmium chloride*	10108-64-2	233-296-7	0.01	Carcinogenic; Mutagenic; Toxic for Reproduction; Equivalent level of concern having probable serious effects to human health
153	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear++	68515-50-4	271-093-5	0.005	Toxic for reproduction

154	Sodium peroxometaborate*	7632-04-4	231-556-4	0.01	Toxic for reproduction
155	Sodium perborate; perboric acid, sodium salt*	-	239-172-9; 234-390-0	0.01	Toxic for reproduction
156	Cadmium fluoride *	7790-79-6	232-222-0	0.01	Carcinogenic; Mutagenic; Toxic for Reproduction; Equivalent level of concern having probable serious effects to human health
157	Cadmium sulphate *	10124-36-4; 31119-53-6	233-331-6	0.01	Carcinogenic; Mutagenic; Toxic for Reproduction; Equivalent level of concern having probable serious effects to human health
158	2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	3846-71-7	223-346-6	0.005	PBT; vPvB
159	2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	25973-55-1	247-384-8	0.005	PBT; vPvB
160	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE) +++	15571-58-1	239-622-4	0.01	Toxic for Reproduction
161	Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE) +++	-	-	0.01	Toxic for Reproduction
162	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5)	68515-51-5; 68648-93-1	271-094-0; 272-013-1	0.01	Toxic for reproduction
163	5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual isomers of [1] and [2] or any combination thereof]	-	-	0.01	Very persistent and very bioaccumulative
164	1,3-propanesultone	1120-71-4	214-317-9	0.01	Carcinogenic
165	2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	3864-99-1	223-383-8	0.005	vPvB
166	2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	36437-37-3	253-037-1	0.005	vPvB
167	Nitrobenzene	98-95-3	202-716-0	0.01	Toxic for reproduction
168	Perfluorononan-1-oic-acid and its sodium and ammonium salts	375-95-1 21049-39-8 4149-60-4	206-801-3	0.01	Toxic for reproduction; PBT
169	Benzo[def]chrysene (Benzo[a]pyrene)	50-32-8	200-028-5	0.005	Carcinogenic; Mutagenic; Toxic for Reproduction; PBT; vPvB
170	4,4'-isopropylidenediphenol	80-05-7	201-245-8	0.005	Toxic for reproduction

	(bisphenol A)				Endocrine disrupting properties- environment & human health
171	Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts/	-	-	0.005	Toxic for reproduction; PBT
172	4-Heptylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 7 covalently bound predominantly in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]	-	-	0.005	Equivalent level of concern having probable serious effects to the environment
173	p-(1,1-dimethylpropyl)phenol	80-46-6	201-280-9	0.005	Equivalent level of concern having probable serious effects to the environment
174	Perfluorohexane-1-sulphonic acid and its salts (PFHxS)	-	-	0.005	vPvB
175	Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) [with ≥0.1% w/w 4-heptylphenol, branched and linear(4-HPbl)]	-	-	0.01	Endocrine disrupting properties- environment
176	Dodecachloropentacyclo[12.2.1.16, 9.02,13.05,10]octadeca-7,15-diene ("Dechlorane Plus"™) [covering any of its individual anti- and syn-isomers or any combination thereof]	-	-	0.01	vPvB
177	Chrysene	218-01-9 1719-03-5	205-923-4	0.005	Carcinogenic; PBT; vPvB
178	Cadmium nitrate*	10022-68-1 10325-94-7	233-710-6	0.01	Carcinogenic; Mutagenic Specific target organ toxicity after repeated exposure
179	Cadmium hydroxide*	21041-95-2	244-168-5	0.01	Carcinogenic; Mutagenic Specific target organ toxicity after repeated exposure
180	Cadmium carbonate*	513-78-0	208-168-9	0.01	Carcinogenic; Mutagenic Specific target organ toxicity after repeated exposure
181	Benz[a]anthracene	56-55-3 1718-53-2	200-280-6	0.005	Carcinogenic; PBT; vPvB
182	Terphenyl, hydrogenated	61788-32-7	262-967-7	0.005	vPvB
183	Octamethylcyclotetrasiloxane(D4)	556-67-2	209-136-7	0.005	PBT; vPvB
184	Lead	7439-92-1	231-100-4	0.01	Toxic for reproduction
185	Ethylenediamine (EDA)	107-15-3	203-468-6	0.005	Respiratory sensitising

					properties
186	Dodecamethylcyclohexasiloxane (D6)	540-97-6	208-762-8	0.005	PBT; vPvB
187	Disodium octaborate*	12008-41-2	234-541-0	0.005	Toxic for reproduction
188	Dicyclohexyl phthalate (DCHP)	84-61-7	201-545-9	0.005	Toxic for reproduction; Endocrine disrupting properties
189	Decamethylcyclopentasiloxane (D5)	541-02-6	208-764-9	0.005	PBT; vPvB
190	Benzo[ghi]perylene	191-24-2	205-883-8	0.005	PBT; vPvB
191	Benzene-1,2,4- tricarboxylic acid 1,2 anhydride (TMA)	552-30-7	209-008-0	0.005	Respiratory sensitising properties
192	Pyrene	129-00-0 1718-52-1	204-927-3	0.005	PBT; vPvB
193	Phenanthrene	85-01-8	201-581-5	0.005	vPvB
194	Fluoranthene	206-44-0 93951-69-0	205-912-4	0.005	PBT; vPvB
195	Benzo[k]fluoranthene	207-08-9	205-916-6	0.005	Carcinogenic; PBT; vPvB
196	2,2-bis(4'-hydroxyphenyl)-4-methylpentane	6807-17-6	401-720-1	0.005	Toxic for reproduction
197	1,7,7-trimethyl-3-(phenylmethylene)-Bicyclo[2.2.1]heptan-2-one	15087-24-8	239-139-9	0.005	Endocrine disrupting properties
198	2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof)	-	-	0.01	Equivalent level of concern having probable serious effects to human health Equivalent level of concern having probable serious effects to the environment/
199	2-methoxyethyl acetate	110-49-6	203-772-9	0.01	Toxic for reproduction
200	Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with ≥ 0.1% w/w of 4-nonylphenol, branched and linear (4-NP)	-	-	0.01	Endocrine disrupting properties
201	4-tert-butylphenol	98-54-4	202-679-0	0.005	Endocrine disrupting properties
202	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	119313-12-1	404-360-3	0.005	Toxic for reproduction
203	2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	71868-10-5	400-600-6	0.005	Toxic for reproduction
204	Diisohexyl phthalate	71850-09-4	276-090-2	0.005	Toxic for reproduction
205	Perfluorobutane sulfonic acid (PFBS) and its salts	-	-	0.005	Equivalent level of concern having probable serious effects on the environment and human health/
206	1-vinylimidazole	1072-63-5	214-012-0	0.005	Toxic for reproduction
207	2-methylimidazole	693-98-1	211-765-7	0.005	Toxic for reproduction
208	Dibutylbis(pentane-2,4-dionato-O,O')tin +++	22673-19-4	245-152-0	0.01	Toxic for reproduction
209	Butyl 4-hydroxybenzoate	94-26-8	202-318-7	0.005	Equivalent level of concern having probable serious effects on the

					human health - Endocrine disrupting properties
210	bis(2-(2-methoxyethoxy)ethyl) ether	143-24-8	205-594-7	0.01	Toxic for reproduction
211	Dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety	-	-	0.01	Toxic for reproduction

(1) CAS no. 7789-12-0 refers to sodium dichromate dihydrate
(2) CAS no. 10588-01-9 refers to anhydrous sodium dichromate
(3) CAS no. 3194-55-6 refers to a specific HBCDD - 1,2,5,6,9,10-hexabromocyclododecane
(4) CAS no. 25637-99-4 refers to unspecific HBCDD isomer composition
(5) CAS no. 1330-43-4 refers to disodium tetraborate, anhydrous
(6) CAS no. 12179-04-3 refers to sodium tetraborate, pentahydrate
(7) CAS no. 1303-96-4 refers to sodium tetraborate, decahydrate

Remark:

1. PBT = Persistent, bio accumulative and toxic as defined in Regulation (EC) No 1907/2006
2. vPvB = Very persistent and very bio accumulative as defined in Regulation (EC) No 1907/2006
3. ND = Not Detected
4. *Result is based on the heavy metal or inorganic element concentration. Due to the limit of the analytical technology available, any further investigation is not feasible. The client is strongly advised to review the chemical formulation to ascertain.
5. **Result is identified by tributyltin (TBT). Due to the limit of the analytical technology available, any further investigation is not feasible. The client is strongly advised to review the chemical formulation to ascertain.
6. §TGIC (1,3,5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione) and β-TGIC (1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione) are reported as a mixture.
7. [a]Refer to Aluminosilicate, Refractory Ceramic Fibres fulfil the three following conditions: a) oxides of aluminium and silicon are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm) c) alkaline oxide and alkali earth oxide (Na2O+K2O+CaO+MgO+BaO) content less or equal to 18% by weight.
8. [b]Refer to Zirconia Aluminosilicate, Refractory Ceramic Fibres fulfil the three following conditions: a) oxides of aluminium, silicon and zirconium are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm). c) alkaline oxide and alkali earth oxide (Na2O+K2O+CaO+MgO+BaO) content less or equal to 18% by weight.
9. [+][1,2-Benzenedicarboxylic acid, dipentylester, branched and linear] is a mixture of phthalates contains DPP, DIPP and N-pentyl-isopentylphtalate.
10. [≠]PFOA and APFO are reported together. The result is based on PFOA concentration. Due to the limit of the analytical technology available, any further investigation is not feasible. The client is strongly advised to review the chemical formulation to ascertain.
11. [++][1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear] is a mixture of phthalates contains dihexyl phthalate.
12. [+++]Result is based on the tin metal concentration, and further confirmation for checking DBT, DOTE & MOTE concentration.

Original Sample

END