

Customer details: Majestic Products B.V
Curieweg 19
3208 KJ Spijkenisse
The Netherlands

SATRA reference: CHM0243673/1610/EN

Your reference:

Date of report: 15th March 2016

Samples received: 4th September 2015
Date(s) work carried out: 5th to 26th October 2015

For the attention of: Vincent Hameleers

TECHNICAL REPORT

Subject: Overall migration testing in accordance with BS EN 1186:2002 and commission regulations 10/2011 on sample of gloves described as 1.44.560.00 M-Safe 246OR Nitril Grippaz.

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 It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.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 $\neq$ 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.

Please note uncertainty of measurement has not been applied to the results in this report. SATRA uncertainty of measurement values are available on request.

Report signed by: Emma Norris
Position: Chemical Technologist
Department: Chemical & Analytical Technology

WORK REQUESTED:

Samples of gloves described as 1.44.560.00 M-Safe 246OR Nitril Grippaz were received on the 4th September 2015 for assessment in accordance with the overall migration limit requirements of Commission Regulation No. 10/2011.

The overall migration limit testing against vegetable oil was carried out by an external laboratory, and reported under their reference AC/REP/137555/4.

Results originally tested and reported under SATRA reference CHM0238857/1540/EN issued on the 27th October 2015.

Results are also applicable to glove styles described as 1.44.550.00 M-Safe 246BK Nitril Grippaz and 1.44.570.00 M-Safe 246B Nitril Grippaz.

CONCLUSIONS:

When tested in accordance with BS EN 1186-9: 2002 the samples described as 1.44.560.00 M-Safe 246OR Nitril Grippaz were found to meet with the overall migration limit requirements when assessed against 10% Ethanol, 3% Acetic acid and 20% Ethanol for 2 hours at 40 °C.

When tested in accordance with BS EN 1186-9: 2002 the samples described as 1.44.560.00 M-Safe 246OR Nitril Grippaz were found to meet with the overall migration limit requirements when assessed against 50% Ethanol for 30 minutes at 40 °C.

When tested in accordance with BS EN 1186-8: 2002 the samples described as 1.44.560.00 M-Safe 246OR Nitril Grippaz were found to meet with the overall migration limit requirements when assessed against sunflower oil for 2 hours at 40 °C.

The specific migration limits for metals were assessed after extraction in 3% Acetic acid for 2 hours at 40°C and were found to meet with the requirements in Commission Regulation (EU) No 10/2011, Annex II.

Results are given in the following tables.

TESTING REQUIRED:

- ~~BS~~ EN 1186 part 9: 2002 Materials and articles in contact with foodstuffs – Plastics Test methods for overall migration into aqueous food simulants by article filling (modified) for 2 hours at 40°C.
 - 10% Ethanol (simulant A Commission Regulation No. 10/2011)
 - 3% Acetic Acid (simulant B in Commission Regulation No. 10/2011)
 - 20% Ethanol (simulant C in Commission Regulation No. 10/2011)
 - 50% Ethanol (simulant D1 in Commission Regulation No. 10/2011)
- TES-AC-500; Based on EN 1186 part 8: 2002 Materials and articles in contact with foodstuffs – Plastics Test methods for overall migration into olive oil by article filling (modified) for 10 days at 40°C. (Performed by an external laboratory)
 - Vegetable oil* (simulant D2 in Commission Regulation No. 10/2011)

- #SATRA SOP CAT-015 – Migration of metal elements (Ba, Co, Cu, Fe, Li, Mn, Zn) into food simulants. Quantification by ICP- OES.

*Note: Sunflower oil was used as an alternative to rectified olive oil – “reference simulant D”. The sunflower oil used has characteristics in accordance with those specified in Annex A of BS EN 1186-1: 2002.

RESULTS AND REQUIREMENTS:

#Migration into aqueous food simulants by article filling (modified) 2 hours at 40°C

The gloves were assessed by reversing the gloves to form a pouch and filling with each simulant. The surface area of each glove was calculated by determining the density of the glove, weighing the part of the glove that was in contact with the simulant and calculating the area assuming a homogeneous material.

Sample	Test Method	Global migration (mg/dm ²)		Mean Global migration (mg/dm ²)	Pass/Fail
1.44.560.00 M-Safe 246OR Nitril Grippaz	BS EN 1186-3 (10% ethanol)	A	7.0	8.0	Pass
		B	9.8		
		C	7.2		
1.44.560.00 M-Safe 246OR Nitril Grippaz	BS EN 1186-3 (3% Acetic acid)	A	11.0	9.3	Pass
		B	7.5		
		C	9.5		
1.44.560.00 M-Safe 246OR Nitril Grippaz	BS EN 1186-3 (20% ethanol)	A	9.8	7.2	Pass
		B	6.7		
		C	5.2		
Requirement	-	-		<10 mg/dm²	-

Migration into aqueous food simulants by article filling (modified) 30 minutes at 40 °C

Sample	Test Method	Global migration (mg/dm ²)		Mean Global migration (mg/dm ²)	Pass/Fail
1.44.560.00 M-Safe 246OR Nitril Grippaz	BS EN 1186-3 (50% ethanol)	A	4.3	4.6	Pass
		B	3.3		
		C	6.3		
Requirement	-	-		<10 mg/dm²	-

Migration into vegetable oil by article filling (modified) 2 hours at 40°C

Sample	Test Method	Global migration (mg/dm ²)		Mean Global migration (mg/dm ²)	Pass/Fail
1.44.560.00 M-Safe 246OR Nitril Grippaz	TES-AC-500/ BS EN 1186 (sunflower oil)	A	6.0	6.5	Pass
		B	6.8		
		C	6.6		
Requirement	-	-		<10 mg/dm²	-

Testing was carried out by an external laboratory

#SATRA SOP CAT-015 – Migration of metal elements (Ba, Co, Cu, Fe, Li, Mn, Zn) into food simulants. Quantification by ICP- OES.

Sample tested	Simulant	Element (mg/kg of foodstuffs)						
		Ba	Co	Cu	Fe	Li	Mn	Zn
1.44.560.00 M-Safe 246OR Nitril Grippaz	3% acetic acid	<0.1	<0.05	<0.05	<0.1	<0.1	<0.1	2.8
Requirement of the Commission Regulation (EU) No 10/2011, Annex II		1	0.05	5	48	0.6	0.6	25

Results are the mean of triplicate determinations

APPENDICES:

The samples described as 1.44.560.00 M-Safe 246OR Nitril Grippaz are suitable for contact with the following food categories of foodstuffs as listed in 10/2011 Annex III, table 2 following contact for 30 minutes at 40 °C

Reference number	Description of foodstuffs
01	Beverages
01.01	Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than or equal to 6% vol: A. Clear drinks: Water, ciders, clear fruit or vegetable juices of normal strength or concentrated, fruit nectars, lemonades, syrups, bitters, infusions, coffee, tea, beers, soft drinks, energy drinks and the like, flavoured water, liquid coffee extract B. Cloudy drinks: Juices and nectars and soft drinks containing fruit pulp, musts containing fruit pulp, liquid chocolate
01.02	Alcoholic beverages of an alcoholic strength of between 6% vol and 20%.
01.03	Alcoholic beverages of an alcoholic strength above 20 % and all cream liquors
02	Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares
02.05	Pastry, biscuits, cakes, bread, and other bakers'wares, dry: A. With fatty substances on the surface
02.06	Pastry, cakes, bread, dough and other bakers'wares, fresh: A. With fatty substances on the surface
03	Chocolate, sugar and products thereof
	Confectionery products
03.01	Chocolate, chocolate-coated products, substitutes and products coated with substitutes
03.02	Confectionery products: A. In solid form: I. With fatty substances on the surface B. In paste form: I. With fatty substances on the surface II. Moist
03.03	Sugar and sugar products B. Molasses, sugar syrups, honey and the like
04	Fruit, vegetables and products thereof

04.01	Whole fruit, fresh or chilled, unpeeled
04.02	Processed fruit: B. Fruit in the form of puree, preserves, pastes or in its own juice or in sugar syrup (jams, compote, and similar products) C. Fruit preserved in a liquid medium: I. In an oily medium II. In an alcoholic medium
04.03	Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and others): C. In paste or cream form
04.04	Whole vegetables, fresh or chilled
04.05	Processed vegetables: B. Fresh vegetables, peeled or cut C. Vegetables in the form of puree, preserves, pastes or in its own juice (including pickled and in brine) D. Preserved vegetables: I. In an oily medium II. In an alcoholic medium
05	Fats and oils
05.01	Animals and vegetable fats and oils, whether natural or treated (including cocoa butter, lard, resolidified butter)
05.02	Margarine, butter and other fats and oils made from water emulsions in oil
06	Animal products and eggs
06.01	Fish: A. Fresh, chilled, processed, salted or smoked including fish eggs B. Preserved fish: I. In an oily medium II. In an aqueous medium
06.02	Crustaceans and molluscs (including oysters, mussels, snails): A. Fresh within the shell B. Shell removed, processed, preserved or cooked with the shell I. In an oily medium II. In an aqueous medium
06.03	Meat of all zoological species (including poultry and game): A. Fresh, chilled, salted, smoked B. Processed meat products (such as ham, salami, bacon, sausages, and other) or in the form of paste, creams C. Marinated meat products in an oily medium

06.04	Preserved meat: A. In an fatty or oily medium B. In an aqueous medium
06.05	Whole eggs, egg yolk, egg white B. Liquid and cooked
07	Milk products
07.01	Milk A. Milk and milk based drinks whole, partly dried and skimmed or partly skimmed
07.02	Fermented milk such as yoghurt, buttermilk and similar products
07.03	Cream and sour cream
07.04	Cheeses: B. Natural cheese without rind or with edible rind (gouda, camembert, and the like) and melting cheese C. Processed cheese (soft cheese, cottage cheese and similar) D. Preserved cheese: I. In an oily medium II. In an aqueous medium (feta, mozzarella and similar)
08	Miscellaneous Products
08.01	Vinegar
08.02	Fried or roasted foods: A. Fried potatoes, fritters and the like B. Of animal origin
08.03	Preparations for soups, broths, sauces, in liquid, solid or powder form (extracts, concentrates); homogenised composite food preparations, prepared dishes including yeast and raising agents: A. Powdered or dried: I. With fatty character B. any other form than powdered or dried: I. With fatty character II. Other
08.04	Sauces: A. With aqueous character B. With fatty character e.g. mayonnaise, sauces derived from mayonnaise, salad creams and other oil/water mixtures e.g. coconut based sauces
08.05	Mustard (except powdered mustard)
08.06	Sandwiches, toasted bread pizza and the like containing any kind of foodstuff A. With fatty substances on the surface

08.07	Ice creams
08.08	Dried foods: A. With fatty substances on the surface
08.10	Concentrated extracts of an alcoholic strength equal to or exceeding 6% vol.
08.11	Cocoa: B. Cocoa paste
08.15	Spices and seasoning in oily medium such as pesto, curry paste



Gloves described as 1.44.560.00 M-Safe 246OR Nitril Grippaz

TERMS AND CONDITIONS OF BUSINESS

1. **GENERAL**
Work done or services undertaken are subject to the terms and conditions detailed below and all other conditions, warranties and representations, expressed or implied are hereby excluded.
2. **PRICES**
Prices are based on current material and production costs, exchange rates, duty and freight and are subject to change without notice.
3. **DELIVERY ESTIMATES**
Delivery estimates are made in good faith and date from receipt of a written order and full information to enable us to proceed. While SATRA or its subsidiaries (hereafter referred to as "SATRA") make every effort to fulfil them, such estimates are subject to unforeseen events and if not maintained, cannot give rise to any claim. Offers "ex stock" are subject to prior sale.
4. **CANCELLATION AND RETURNS**
Cancellation of orders for goods, services, training or consultancy is only acceptable by prior agreement of SATRA and a charge will normally be made.
5. **CLAIMS**
Claims for errors, shortages etc should be notified within 10 days of date of receipt. In the event of goods damaged in transit, packing materials should be retained for examination; otherwise no liability can be accepted.
6. **PAYMENT TERMS**
Payment terms are net 21 days from date of invoice. Failure to comply with the terms of payment may result in delayed delivery of goods and services and a review of the Customer's credit account. Should the customer become subject to an administration order, or becomes bankrupt or goes into liquidation, SATRA has a right to cancel any contract and discontinue any work. SATRA reserves the right to adjust US Dollar and Euro sales price where customer exceeds credit terms and where the exchange rate has moved more than 10% since invoicing.
7. **RETENTION OF TITLE**
All goods remain the property of SATRA until paid in full. Under no circumstances will a customer's purchase order override SATRA's Retention of Title clause. In the case of software, the ownership of the software remains with SATRA. Payment of invoices in full will entitle the customer to use the software under licence until (a) they cease to be a member of SATRA or (b) they cease trading. In both instances, the licence shall then revert to SATRA.
8. **GUARANTEE**
All goods manufactured by SATRA are guaranteed both as regards material and workmanship. Any part returned carriage paid, within twelve months from date of supply and found defective, will be repaired or replaced at SATRA's option free of charge. SATRA admits no liability for loss, damage or delay consequent on any defect in any goods supplied by SATRA.
9. **TEST REPORTS**
Results given in test reports refer only to samples submitted for analysis and tested by 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. SATRA shall not be liable for any subsequent loss or damage incurred by the Customer as a result of information supplied in a test report.
10. **TEST SAMPLES**
Unless otherwise agreed in advance, test samples will be disposed of 6 weeks after the date of the final report. If required, samples can be returned at the Customer's expense.
11. **RESPONSIBILITY**
Every effort is made to ensure accuracy in description, drawings and other information in correspondence, catalogues, etc but no warranty is given in this respect and SATRA shall not be liable for any error therein. SATRA carries out all tests and/or advises only on the basis that the same are carried out, made or given without any responsibility whether for negligence or otherwise. SATRA and its servants or agents will not be liable for any damage or loss direct or indirect of whatsoever kind, whether or not the same results directly or indirectly from negligence on the part of SATRA or its servants or agents.
12. **CONFIDENTIALITY**
Unless specifically excluded in the terms of an individual contract between SATRA and its Customer, the following shall apply to all reports, advice, drawings, photographs, specifications or data:
 - i. The above shall not be disclosed to third parties or used in litigation without the consent of SATRA.
 - ii. Where SATRA has given consent to disclosure, the Customer shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes test, reporting and advising. The Customer shall indemnify SATRA for any failure to do so.
 - iii. The above items are submitted to the Customer as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which may come into the public domain.
13. **CONSTRUCTION AND ARBITRATION**
The laws of England shall govern all contracts and the parties submit to exclusive jurisdiction of the courts of England, unless otherwise agreed.

Issue Date: 1st October 2009