

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:

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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 |
|---|-------------------------------|--|------|---|-----------|
| | | A | B | | |
| 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 |
|---|----------------------------|--|-----|---|-----------|
| | | A | B | | |
| 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 | <p>Processed fruit:</p> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> I. In an oily medium II. In an alcoholic medium |
| 04.03 | <p>Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and others):</p> <ul style="list-style-type: none"> C. In paste or cream form |
| 04.04 | Whole vegetables, fresh or chilled |
| 04.05 | <p>Processed vegetables:</p> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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 | <p>Fish:</p> <ul style="list-style-type: none"> A. Fresh, chilled, processed, salted or smoked including fish eggs B. Preserved fish: <ul style="list-style-type: none"> I. In an oily medium II. In an aqueous medium |
| 06.02 | <p>Crustaceans and molluscs (including oysters, mussels, snails):</p> <ul style="list-style-type: none"> A. Fresh within the shell B. Shell removed, processed, preserved or cooked with the shell <ul style="list-style-type: none"> I. In an oily medium II. In an aqueous medium |
| 06.03 | <p>Meat of all zoological species (including poultry and game):</p> <ul style="list-style-type: none"> 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

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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