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SATRA reference: CHM0239908/1547/EN
/Issue 2

Your reference:

Date of report: 4th December 2015

Samples received: 20th October 2015

Date(s) work carried out: 18th November 2015

For the attention of: Abdul Ahad Khan

TECHNICAL REPORT

Subject: FDA part 177 indirect food additives: Polymers Sub part C – substances for use only as components of articles intended for repeated use. Section 177.2600 on gloves described as AC5P-4401-2NFTI.

This report replaces CHM0239908/1547/EN issued on the 20th November 2015.

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 It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.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

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

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WORK REQUESTED:

Samples of gloves described as AC5P-4401-2NFTI were received on the 20th October 2015 for testing in accordance with the requirements of Food and Drug Administration (FDA) part 177 indirect food additives: Polymers Sub part C – substances for use only as components of articles intended for repeated use. Section 177.2600 Rubber articles intended for repeated use.

CONCLUSIONS:

The samples were tested in accordance with the methods and requirements given in FDA regulations Section 177.2600 and were found to meet with the requirements when assessed against distilled water and n-Hexane.

Testing completed on the 18th November 2015. Full results are given below.

RESULTS AND REQUIREMENTS:

Extraction simulant	Extractable matter requirement (mg/inch ²)	
	7 hour extraction under reflux	Successive 2 hour extraction under reflux
Distilled water	< 20	< 1
n-Hexane	< 175	< 4

Food and Drug Administration (FDA) part 177 indirect food additives: Polymers Sub part C – substances for use only as components of articles intended for repeated use. Section 177.2600 Rubber articles intended for repeated use.

SAMPLES: AC5P-4401-2NFTI

Extraction simulant	Extractable matter (mg/inch ²)				Pass / Fail
	7 hour extraction under reflux		Successive 2 hour extraction under reflux		
Distilled water	1	4.5	1	1.3	Pass
	2	5.0	2	<1	
	3	<1	3	Void result	
	Mean	3.1	Mean	<1	
n-Hexane	1	4.2	1	<1	Pass
	2	3.3	2	<1	
	3	3.4	3	<1	
	Mean	3.6	Mean	<1	

APPENDICES:



Gloves described as AC5P-4401-2NFTI

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Issue Date: 1st October 2009

Signed:

