



Study Title : SKIN SENSITIZATION STUDY OF LATEX EXAMINATION GLOVES IN GUINEA PIGS BY MAXIMIZATION TEST [as per ISO 10993-10: 2010 (E)]

Sponsor : NATHAN TRADING CO., LTD.,
58 MOO 12 PALAN SUB-DISTRICT
NATHAN DISTRICT,
UBON RATCHATHANI 34170

Study No. : BIO-ATX 2406

Test Facility : Bioneds India Pvt. Ltd.

Test Item : Latex Examination Gloves

Report Date : 20 November 2020

SUMMARY:

The study was conducted in a GLP and ISO 17025 accredited Lab and in accordance with all applicable ISO 10993 standards. TÜV SÜD Expert Toxicologists have reviewed the technical content of the study plan and study report in compliance of applicable guidelines and standards and observed no deviations throughout the entire duration of the study.

Under the test conditions reported, it is concluded that the polar and non-polar extracts of Latex Examination Gloves was found to be "Non-sensitizer" to Guinea pigs as per ISO 10993 part 10: 2010 (E).

Dr. Shailendra Singh
Head – Medical & Health Services
TÜV SÜD South Asia Pvt. Ltd.
Date: 20 November 2020

PAN No.: AABCT0716G
TAN No.: MUMT09385F
Service Tax Code No.:
AABCT0716GSD004
GST No. : 27150828488C

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Study Title : SKIN IRRITATION TEST OF LATEX EXAMINATION GLOVES IN NEW ZEALAND WHITE RABBITS [as per ISO 10993-10: 2010 (E)]

Sponsor : NATHAN TRADING CO., LTD.,
58 MOO 12 PALAN SUB-DISTRICT
NATHAN DISTRICT,
UBON RATCHATHANI 34170

Study No. : BIO-ATX 2407

Test Facility : Bioneds India Pvt. Ltd.

Test Item : Latex Examination Gloves

Report Date : 20 November 2020

SUMMARY:

The study was conducted in a GLP and ISO 17025 accredited Lab and in accordance with all applicable ISO 10993 standards. TÜV SÜD Expert Toxicologists have reviewed the technical content of the study plan and study report in compliance of applicable guidelines and standards and observed no deviations throughout the entire duration of the study.

Under the test conditions reported, it is concluded that there was no evidence of irritation of test item when applied topically to female New Zealand White rabbits. Therefore, the test item, Latex Examination Gloves classified as “Negligible irritant” to the skin of New Zealand White rabbits as per ISO 10993 part 10: 2010 (E).

Dr. Shailendra Singh
Head – Medical & Health Services
TÜV SÜD South Asia Pvt. Ltd.
Date: 20 November 2020

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Study Title : *In Vitro* Cytotoxicity Study of Latex Examination Gloves by Elution Method [As per ISO 10993-5:2009(E)]

Sponsor : Nathan Trading Co., Ltd.
58 Moo, 12 Palan Sub-District,
Nathan District,
Ubon Ratchathani 34170

Study No. : BIO-GNT 1018

Test Facility : Bioneds India Pvt. Ltd.

Test Item : Latex Examination Gloves

Report Date : 21st October 2020

SUMMARY:

The study was conducted in a GLP and ISO 17025 accredited Lab and in accordance with all applicable ISO 10993 standards. TÜV SÜD Expert Toxicologists have reviewed the technical content of the study plan and study report in compliance of applicable guidelines and standards and observed no deviations throughout the entire duration of the study.

Under the test conditions reported Latex Examination Gloves was considered as cytotoxic at 100% test item extract and "non-cytotoxic" at 50%, 25%, 12.5% and 6.25% test item extracts to the subconfluent monolayer of L-929 mouse fibroblast cells.

Dr. Shailendra Singh
Head – Medical & Health Services
TÜV SÜD South Asia Pvt. Ltd.
Date: 21st October 2020



South Asia

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Study Title : ACUTE SYSTEMIC TOXICITY STUDY OF LATEX EXAMINATION GLOVES, POWDER FREE IN SWISS ALBINO MICE [As per ISO 10993-11: 2017(E)]

Sponsor : NATHAN TRADING CO., LTD.,
58 MOO 12 PALAN SUB-DISTRICT
NATHAN DISTRICT,
UBON RATCHATHANI 34170

Study No. : BIO-ATX 2849

Test Facility : Bioneds India Pvt. Ltd.

Test Item : Latex Examination Gloves, Powder Free

Report Date : 21 January 2021

SUMMARY:

The study was conducted in a GLP and ISO 17025 accredited Lab and in accordance with all applicable ISO 10993 standards. TÜV SÜD Expert Toxicologists have reviewed the technical content of the study plan and study report in compliance of applicable guidelines and standards and observed no deviations throughout the entire duration of the study.

Under the test conditions reported, it is concluded that the polar and non-polar extracts of test item, Latex Examination Gloves, Powder Free when administered to Swiss Albino Mice through intravenous and intraperitoneal routes respectively at a dose volume of 50 mL/kg body weight did not reveal any systemic toxicity under the experimental conditions employed.

Dr. Shailendra Singh
Head – Medical & Health Services
TÜV SÜD South Asia Pvt. Ltd.
Date: 21 January 2021

PAN No.: AABCT0716G
TAN No.: MUMT09385F
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