



South Asia

Choose certainty.  
Add value.

**Study Title** : Skin Irritation Test of Examination Gloves, Nitrile Powder Free 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 2145

**Test Facility** : Bionees India Pvt. Ltd.

**Test Item** : Examination Gloves, Nitrile Powder Free

**Report Date** : 25<sup>th</sup> September 2020

#### SUMMARY:

The study was conducted in a GLP and ISO 17025 accredited Lab and in accordance with all applicable ISO 10993 standards. TUV SUD 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, Examination Gloves, Nitrile Powder Free was 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: 25<sup>th</sup> September 2020



South Asia

Choose certainty.  
Add value.

**Study Title** : *In Vitro* Cytotoxicity Study of Examination Gloves, Nitrile Powder Free 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 946

**Test Facility** : Bionees India Pvt. Ltd.

**Test Item** : Examination Gloves, Nitrile Powder Free

**Report Date** : 08<sup>th</sup> September 2020

#### SUMMARY:

The study was conducted in a GLP and ISO 17025 accredited Lab and in accordance with all applicable ISO 10993 standards. TUV SUD 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, Examination Gloves, Nitrile Powder Free are considered as cytotoxic at 100% test item extract and “non-cytotoxic” at 50%, 25%, 12.5% and 6.25% 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: 08<sup>th</sup> September 2020



South Asia

Choose certainty.  
Add value.

**Study Title** : Skin Sensitization Study of Examination Gloves, Nitrile Powder Free 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 2144

**Test Facility** : Bionees India Pvt. Ltd.

**Test Item** : Examination Gloves, Nitrile Powder Free

**Report Date** : 07<sup>th</sup> 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, it is concluded that the polar and non-polar extracts of Examination Gloves, Nitrile Powder Free was found to be "Non-sensitizer" to Guinea pigs.

**Dr. Shailendra Singh**  
Head – Medical & Health Services  
TÜV SÜD South Asia Pvt. Ltd.  
Date: 07<sup>th</sup> October 2020



South Asia

Choose certainty.  
Add value.

**Study Title** : ACUTE SYSTEMIC TOXICITY STUDY OF EXAMINATION GLOVES, NITRILE 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 2828

**Test Facility** : Bioneds India Pvt. Ltd.

**Test Item** : Examination Gloves, Nitrile 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, Examination Gloves, Nitrile 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

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