



TEST REPORT

NUMBER : THJ0068808

APPLICANT: INGA NANO TECHNOLOGY CO., LTD.
NO.13 LANE 863
GAOSHIH RD. YANGMEI TOWNSHIP
TAOYUAN COUNTY TAIWAN

DATE : MAR 28, 2008

SAMPLE DESCRIPTION:

ONE (1) GROUP OF SUBMITTED SAMPLES SAID TO BE :
ITEM NAME : NON-WOVEN FABRIC IN SILVER
ITEM NO. : S-AG
QUANTITY : 1 GROUP
COUNTRY OF ORIGIN : TAIWAN
DATE SAMPLE RECEIVED : JAN 23, 2008
DATE TEST STARTED : JAN 23, 2008

TEST CONDUCTED:

AS REQUESTED BY THE APPLICANT, FOR DETAILS PLEASE REFER TO ATTACHED PAGES.

CONCLUSION:

THE TEST ARTICLE MEETS THE REQUIREMENT OF THE TEST AS PER THE INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO 10993-5 BIOLOGICAL EVALUATION OF MEDICAL DEVICES - PART 5: TESTS FOR *In Vitro* CYTOTOXICITY, REFERENCE NUMBER ISO 10993-5:1999), AND IS NOT CONSIDERED CYTOTOXIC.

THIS TEST ARTICLE ELICITED A NEGLIGIBLE DERMAL RESPONSE IN RABBITS UNDER THE CONDITIONS OF THIS TEST WITH REFERENCE TO THE INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO 10993-10 BIOLOGICAL EVALUATION OF MEDICAL DEVICES - PART 10: TESTS FOR IRRITATION AND DELAYED-TYPE HYPERSENSITIVITY, REFERENCE NUMBER ISO 10993-10:2002).

AUTHORIZED BY:
ON BEHALF OF INTERTEK TESTING SERVICES
TAIWAN LIMITED



K. Y. LIANG
DIRECTOR

THIS REPORT SHALL NOT BE REPRODUCED
EXCEPT IN FULL, WITHOUT THE WRITTEN
APPROVAL OF THE LABORATORY.



NUMBER: THJ0068808

TEST CONDUCTED

1. AGAR DIFFUSION TEST

THREE MILLITITERS OF L-929 MOUSE FIBROBLAST CELL SUSPENSION WERE PLACED INTO WELLS OF SIX WELL, MULTIWELL TISSUE CULTURE PLATES, TO PREPARE MONOLAYERS OF CELLS. FOLLOWING INCUBATION, THE CULTURE MEDIUM WAS ASPIRATED FROM THE MONOLAYERS. THE MEDIUM WAS REPLACED WITH SERUM-SUPPLEMENTED CULTURE MEDIUM CONTAINING NOT MORE THAN 2% OF AGAR. THE AGAR LAYER WAS THIN ENOUGH TO PERMIT DIFFUSION OF ANY LEACHED CHEMICALS. THE TEST ARTICLE AND THE NEGATIVE AND POSITIVE CONTROLS WERE PLACED, IN TRIPPLICATE CULTURES, SO THAT THEY WERE IN CONTACT WITH THE SOLIDIFIED AGAR SURFACE. ALL CULTURES WERE THEN INCUBATED FOR NOT LESS THAN 24 HOURS IN A HUMIDIFIED INCUBATOR AT 37 (±1)° C AND 5 (±1)% CARBON DIOXIDE. AFTER INCUBATION, AN INVERTED MICROSCOPE WAS USED TO EXAMINE EACH CULTURE.

RESULT:

| | | |
|-------------------------|-------------------------|---------------------|
| <u>NEGATIVE CONTROL</u> | <u>POSITIVE CONTROL</u> | <u>TEST ARTICLE</u> |
| NEGATIVE | POSITIVE | NEGATIVE |

INTERPRETATION OF RESULTS:

THE BIOLOGICAL REACTIVITY (CELLULAR DEGENERATION AND MALFORMATION) WAS DESCRIBED AND RATED ON A SCALE OF 0 TO 4 (SEE TABLE). THE RESPONSES OBTAINED FROM THE NEGATIVE AND POSITIVE CONTROLS WERE ALSO MEASURED. THE TEST SYSTEM WAS CONSIDERED SUITABLE BECAUSE THE OBSERVED RESPONSE CORRESPONDS TO THE LABELED BIOLOGICAL REACTIVITY GRADE OF THE RELEVANT REFERENCE STANDARD. THE RESPONSE FROM THE TEST ARTICLE WAS ALSO MEASURED. THE TEST ARTICLE MEETS THE REQUIREMENTS OF THE TEST IF NONE OF THE CELL CULTURES EXPOSED TO THE TEST ARTICLE EXHIBIT GREATER THAN A MILD REACTIVITY (GRADE 2). THE TEST COULD HAVE BEEN REPEATED IF THE SUITABILITY OF THE SYSTEM WAS NOT CONFIRMED.



NUMBER: THJ0068808

TEST CONDUCTED

TABLE
REACTIVITY GRADES FOR AGAR DIFFUSION TEST

| GRADE | REACTIVITY | DESCRIPTION OF REACTIVITY ZONE |
|-------|------------|---|
| 0 | NONE | NO DETECTABLE ZONE AROUND OR UNDER SPECIMEN |
| 1 | SLIGHT | SOME MALFORMED OR DEGENERATED CELLS UNDER SPECIMEN |
| 2 | MILD | ZONE LIMITED TO AREA UNDER SPECIMEN |
| 3 | MODERATE | ZONE EXTENDS 0.5 TO 1.0 cm BEYOND SPECIMEN |
| 4 | SEVERE | ZONE EXTENDS GREATER THAN 1.0 cm BEYOND SPECIMEN BUT DOES NOT INVOLVE ENTIRE DISH |



NUMBER: THJ0068808

TEST CONDUCTED

2. PRIMARY DERMAL IRRITATION IN RABBITS (ISO)

THREE (3) NEW ZEALAND WHITE RABBITS EACH RECEIVED A SINGLE DERMAL APPLICATION OF 25 mm x 25 mm OF THE TEST ARTICLE ON TWO (2) TEST SITES, BOTH NON-ABRADED. EACH ANIMAL ALSO HAD TWO (2) NEGATIVE CONTROL SITES CONSISTING ONLY OF GAUZE MOISTENED WITH PHYSIOLOGICAL SALINE. THE TEST SITES WERE SEMI-OCCLUDED FOR FOUR (4) HOURS AND WERE OBSERVED INDIVIDUALLY FOR ERYTHEMA, EDEMA, AND OTHER EFFECTS FIVE 5, 24, 48 AND 72 HOURS AFTER APPLICATION. THE TEST ARTICLE, IN ONE (1) INCH SQUARES, WAS MOISTENED WITH PHYSIOLOGICAL SALINE UPON DOSING.

RESULT:

PRIMARY IRRITATION INDEX:* 0.00

NOTE : *REFER TO TABLE FOR SPECIFIC EVALUATION.

TABLE

DERMAL IRRITATION RESPONSE CATEGORIES IN THE RABBIT

| RESPONSE CATEGORY | MEAN SCORE |
|-------------------|------------|
| NEGLIGIBLE | 0.0 TO 0.4 |
| SLIGHT | 0.5 TO 1.9 |
| MODERATE | 2.0 TO 4.9 |
| SEVERE | 5.0 TO 8.0 |

END OF REPORT

TEST CONDUCTED

PHOTO

