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TEST REPORT

Test Report No: WT16081272

Client: **Sungallon Plastics(Shenzhen) Company Limited**

Name of Samples: **TPE GP520 Series(Medical Using)**

Model / Type: /

Test Type: Registration ( )

Registration Supplement ( )

Others (✓) Commission Test

Guangzhou Medical Instruments Quality Surveillance and Inspection Center of State Food and Drug Administration

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Guangzhou Medical Instruments Quality Surveillance and Inspection Center of State Food and Drug Administration

Test Report №: WT16081272

Name of Samples	TPE GP520 Series(Medical Using) Send-off (√) Spot check ( )	Samples' Serial №	WT16081272
Trademark	CALLONPRENE	Model / Type	/
Client	Sungallon Plastics(Shenzhen) Company Limited	Test Type	Commission Test
Client's Address	Building D,No.2,Kukeng Dafu Industrial Area,Aobei Community,GuanLan,Longhua New District,Shenzhen,China	Products' № / Lot №	1610057-03-7202
Manufacturer	Sungallon Plastics(Shenzhen) Company Limited	Sampling Bill №	/
Corporation being inspected	Sungallon Plastics(Shenzhen) Company Limited	Manufacturing date	2016.10.14
Sampled by	/	Samples' Quantity	/
Sampling Place	/	Cardinal Number of Samples	/
Sampling Date	/	Test Place	DongGuan Laboratory
Receiving Date	2016.12.05	Test Date	2016.12.05～2017.06.14
Test Items	Tests for in vitro cytotoxicity, Guinea Pig Maximization Test, Animal Irritation Test		
Test According to	ISO 10993-5:2009 Biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity . ISO 10993-10:2010 Biological evaluation of medical devices—Part 10: Tests for irritation and skin sensitization.		
Test Conclusion	For test results, see attachment. (Stamps of Test Organization) Issued Date : 二〇一七年六月二十三日		
Remarks	1) In this test report, —— means the item is not applicable, and / means the item is blank.		
Signature	Tested by: Reviewed by: Approved by(authorized signatory):		

1. Test summary

№	Test Items	Test Results	Monomial Conclusion	Remarks
1	Test for in vitro cytotoxicity	Slight cytotoxicity.	/	/
2	Guinea Pig Maximization Test	No sensitization.	/	/
3	Animal Irritation Test	Negligible.	/	/
	The end			

Name of Samples:	TPE GP520 Series (Medical Using)	Test Items:	Test for in vitro cytotoxicity
Model / Type:	/	Test environment :	Temperature:22℃ humidity:60%
Products' № / Lot №:	1610057-03-7202	Test Date :	2017.01.16 ~ 2017.01.26
Producing date:	2016.10.14	Test Standard :	ISO 10993-5:2009 Biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity

1 Cell Lines

ATCC CCL1 mouse fibroblasts L929 cells（Supplied by Shanghai Institute for Biological Sciences，CAS）

2 Sample and Test Specimen

2.1 Extracts Of Sample：Base on ISO 10993-12:2012，The test sample should be extracted with RPMI1640 culture medium at the ratio of 0.2g/mL under aseptic operation, 37℃ for 24h.

2.2 Blank control ：The same batch of RPMI1640 culture medium without test material, 37℃ for 24h.

2.3 Negative control：High-density polyethylene bottles were washed with pure water ,after ultraviolet radiation, shear it to fragments and extracted with RPMI1640 culture medium under aseptic operation , 37℃ for 24h.

2.4 Positive control ：Organo-tin poly（vinyl chloride）were washed with pure water ,after ultraviolet radiation, cut into pieces and extracted with MEM culture medium at the ratio of 0.2g/mL under aseptic operation, (37±1)℃ for (24±2)h.

3 Test Method

3.1 Test Standard :ISO 10993-5:2009 Biological evaluation of medical devices Part 5：Test for in vitro cytotoxicity .

3.2 Method : Remove and resuspend the cells by enzymatic ,count the cells and inoculate to the 12 culture dishs which diameter is 35mm (1×10^5/mL) ,2mL per dish . Incubate the cultures at 37±1℃ with 5% (volume fraction) carbon dioxide until the cultures have grown to subconfluency.

Discard the culture medium ,add the extracts of sample, blank control solution, negative control solution, positive control solution respectively, 3 parallel samples for each , 2.0mL/ dish. Incubate the cultures at 37±1℃ with 5% (volume fraction) carbon dioxide for 48h.

4 Test Result

After 48 hours culture, observe the culture dish under the microscope (see Table 1)：

5 Conclusions

After 48h culture, the cytotoxicity grades of blank control and negative control is 0, positive control is 4 , and test group is 1.

According to the standard, the test sample has slight cytotoxicity.

Table 1 The Result Of The Test

Group	Conditions of all cultures	Reactivity	Grade
Blank control group	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.	None	0
Negative control group	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.	None	0
Positive control group	Nearly complete or complete destruction of the cell layers.	Severe	4
Test group	Not more than 20 % of the cells are round, loosely attached and without intracytoplasmatic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable	Slight	1

Name of Samples:	TPE GP520 Series (Medical Using)	Test Items:	Guinea Pig Maximization Test
Model / Type:	/	Test environment:	Temperature:22℃ Humidity:60%
Products' № / Lot №:	1610057-03-7202	Test Date:	2017.03.31 ~ 2017.05.07
Producing date:	2016.10.14	Test Standard :	ISO 10993-10:2010 Biological evaluation of medical devices—Part 10: Tests for irritation and skin sensitization

1 Experimental animals

15 healthy albino guinea pigs. Weight: 345 ~ 391g.

Huadongxinhua experiment alanimal farms of Huadu District. Passed No.: SCXK(粤)2014-0023 (44007600004149).

Ten animals for test sample group and five animals for control group.

2 Sample and Test Specimen

2.1 Testing extracts: The testing extracts shall be prepared as specified in ISO10993-10:2010. The test sample should be extracted with 0.9% physiological saline at the ratio of 0.2g/mL under aseptic operation,37℃ for72h.

2.2 Extracts of negative control: 0.9% Physiological saline is prepared with the same condition。

2.3A:50:50(volume ratio) stable emulsion of Freund's complete adjuvant mixed with 0.9% sterile physiological saline.

2.4 B: Extract of the test sample emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and 0.9% sterile physiological saline.

3 Test Method

Clip and shave the fur on all treatment sites prior to all steps in the test procedure. For intradermal injections inject 0.1ml Freund's complete adjuvant for preliminary.

Intradermal induction phase .Make a pair of 0.1ml intradermal injections of each of following, into each animal, at the injection sites as shown in the standard in the clipped interscapular region.

Topical induction phase.7days after completion of the intradermal induction phase, administer the test sample by topical application to the interscapular region of each animal, using a path of area approximately 8cm^2 absorbent gauze, so as to cover the intradermal injection sites. Secure the patches with an occlusive dressing. Remove the dressings and patches after 48h.Treat the control animals similarly, using the blank liquid alone.

Challenge phase. At 14days after completion of the topical induction phase, challenge all test and control animals with the test sample. Administer the test sample and a vehicle control by topical application to the upper flank of each animal. Secure the patches with an occlusive dressing. Remove the dressings and patches after 24h.

4 Test Result

Observe the appearance of the challenge skin sites of the test and control animals 24 h and 48 h after removal of the dressings (Table 2).

Table 2 Result of skin hypersensitivity test

Group	Time	Grading scale	Quantity of animals	Ratio of hypersensitivity
Testing group	24h	0	10	0
	48h	0	10	0
Control group	24h	0	5	0
	48h	0	5	0

5 Conclusions

During testing, the response of the test group is not more obvious than that of the control group. The grades in the test group is not more than that in the control group while the grades in the control group is less than 1.According to the standard, the samples are considered to be no sensitization.

Name of Samples:	TPE GP520 Series (Medical Using)	Test Items:	Animal Irritation Test
Model / Type:	/	Test environment :	Temperature:22℃ humidity:60%
Products' № / Lot №:	1610057-03-7202	Test Date	2017.02.24 ~ 2017.03.03
Producing date:	2016.10.14	Test Standard :	ISO 10993-10:2010 Biological evaluation of medical devices—Part 10: Tests for irritation and skin sensitization

1 Experimental animals

3 healthy New Zealand rabbits. Weight 2.1~2.6 kg. Source:. Guangdong Medical Laboratory Animal Center. Passed No. :SCXK（粤）2014-0035（44411600003346）.

2 Sample and Test Specimen

2.1 Test sample: Based on ISO 10993-10:2010，The test sample should be extracted with 0.9% physiological saline at the ratio of 0.2g/ml under aseptic operation, 37℃ for 72h.

2.2 Negative control: The same batch of physiological saline is prepared with the same condition.

3 Test Method

3.1 Test Standard:

ISO 10993-10:2010 Biological evaluation of medical devices—Part 10: Tests for irritation and skin sensitization

3.2 Method:

Clip the fur within 12h of testing on the backs of the animals a sufficient distance on both sides of the spine for application and observation of all test sites（approximately 10cm×15cm）.

Apply generally 0.5ml appropriate extracts to the 2.5cm×2.5cm absorbent gauze patches. Apply the patch to the skin on each side of each rabbit as shown in ISO10993-10:2010. Similarly, apply the control patch of gauze moistened with the negative control to each rabbit. Cover the application sites with a bandage for a minimum of 4 h. At the end of the contact time, remove the dressings and mark the positions of the sites with permanent ink. Remove residual test material by washing with lukewarm water and careful drying . Observe the appearance of the skin.

4 Test Result

Record the appearance of each application site at 1h, 24h, 48h and 72h following removal of the patches(Table 3).

Use only 24h, 48h,and 72h observations for calculations.

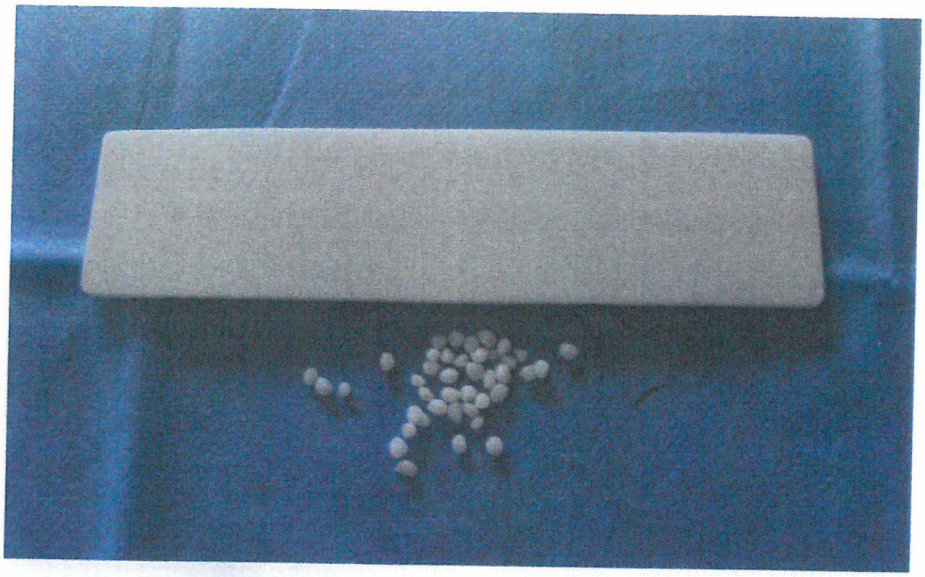
For each animal, add together the Primary Irritation Scores for the test material for both erythema and oedema at each time point and divide the sum but the total number of observations.(One observation in this context includes both erythema and oedema at each test site.) Calculate the Primary Irritation Score (S_1) for the test material. When negative control is used, calculate the Primary Irritation Score (S_2) for the controls and subtract that score from S_1 to obtain the Primary Irritation Score. Add the scores for each animal and divide the total by the number of animals. This value is the Primary Irritation Index (Table 3)

Table 3 Skin irritation response categories

Number	Primary Irritation Score for test material	Primary Irritation Score for controls	Primary Irritation Index	Irritation response categories
1	0	0	0	Negligible
2	0	0		
3	0	0		

5 Conclusions

The Primary Irritation Index of the New Zealand rabbits is 0. According to the standard, the irritation response categories of the sample is Negligible.

Photos and Explanations

Samples' Descriptions
TPE GP520 Series(Medical Using)
Types and Specifications or Other Explanations
Model / Type: / Products' № / Lot №: 1610057-03-7202 Producing date: 2016.10.14

STATEMENT

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