

Final Report

Study Title Reverse mutation in five histidine-requiring strains of *Salmonella typhimurium*

Test Article PIP silicone gel breast implants
IMGHC-TX-H, batch 16306
IMGHC-TX-H, batch 02808
IMGHC-TX-H, batch 27609
IMGHC-TX-H, batch 41609
IMGHC-TX-S, batch 37908
[REDACTED] control silicone gel breast implant:
[REDACTED]

Study Director [REDACTED]

Sponsor Medicines and Healthcare products Regulatory Agency
151 Buckingham Palace Road
London
SW1W 9SZ
United Kingdom

Study Monitor [REDACTED]

Test Facility Covance Laboratories Ltd
Otley Road, Harrogate
North Yorkshire HG3 1PY, ENGLAND

Covance Client Identifier 1008167

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Report Issued November 2012

Page Number 1 of 274

**STUDY DIRECTOR AUTHENTICATION
AND GLP COMPLIANCE STATEMENT**

**PIP silicone gel breast implants IMGHC-TX-H, batch 16306,
IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H,
batch 41609, IMGHC-TX-S, batch 37908 and [REDACTED] silicone gel
breast implant [REDACTED]: Reverse mutation in five
histidine-requiring strains of *Salmonella typhimurium***

I, the undersigned, hereby declare that the work was performed under my supervision and that the findings provide a true and accurate record of the results obtained.

The study was performed in accordance with the agreed protocol and with Covance Laboratories Limited Standard Operating Procedures, unless otherwise stated, and the study objectives were achieved.

The study was conducted in compliance with the United Kingdom Good Laboratory Practice Regulations 1999, Statutory Instrument No. 3106 as amended by the Good Laboratory Practice (Codification Amendments Etc.) Regulations 2004 and the OECD Principles on Good Laboratory Practice (revised 1997, issued January 1998) ENV/MC/CHEM (98) 17.

[REDACTED]

Study Director

29 November 2012
Date

QUALITY ASSURANCE STATEMENT

PIP silicone gel breast implants IMGHC-TX-H, batch 16306, IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H, batch 41609, IMGHC-TX-S, batch 37908 and [REDACTED] control silicone gel breast implant [REDACTED]: Reverse mutation in five histidine-requiring strains of *Salmonella typhimurium*

This study has been reviewed by the GLP Quality Assurance Unit of Covance and the report accurately reflects the raw data. The following inspections were conducted and findings reported to the Study Director (SD) and associated management.

Critical procedures, which are performed routinely in an operational area, may be audited as part of a "process" inspection programme. This can be in addition to phases scheduled on an individual study basis. Selected process inspections conducted and considered applicable to this study are included below.

In addition to the inspection programmes detailed below, a facility inspection programme is also operated. Details of this programme, which covers all areas of the facility annually (at a minimum), are set out in standard operating procedures.

Inspection Dates		Phase	Date Reported to SD and SD Management
From	To		
29 May 2012	29 May 2012	Protocol Review	29 May 2012
22 Jun 2012	22 Jun 2012	Protocol Amendment Review	22 Jun 2012
27 Jun 2012	27 Jun 2012	Dose Preparation	27 Jun 2012
06 Jul 2012	10 Jul 2012	Extraction	10 Jul 2012
08 Aug 2012	13 Aug 2012	Draft Report and Data Review	13 Aug 2012
27 Nov 2012	27 Nov 2012	Final Report Review	27 Nov 2012

Inspection Dates		Phase	Date Reported to SD and SD Management
From	To		
06 Jun 2012	06 Jun 2012	Dose Preparation	06 Jun 2012
06 Jun 2012	06 Jun 2012	eArchiving Procedure	07 Jun 2012
11 Jun 2012	11 Jun 2012	Culture Establishment	11 Jun 2012
20 Jun 2012	20 Jun 2012	Historical Control Ranges	20 Jun 2012
02 Jul 2012	02 Jul 2012	S9 Quality Control Checks	02 Jul 2012
04 Jul 2012	04 Jul 2012	Data Collation and Transfer	04 Jul 2012

[REDACTED]

29 Nov 2012

Date

Quality Assurance Unit

REVIEWING SCIENTIST'S STATEMENT

PIP silicone gel breast implants IMGHC-TX-H, batch 16306, IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H, batch 41609, IMGHC-TX-S, batch 37908 and [REDACTED] control silicone gel breast implant [REDACTED]; Reverse mutation in five histidine-requiring strains of *Salmonella typhimurium*

I, the undersigned, hereby declare that I have reviewed this report in conjunction with the Study Director and that the interpretation and presentation of the data in the report are consistent with the results obtained.

[REDACTED]

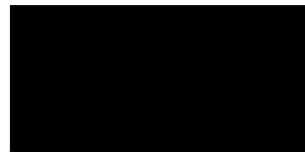
21 November 2012
Date

RESPONSIBLE PERSONNEL

**PIP silicone gel breast implants IMGHC-TX-H, batch 16306,
IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H,
batch 41609, IMGHC-TX-S, batch 37908 and [REDACTED] control silicone gel
breast implant [REDACTED]; Reverse mutation in five
histidine-requiring strains of *Salmonella typhimurium***

The following personnel were responsible for key elements of the study:

Study Director
Laboratory Supervisor
Study Monitor¹



¹ Located at Medicines and Healthcare products Regulatory Agency, London.

ARCHIVE STATEMENT

**PIP silicone gel breast implants IMGHC-TX-H, batch 16306,
IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H,
batch 41609, IMGHC-TX-S, batch 37908 and [REDACTED] control silicone gel
breast implant [REDACTED]; Reverse mutation in five
histidine-requiring strains of *Salmonella typhimurium***

All primary data, or authenticated copies thereof, specimens and the final report will be retained in the Covance Laboratories Limited archives for one year after issue of the Final Report. A copy of the electronic data will also be retained. At this time, the Study Monitor will be contacted to determine whether the data should be returned, retained or destroyed on their behalf. The Study Monitor will be notified of the financial implications of each of these options at that time. One copy of the protocol and final report will be held in the Covance Laboratory Limited archives as per Covance company policy.

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SUMMARY

PIP silicone gel breast implants models IMGHC-TX-H, batch 16306, IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H, batch 41609, IMGHC-TX-S, batch 37908 and [REDACTED] control silicone gel breast implant model [REDACTED] were assayed for mutation in five histidine-requiring strains (TA98, TA100, TA1535, TA1537 and TA102) of *Salmonella typhimurium*, both in the absence and in the presence of metabolic activation by an Aroclor 1254-induced rat liver post-mitochondrial fraction (S-9), in two separate experiments.

All test article treatments in this study were performed using extractions of the insoluble silicone gel that comprised the inner part of each implant. Extracts were prepared in anhydrous analytical grade dimethyl sulphoxide (DMSO) or purified water for irrigation (water) at concentrations of 200 mg/mL (equivalent), with the extractions being conducted at 37°C for 72 hours, with shaking, in line with principles of ISO Guideline 10993, Part 12, 2007. As all treatments were performed using extracts of the test articles, all treatment concentrations are expressed as equivalent concentrations.

Initial non-polar (organic) vehicle extractions were conducted in hexane (in order to be consistent with chemical analysis work previously conducted for the Sponsor), however under the extraction conditions employed for this study, when the hexane was evaporated to dryness prior to resuspension in DMSO (required to have extracts in a vehicle compatible with the assay system), it was clear that the hexane had dissolved some of the silicone gel, which remained in the extraction flasks and could not be removed during the evaporation and resuspension steps. This extraction methodology was therefore not considered appropriate to prepare non-polar (organic) vehicle test article extract samples for assaying in this biological assay system. It was therefore agreed with the Sponsor that non-polar (organic) extracts for use in this study would be prepared by direct extraction in DMSO.

Experiment 1 treatments of all the tester strains with each silicone gel DMSO extract were performed in the absence and in the presence of S-9, using final concentrations of PIP silicone gel breast implants models IMGHC-TX-H, batch 16306, IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H, batch 41609, IMGHC-TX-S, batch 37908 and [REDACTED] control silicone gel breast implant model [REDACTED] silicone gel extract at 200, 632.4, 2000, 6324 and 20000 µg/plate (equivalent), plus negative (blank extraction vehicle),

untreated (vehicle) and positive controls. Following these treatments there was no clear evidence of toxicity observed, but small reductions in revertant numbers at one or more of the higher treatment concentrations in strain TA1537 in the presence of S-9 with all DMSO extracts and in the absence of S-9 with some DMSO extracts may have been due to test article toxicity.

Experiment 1 treatments of all the tester strains with each silicone gel water extract were performed in the absence and in the presence of S-9, using final concentrations of PIP silicone gel breast implants models IMGHC-TX-H, batch 16306, IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H, batch 41609, IMGHC-TX-S, batch 37908 and [REDACTED] control silicone gel breast implant model [REDACTED] at 1000, 3162, 10000, 31620 and 100000 µg/plate (equivalent), plus negative (blank extraction vehicle), untreated (vehicle) and positive controls. Following these treatments, no clear evidence of toxicity was observed, but occasional small reductions in revertant numbers were observed in some strains with some water extracts (most notably in strain TA100 in the presence of S-9 with PIP silicone gel breast implant IMGHC-TX-H, batch 16306, and in strain TA102 in the presence of S-9 with PIP silicone gel breast implants IMGHC-TX-H, batch 16306 and IMGHC-TX-H, batch 27609), and these may have been the result of test article related toxic effects.

Experiment 2 treatments of all the tester strains with PIP silicone gel breast implants models IMGHC-TX-H, batch 16306, IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H, batch 41609, IMGHC-TX-S, batch 37908 and [REDACTED] control silicone gel breast implant model [REDACTED] silicone gel DMSO extracts were performed in the absence and in the presence of S-9. The maximum test concentration of 20000 µg/plate (equivalent) was retained for all extracts in all strains. Narrowed concentration intervals were employed covering the range 1250 - 20000 µg/plate (equivalent), in order to examine more closely those concentrations of each silicone gel DMSO extract approaching the maximum test concentration, and considered therefore most likely to provide evidence of any mutagenic activity. In addition, all treatments in the presence of S-9 were further modified by the inclusion of a pre-incubation step. In this way, it was hoped to increase the range of mutagenic chemicals that could be detected using this assay system. Following these treatments no clear evidence of toxicity was observed.

Experiment 2 treatments of all the tester strains with PIP silicone gel breast implants models IMGHC-TX-H, batch 16306, IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H, batch 41609, IMGHC-TX-S, batch 37908 and [REDACTED] control silicone gel breast implant model [REDACTED] silicone gel

water extracts were performed in the absence and in the presence of S-9. The maximum test concentration of 100000 µg/plate (equivalent) was retained for all extracts in all strains. Narrowed concentration intervals were employed covering the range 6250 - 100000 µg/plate (equivalent), in order to examine more closely those concentrations of each silicone gel DMSO extract approaching the maximum test concentration and considered therefore most likely to provide evidence of any mutagenic activity. In addition, all treatments in the presence of S-9 were further modified by the inclusion of a pre-incubation step. Following these treatments, no clear evidence of toxicity was observed, but small reductions in revertant numbers in strain TA1537 in the presence of S-9 with PIP silicone gel breast implants IMGHC-TX-H, batch 02808 and IMGHC-TX-H, batch 27609 may have been due to test article related toxicity.

All the test article water and DMSO extracts were completely soluble in the aqueous assay system at all concentrations treated, in each of the experiments performed.

Negative (vehicle; blank extraction vehicle and untreated; vehicle) and positive control treatments were included for all strains in both experiments. The mean numbers of revertant colonies all fell within acceptable ranges for negative control treatments, and were significantly elevated by positive control treatments.

Following PIP silicone gel breast implants models IMGHC-TX-H, batch 16306, IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H, batch 41609, IMGHC-TX-S, batch 37908 and [REDACTED] control silicone gel breast implant model [REDACTED] silicone gel water and DMSO extract treatments of all the tester strains, in both the absence and presence of S-9, only the DMSO extract of PIP Silicone gel breast implant, model IMGHC-TX-S, batch 37908 treatments in strain TA102 in the absence of S-9 in Experiment 1, the water extract of PIP Silicone gel breast implant, model IMGHC-TX-H, batch 02808 treatments in strain TA100 in the absence of S-9 Experiment 1 and the DMSO extracts of PIP Silicone gel breast implant model IMGHC-TX-H, batch 41609 and [REDACTED] control silicone gel breast implant, model [REDACTED] treatments in strains TA100 and TA1537 respectively, in the presence of S-9 in Experiment 2, resulted in increases in revertant numbers that were statistically significant when the data were analysed at the 1% level using Dunnett's test. In each case these increases were sufficiently small in magnitude that they might reasonably be expected to have occurred due to normal biological variability, provided little or no evidence of a concentration-relationship, and were not reproduced in the corresponding other independent experiment. Accordingly, these increases were not sufficient to be considered as evidence of any test article mutagenic activity.

No other increases in revertant numbers were observed that were considered notable or were statistically significant when the data were analysed at the 1% level using Dunnett's test. This study was considered therefore to have provided no evidence of any PIP silicone gel breast implants models IMGHC-TX-H, batch 16306, IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H, batch 41609, IMGHC-TX-S, batch 37908 or [REDACTED] control silicone gel breast implant model [REDACTED] mutagenic activity in this assay system.

It was concluded that PIP silicone gel breast implants models IMGHC-TX-H, batch 16306, IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H, batch 41609, IMGHC-TX-S, batch 37908 and [REDACTED] control silicone gel breast implant model [REDACTED] did not induce mutation in five histidine-requiring strains (TA98, TA100, TA1535, TA1537 and TA102) of *Salmonella typhimurium* when tested under the conditions of this study. These conditions included treatments with sterile anhydrous analytical grade dimethyl sulphoxide (DMSO) and purified water for irrigation (water) extracts of silicone gel from each breast implant at concentrations up to 20000 or 100000 µg/plate (equivalent) respectively, in the absence and in the presence of a rat liver metabolic activation system (S-9).

INTRODUCTION

The Ames test is a rapid, reliable and economical method of evaluating the mutagenic potential of a test article by measuring genetic activity in one or more histidine-requiring strains of *Salmonella typhimurium* in the absence and presence of a liver metabolising system (Ames *et al.*, 1975). A large database has been accumulated with this assay, confirming its ability to detect genetically active compounds of most chemical classes with around 80-90% sensitivity and specificity (Gatehouse *et al.*, 1990). The following bacterial strains were used in this study:

Table 1: Bacterial Strains

Organism	Strain	Type of mutation in the histidine gene
<i>S. typhimurium</i>	TA98	frame-shift
<i>S. typhimurium</i>	TA100	base-pair substitution
<i>S. typhimurium</i>	TA1535	base-pair substitution
<i>S. typhimurium</i>	TA1537	frame-shift
<i>S. typhimurium</i>	TA102	base-pair substitution

With the exception of strain TA102, these strains require biotin as well as histidine for growth. In strain TA102 the critical mutation in the histidine gene is located on a multicopy plasmid pAQ1. This strain is particularly sensitive to the activities of oxidative and cross-linking mutagens. The pKM101 plasmid derivatives (TA98, TA100 and TA102) have increased sensitivity to certain mutagens as the pKM101 plasmid codes for an error-prone DNA repair system (Maron and Ames, 1983).

When exposed to a mutagen, some of the bacteria in the treated population, through chemical interaction with the compound, undergo genetic changes which cause them to revert to a non-histidine-requiring state and thus grow in the absence of exogenous histidine. Different tester strains are used because each is mutated by particular chemical classes of compound. A compound that is mutagenic in one strain need not be so in another (Garner, 1979).

The silicone gel breast implants used for this study comprised an insoluble outer shell surrounding an insoluble silicone gel, the latter (inner) part of each implant being considered as the test article. As this material is insoluble in all commonly used vehicles, extracts of each test article were prepared according to the principles of ISO Guideline 10993, Part 3, 2003 and Part 12, 2007 and assessed in this study.

The objective of this study was therefore to evaluate the potential mutagenic activity of PIP silicone gel breast implants models IMGHC-TX-H, batch 16306, IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H, batch 41609, IMGHC-TX-S, batch 37908 and [REDACTED] control silicone gel breast implant model [REDACTED] by examining their ability to revert five histidine-requiring strains of *Salmonella typhimurium* in the absence and in the presence of a rat liver metabolising system (S-9). The procedures used in this study were in accordance with [OECD Guideline 471 \(1997\)](#), [UKEMS Guidelines \(Gatehouse *et al.*, 1990\)](#), [ICH-S2A \(1995\)](#) and [ICH-S2B \(1997\)](#).

This study was performed according to the protocol and one amendment.

The study was initiated on 25 May 2012. Experimental work started on 7 June 2012 and was completed on 13 July 2012. The study completion date is considered to be the date the Study Director signs the final report.

MATERIALS

Test article

PIP silicone gel breast implants, models: IMGHC-TX-H, batch 16306, IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H, batch 41609 and IMGHC-TX-S, batch 37908 and one [REDACTED] control silicone gel breast implant model: [REDACTED], were received on 23 May 2012 (all PIP implants) or 25 May 2012 ([REDACTED] implant) and stored at 15-30°C, protected from light. All these silicone gel breast implants were supplied as intact breast implants comprising an outer shell surrounding the inner silicone gel. The latter (inner) silicone gel component of each implant were clear white gels, and this part of the breast implant was that considered as the test article. All silicone gel samples taken for extraction throughout this study were from a single breast implant for each model/batch/manufacture. The expiry dates of the breast implants were given as shown in the table below:

Test Article	Expiry Date
IMGHC-TX-H, batch 16306	April 2011*
IMGHC-TX-H, batch 02808	January 2013
IMGHC-TX-H, batch 27609	June 2014
IMGHC-TX-H, batch 41609	November 2014
IMGHC-TX-S, batch 37908	June 2013
[REDACTED]	October 2016.

* The Sponsor confirmed that PIP silicone breast implant Model IMGHC-TX-H, Batch 16306 was suitable for use in this study at the time of assay, despite the package expiry date having already passed.

The test article information provided by the Sponsor is considered an adequate description of the characterisation and stability of the test articles. Determinations of stability and characteristics of the test articles were the responsibility of the Sponsor. Due to the nature of the test articles (prosthetic implants) specific purity values for these materials were not considered appropriate and no certificates of analysis were provided by the Sponsor.

As the test articles were insoluble in all commonly used vehicles, extracts of the test articles were prepared according to the principles of [ISO Guideline 10993, Part 3, 2003](#) and [Part 12, 2007](#). The test articles were extracted at 200 mg/mL for 72 hours at 37°C, with shaking, in one polar (aqueous) vehicle (water) and one non-polar (organic) vehicle (DMSO). Maximum concentrations of 100000 µg/plate

(equivalent) (water extract) and 20000 µg/plate (equivalent) (DMSO extract) were selected for Experiment 1, in order that treatments were performed up to the maximum achievable concentrations, and therefore compliant with the requirements of current regulatory guidelines ([Gatehouse *et al.*, 1990](#); [OECD, 1997](#); [ICH-S2A, 1995](#); [ICH-S2B, 1997](#)). Maximum concentrations of 100000 µg/plate (equivalent) (water extract) and 20000 µg/plate (equivalent) (DMSO extract) were also retained for Experiment 2.

Initial non-polar (organic) vehicle extractions were conducted in hexane (in order to be consistent with chemical analysis work previously conducted for the Sponsor), however under the extraction conditions employed for this study, when the hexane was evaporated to dryness prior to resuspension in DMSO (required to have extracts in a vehicle compatible with the assay system), it was clear that the hexane had dissolved some of the silicone gel, which remained in the extraction flasks and could not be removed during the evaporation and resuspension steps. This extraction methodology was therefore not considered appropriate to prepare non-polar (organic) vehicle test article extract samples for assaying in this biological assay system. It was therefore agreed with the Sponsor that non-polar (organic) extracts for use in this study would be prepared by direct extraction in DMSO.

For each test article, a silicone gel breast implant was initially weighed, then pierced to allow sampling of the silicone gel present within the outer shell. All operations were performed aseptically. An appropriate aliquot of the inner silicone gel for extraction was taken and cut into pieces (of approximately 1 cm³). A volume of appropriate extraction vehicle (water or DMSO) was added such that each extraction was performed at 200 mg/mL, and then extracted for 72 hours at 37°C, with shaking, in order to provide extracts that are considered an appropriate exaggeration of product use ([ISO 10993-12:2007 Biological evaluation of medical devices – Part 12](#)). For the water extracts, the resultant extracts were filter sterilised (Pall acrodisc, 0.2 µm pore size) prior to dilution or treatment. Subsequent dilutions of each extract were made using DMSO/water (as appropriate). The test article extracts were protected from light and used within approximately 7 hours of the end of the extraction period follows:

Table 2: Silicone gel breast implants concentrations tested

Experiment	S-9	Concentration of treatment extract (mg/mL)*	Final concentration (µg/plate)*
Mutation Experiment 1 DMSO Extract	- and +	2.00	200
		6.324	632.4
		20.00	2000
		63.24	6324
		200.0	20000
Mutation Experiment 1 Water extract	- and +	2.000	1000
		6.324	3162
		20.00	10000
		63.24	31620
		200.0	100000
Mutation Experiment 2 DMSO Extract	- and +	12.50	1250
		25.00	2500
		50.00	5000
		100.0	10000
		200.0	20000
Mutation Experiment 2 Water extract	- and +	12.50	6250
		25.00	12500
		50.00	25000
		100.0	50000
		200.0	100000

* As all formulations were test article extracts, all concentrations should be considered as equivalent

All water extract treatments were performed using 0.5 mL volume additions per treatment, and all DMSO extract treatments were performed using 0.1 mL additions per treatment.

Analysis of achieved concentration

Duplicate samples (approximately 1 mL) of each test article extract and blank extraction vehicle on each extraction occasion were retained for analysis of achieved concentration. Samples were taken from the same bulk extraction as were used for treatment. Samples were stored at 15-25°C, protected from light, prior to dispatch of one replicate of each to the following address for analysis at the end of the experimental phase.

FAO [REDACTED]
LGC
The Health Business Park
Runcorn
Cheshire
WA7 4QX.

The remaining portion of [REDACTED] control silicone gel breast implant model [REDACTED] was also dispatched with the samples.

The remaining samples were retained at Covance. The reserve samples may be delivered and analysed if requested by the analysis site, otherwise they will be discarded after finalisation of the study report. Data generated from analysis of the extraction samples will be reported separately and does not constitute part of this report.

Controls

Negative control treatments were performed using the same addition volumes per plate as the test article treatments, 0.1 mL for DMSO extracts or 0.5 mL for water extracts, and positive control treatments were performed at volume additions of 0.1 mL for plate incorporation treatments or 0.05 mL for pre-incubation treatments. Vehicle controls comprised treatments with the blank extraction vehicle, i.e. the appropriate extraction vehicle (DMSO or water) carried through the same procedures used to extract the test articles (except without any test article present for these blank extraction vehicles), including filter-sterilisation for the water extracts. Untreated controls were also included as further negative controls, and comprised treatments with the appropriate vehicle (DMSO or water) that had not been subject to the extraction process. The positive control chemicals were supplied and used according to the following table:

Table 3: Positive Controls

Chemical*	Stock ** concentration (µg/mL)	Final concentration (µg/plate)	Strain(s)	S-9
2-nitrofluorene (2NF)	50	5	TA98	-
Sodium azide (NaN ₃)	20	2	TA100, TA1535	-
9-aminoacridine (AAC)	500	50	TA1537	-
Mitomycin C (MMC)	2	0.2	TA102	-
Benzo[a]pyrene (B[a]P)	100***	10	TA98	+
2-aminoanthracene (AAN)	50***	5	TA100, TA1535, TA1537	+
	200***	20	TA102	+

* Obtained from Sigma-Aldrich Chemical Co, Poole, UK.

** Stock solutions were formulated in water (NaN₃ and MMC), or in DMSO (2NF, AAC, AAN and B[a]P). All stock solutions were stored in aliquots protected from light at 2-8°C, with the exception of B[a]P which was stored in aliquots at <-50°C and MMC which was prepared freshly on the day of use or stored in aliquots at <-50°C.

*** Concentrations were twice that stated for the pre-incubation methodology (0.05 mL per plate).

Metabolic activation system

The mammalian liver post-mitochondrial fraction (S-9) used for metabolic activation was obtained from Molecular Toxicology Incorporated, USA where it was prepared from male Sprague Dawley rats induced with Aroclor 1254. The batches of MolTox™ S-9 were stored frozen in aliquots at <-50°C, and thawed just prior to use (Booth *et al.*, 1980). Each batch was checked by the manufacturer for sterility, protein content, ability to convert ethidium bromide and cyclophosphamide to bacterial mutagens, and cytochrome P-450-catalysed enzyme activities (alkoxyresorufin-O-dealkylase activities). The quality control statements, relating to the batches of S-9 preparation used, are included in [Appendix 8](#) of this report.

Treatments were carried out both in the absence and presence of S-9 by addition of either buffer solution or 10% S-9 mix respectively, prepared according to the following table (per 100 mL mix):

Table 4: Buffer solution and 10% S-9 mix

Ingredient	Final content per mL in:	
	10% S-9 mix	Buffer solution
Sodium phosphate buffer pH 7.4	100 µMoles	100 µMoles
Glucose-6-phosphate (disodium)	5 µMoles	-
β-Nicotinamide adenine dinucleotide phosphate (NADP) (disodium)	4 µMoles	-
Magnesium chloride	8 µMoles	-
Potassium chloride	33 µMoles	-
Water	To volume	To volume
S-9	100 µL	-

Amino acids

The amino acid L-histidine HCl (in 250 mM MgCl₂), along with d-biotin were added, at concentrations of 20 µg and 24.4 µg per plate respectively, at the time of plating by supplementing the S-9 mix or buffer solution for plate incorporation treatments or by supplementing the soft agar for pre-incubation treatments.

Bacteria

Five strains of *Salmonella typhimurium* bacteria (TA98, TA100, TA1535, TA1537 and TA102) were used in this study. Strains TA98, TA1535 and TA1537 were originally obtained from the UK NCTC. Strains TA100 and TA102 were derived from cultures originally obtained from Covance Laboratories Inc., USA. For all assays, bacteria were cultured at 37±1°C for 10 hours in nutrient broth, containing

ampicillin (TA98, TA100) or ampicillin and tetracycline (TA102) as appropriate, to provide bacterial cultures in the range of approximately 10^8 to 10^9 cells/mL, based on cell count data from testing of each strain batch. Incubation was carried out with shaking in an anhydric incubator, set to turn on using a timer switch.

The inocula were taken from master plates or vials of frozen cultures, which had been checked for strain characteristics (histidine dependence, *rfa* character, *uvrB* character and resistance to ampicillin or ampicillin plus tetracycline). Checks were carried out according to Maron and Ames ([Maron and Ames, 1983](#)) and De Serres and Shelby ([De Serres and Shelby, 1979](#)).

METHODS

Mutation Experiments

PIP silicone gel breast implants models IMGHC-TX-H, batch 16306, IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H, batch 41609, IMGHC-TX-S, batch 37908 and [REDACTED] control silicone gel breast implant model [REDACTED] were tested for mutation (and toxicity) in five strains of *Salmonella typhimurium* (TA98, TA100, TA1535, TA1537 and TA102), in two separate experiments, at the concentrations detailed previously, using triplicate plates without and with S-9. Negative (vehicle and untreated) controls were included in quintuplicate, and positive controls were included in triplicate in both assays without and with S-9. These platings were achieved by the following sequence of additions to 2.5 mL molten agar at $46\pm 1^\circ\text{C}$:

- 0.1 mL bacterial culture
- 0.1 mL test article extract in DMSO or control, or 0.5 mL test article extract in water or control
- 0.5 mL 10% S-9 mix or buffer solution

followed by rapid mixing and pouring on to Vogel-Bonner E agar plates. When set, the plates were inverted and incubated at $37\pm 1^\circ\text{C}$ in the dark for 3 days. Following incubation, these plates were examined for evidence of toxicity to the background lawn, and where possible revertant colonies were counted (see Colony counting).

As the results of Experiment 1 were negative, treatments in the presence of S-9 in Experiment 2 included a pre-incubation step. Quantities of test article or control solution, bacteria and S-9 mix detailed above, were mixed together and incubated for 20 minutes at $37\pm 1^\circ\text{C}$, before the addition of 2.5 mL molten agar at $46\pm 1^\circ\text{C}$. Additions of 0.5 mL of 500 mM sodium phosphate buffer (pH 7.4) were employed for the DMSO extract treatments in Experiment 2 in order to reduced the solvent concentrations during the pre-incubation period. In order to “correct” for the additional volume in the pre-incubation mix with these DMSO extract pre-incubation treatments, these cultures were plated out using 2 mL of 1.125 % soft agar, therefore the additions to each plate were comparable to that of the plate-incorporation treatments. DMSO, and some other organic vehicles are known to be near to toxic levels when added at volumes of 0.1 mL in this assay system when employing the pre-incubation methodology. By employing the modification indicated, the DMSO concentration in the pre-incubation mix was decreased, and thus minimised or eliminated any toxic effects of the solvent.

Plating of these treatments then proceeded as for the normal plate-incorporation procedure. In this way, it was hoped to increase the range of mutagenic chemicals that could be detected in the assay.

Colony counting

Colonies were counted electronically using a Sorcerer Colony Counter (Perceptive Instruments) or manually where confounding factors such as bubbles or splits in the agar affected the accuracy of the automated counter. The background lawn was inspected for signs of toxicity.

Analysis of results

Treatment of data

Individual plate counts from each test article extract (or control) in each vehicle in each strain in each experiment were recorded separately and the mean and standard deviation of the plate counts for each treatment were determined. Vehicle control counts were compared with the accepted normal ranges for our laboratory for numbers of spontaneous revertants on vehicle control plates ([Appendix 6](#)) and numbers of induced revertants on positive control plates ([Appendix 7](#)). Data were considered acceptable if the mean vehicle control counts fell within the historical 99% confidence intervals for group means and/or each vehicle control plate count fell within the historical 99% reference ranges, and the positive control plate counts were comparable with the historical 99% reference ranges. The ranges that are quoted are based on a large volume of historical control data accumulated from experiments where the correct strain and assay functioning are considered to have been confirmed. Data for our laboratory are consistent with ranges of spontaneous revertants per plate considered acceptable elsewhere ([De Serres and Shelby, 1979](#)).

For evaluation of test article and positive control data there are many statistical methods in use, and several are acceptable ([Venitt *et al.*, 1983](#); [Mahon *et al.*, 1989](#)). Dunnett's test was used to compare the counts at each concentration with the control. The presence or otherwise of a concentration response was checked by non-statistical analysis, up to limiting levels (for example toxicity, precipitation or 5000 µg/plate).

Acceptance criteria

The assay was considered valid if the following criteria were met:

1. The vehicle control counts fell within the normal ranges as defined in [Appendix 6](#).
2. The positive control chemicals induced increases in revertant numbers of ≥ 2.0 -fold (in strains TA98, TA100, or TA102) or ≥ 3.0 -fold (in strains TA1535 or TA1537) the concurrent control, confirming discrimination between different strains, and an active S-9 preparation.

Evaluation criteria

For valid data, a test article was considered to be mutagenic if:

1. When assessed using Dunnett's test, an increase in revertant numbers gave a significant response ($p \leq 0.01$) which was concentration related.
2. The positive trend/effects described above were reproducible.

A test article was considered positive in this assay if all of the above criteria were met.

A test article was considered negative in this assay if none of the above criteria were met.

Results which only partially satisfied the above criteria were dealt with on a case-by-case basis. Biological relevance was taken into account, for example consistency of response within and between concentrations and (where applicable) between experiments.

Major computer systems

The major computer systems used on this study were as follows:

Table 5: Computer systems

Activity	Computer System
Scheduling	(CMS) Covance Management Systems
Formulations	Pristima
In-life data collection	Ames Study Manager/Sorcerer
Data generation and collection	Dunnett's Data Reporter
Report generation	Microsoft Office/Adobe Acrobat

Version numbers of the systems are held on file at Covance.

RESULTS

Toxicity, solubility and concentration selection

Details of all test article extract treatment concentrations and final PIP silicone gel breast implants models IMGHC-TX-H, batch 16306, IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H, batch 41609, IMGHC-TX-S, batch 37908 and [REDACTED] control silicone gel breast implant model [REDACTED] concentrations are provided in the Test article section.

Experiment 1 treatments of all the tester strains with each silicone gel DMSO extract were performed in the absence and in the presence of S-9, using final concentrations of PIP silicone gel breast implants models IMGHC-TX-H, batch 16306, IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H, batch 41609, IMGHC-TX-S, batch 37908 and [REDACTED] control silicone gel breast implant model [REDACTED] silicone gel extract at 200, 632.4, 2000, 6324 and 20000 µg/plate (equivalent), plus negative (blank extraction vehicle), untreated (vehicle) and positive controls. Following these treatments there was no clear evidence of toxicity observed (as would normally be indicated by a diminution of the background bacterial lawn, and/or a marked and dose-related reduction in revertant numbers), but small reductions in revertant numbers at one or more of the higher treatment concentrations in strain TA1537 in the presence of S-9 with all DMSO extracts and in the absence of S-9 with some DMSO extracts may have been due to test article toxicity.

Experiment 1 treatments of all the tester strains with each silicone gel water extract were performed in the absence and in the presence of S-9, using final concentrations of PIP silicone gel breast implants models IMGHC-TX-H, batch 16306, IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H, batch 41609, IMGHC-TX-S, batch 37908 and [REDACTED] control silicone gel breast implant model [REDACTED] at 1000, 3162, 10000, 31620 and 100000 µg/plate (equivalent), plus negative (blank extraction vehicle), untreated (vehicle) and positive controls. Following these treatments, no clear evidence of toxicity was observed, but occasional small reductions in revertant numbers were observed in some strains with some water extracts (most notably in strain TA100 in the presence of S-9 with PIP silicone gel breast implant IMGHC-TX-H, batch 16306, and in strain TA102 in the presence of S-9 with PIP silicone gel breast implants IMGHC-TX-H, batch 16306 and IMGHC-TX-H, batch 27609), and these may have been the result of test article related toxic effects.

Experiment 2 treatments of all the tester strains with PIP silicone gel breast implants models IMGHC-TX-H, batch 16306, IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H, batch 41609, IMGHC-TX-S, batch 37908 and [REDACTED] control silicone gel breast implant model [REDACTED] silicone gel DMSO extracts were performed in the absence and in the presence of S-9. The maximum test concentration of 20000 µg/plate (equivalent) was retained for all extracts in all strains. Narrowed concentration intervals were employed covering the range 1250 - 20000 µg/plate (equivalent), in order to examine more closely those concentrations of each silicone gel DMSO extract approaching the maximum test concentration, and considered therefore most likely to provide evidence of any mutagenic activity. In addition, all treatments in the presence of S-9 were further modified by the inclusion of a pre-incubation step. In this way, it was hoped to increase the range of mutagenic chemicals that could be detected using this assay system. Following these treatments no clear evidence of toxicity was observed.

Experiment 2 treatments of all the tester strains with PIP silicone gel breast implants models IMGHC-TX-H, batch 16306, IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H, batch 41609, IMGHC-TX-S, batch 37908 and [REDACTED] control silicone gel breast implant model [REDACTED] silicone gel water extracts were performed in the absence and in the presence of S-9. The maximum test concentration of 100000 µg/plate (equivalent) was retained for all extracts in all strains. Narrowed concentration intervals were employed covering the range 6250 - 100000 µg/plate (equivalent), in order to examine more closely those concentrations of each silicone gel DMSO extract approaching the maximum test concentration and considered therefore most likely to provide evidence of any mutagenic activity. In addition, all treatments in the presence of S-9 were further modified by the inclusion of a pre-incubation step. Following these treatments, no clear evidence of toxicity was observed, but small reductions in revertant numbers in strain TA1537 in the presence of S-9 with PIP silicone gel breast implants IMGHC-TX-H, batch 02808 and IMGHC-TX-H, batch 27609 may have been due to test article related toxicity.

All the test article water and DMSO extracts were completely soluble in the aqueous assay system at all concentrations treated, in each of the experiments performed.

Data acceptability and validity

The individual mutagenicity plate counts were averaged to give mean values, which are presented in [Appendix 1](#), [Appendix 2](#), [Appendix 3](#) and [Appendix 4](#). From the data it can be seen that mean vehicle control counts fell within the normal historical ranges

(Appendix 6). The positive control chemicals all induced increases in revertant numbers of ≥ 2.0 -fold (in strains TA98, TA100 or TA102) or ≥ 3.0 -fold (in strains TA1535 or TA1537) confirming discrimination between different strains, and an active S-9 preparation. The study therefore demonstrated correct strain and assay functioning and was accepted as valid.

Mutation

Following all PIP silicone gel breast implants models IMGHC-TX-H, batch 16306, IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H, batch 41609, IMGHC-TX-S, batch 37908 and [REDACTED] control silicone gel breast implant model [REDACTED] silicone gel water and DMSO extract treatments of all the tester strains, in both the absence and presence of S-9, only the DMSO extract of PIP Silicone gel breast implant, model IMGHC-TX-S, batch 37908 treatments in strain TA102 in the absence of S-9 in Experiment 1, the water extract of PIP Silicone gel breast implant, model IMGHC-TX-H, batch 02808 treatments in strain TA100 in the absence of S-9 Experiment 1 and the DMSO extracts of PIP Silicone gel breast implant model IMGHC-TX-H, batch 41609 and [REDACTED] control silicone gel breast implant, model [REDACTED] treatments in strains TA100 and TA1537 respectively, in the presence of S-9 in Experiment 2, resulted in increases in revertant numbers that were statistically significant when the data were analysed at the 1% level using Dunnett's test (Appendix 1, Appendix 2 and Appendix 3, Table 54, Table 99, Table 123 and Table 138). In each case these increases were sufficiently small in magnitude that they might reasonably be expected to have occurred due to normal biological variability. They also all provided little or no evidence of a concentration-relationship, and were not reproduced in the corresponding other independent experiment. Accordingly, these increases were not sufficient to be considered as evidence of any test article mutagenic activity.

No other increases in revertant numbers were observed that were considered notable or were statistically significant when the data were analysed at the 1% level using Dunnett's test. This study was considered therefore to have provided no evidence of any PIP silicone gel breast implants models IMGHC-TX-H, batch 16306, IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H, batch 41609, IMGHC-TX-S, batch 37908 or [REDACTED] control silicone gel breast implant model [REDACTED] mutagenic activity in this assay system when tested under the conditions employed for this study.

CONCLUSION

It was concluded that PIP silicone gel breast implants models IMGHC-TX-H, batch 16306, IMGHC-TX-H, batch 02808, IMGHC-TX-H, batch 27609, IMGHC-TX-H, batch 41609, IMGHC-TX-S, batch 37908 and [REDACTED] control silicone gel breast implant model [REDACTED] did not induce mutation in five histidine-requiring strains (TA98, TA100, TA1535, TA1537 and TA102) of *Salmonella typhimurium* when tested under the conditions of this study. These conditions included treatments with sterile anhydrous analytical grade dimethyl sulphoxide (DMSO) and purified water for irrigation (water) extracts of silicone gel from each breast implant at concentrations up to 20000 or 100000 µg/plate (equivalent) respectively, in the absence and in the presence of a rat liver metabolic activation system (S-9).

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APPENDICES

Appendix 1

Raw plate counts and calculated mutagenicity data Experiment 1 DMSO Extract

Table 6: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		15, 16, 25, 25, 10	18.2	5		6.6		
Untreated (DMSO) Controls		16, 21, 21, 23, 23	20.8	5	1.1	2.9		
PIP IMGHC-TX-H # 16306	200	20, 29, 18	22.3	3	1.2	5.9	0.92	NS
PIP IMGHC-TX-H # 16306	632.4	28, 13, 24	21.7	3	1.2	7.8	0.73	NS
PIP IMGHC-TX-H # 16306	2000	20, 20, 18	19.3	3	1.1	1.2	0.35	NS
PIP IMGHC-TX-H # 16306	6324	10, 24, 20	18.0	3	1.0	7.2	-0.05	NS
PIP IMGHC-TX-H # 16306	20000	26, 13, 20	19.7	3	1.1	6.5	0.34	NS
2NF	5	728, 856, 950	844.7	3	46.4	111.4		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 7: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA98 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		29, 25, 20, 28, 40	28.4	5		7.4		
Untreated (DMSO) Controls		18, 24, 25, 19, 29	23.0	5	0.8	4.5		
PIP IMGHC-TX-H # 16306	200	25, 36, 24	28.3	3	1.0	6.7	0.01	NS
PIP IMGHC-TX-H # 16306	632.4	39, 28, 30	32.3	3	1.1	5.9	0.94	NS
PIP IMGHC-TX-H # 16306	2000	29, 20, 26	25.0	3	0.9	4.6	-0.77	NS
PIP IMGHC-TX-H # 16306	6324	24, 25, 28	25.7	3	0.9	2.1	-0.58	NS
PIP IMGHC-TX-H # 16306	20000	30, 21, 20	23.7	3	0.8	5.5	-1.13	NS
B[a]P	10	303, 314, 289	302.0	3	10.6	12.5		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 8: PIP silicone gel breast implants IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		74, 109, 108, 112, 104	101.4	5		15.6		
Untreated (DMSO) Controls		101, 91, 109, 101, 74	95.2	5	0.9	13.5		
PIP IMGHC-TX-H # 16306	200	80, 91, 83	84.7	3	0.8	5.7	-1.97	NS
PIP IMGHC-TX-H # 16306	632.4	73, 107, 89	89.7	3	0.9	17.0	-1.40	NS
PIP IMGHC-TX-H # 16306	2000	79, 88, 85	84.0	3	0.8	4.6	-2.05	NS
PIP IMGHC-TX-H # 16306	6324	89, 99, 93	93.7	3	0.9	5.0	-0.85	NS
PIP IMGHC-TX-H # 16306	20000	94, 91, 100	95.0	3	0.9	4.6	-0.69	NS
NaN ₃	2	698, 776, 771	748.3	3	7.4	43.7		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 9: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		98, 110, 94, 84, 108	98.8	5		10.6		
Untreated (DMSO) Controls		93, 109, 101, 96, 88	97.4	5	1.0	8.0		
PIP IMGHC-TX-H # 16306	200	99, 93, 86	92.7	3	0.9	6.5	-0.67	NS
PIP IMGHC-TX-H # 16306	632.4	90, 80, 88	86.0	3	0.9	5.3	-1.45	NS
PIP IMGHC-TX-H # 16306	2000	112, 104, 99	105.0	3	1.1	6.6	0.70	NS
PIP IMGHC-TX-H # 16306	6324	101, 86, 100	95.7	3	1.0	8.4	-0.34	NS
PIP IMGHC-TX-H # 16306	20000	127, 99, 76	100.7	3	1.0	25.5	0.11	NS
AAN	5	1144, 1284, 1184	1204.0	3	12.2	72.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 10: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		19, 20, 8, 23, 24	18.8	5		6.4		
Untreated (DMSO) Controls		18, 16, 14, 16, 16	16.0	5	0.9	1.4		
PIP IMGHC-TX-H # 16306	200	11, 16, 21	16.0	3	0.9	5.0	-0.64	NS
PIP IMGHC-TX-H # 16306	632.4	21, 18, 11	16.7	3	0.9	5.1	-0.47	NS
PIP IMGHC-TX-H # 16306	2000	20, 23, 11	18.0	3	1.0	6.2	-0.16	NS
PIP IMGHC-TX-H # 16306	6324	19, 23, 24	22.0	3	1.2	2.6	0.87	NS
PIP IMGHC-TX-H # 16306	20000	18, 20, 18	18.7	3	1.0	1.2	0.10	NS
NaN ₃	2	521, 702, 725	649.3	3	34.5	111.7		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 11: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		21, 11, 14, 18, 21	17.0	5		4.4		
Untreated (DMSO) Controls		24, 21, 9, 14, 19	17.4	5	1.0	5.9		
PIP IMGHC-TX-H # 16306	200	14, 14, 14	14.0	3	0.8	0.0	-1.00	NS
PIP IMGHC-TX-H # 16306	632.4	13, 20, 21	18.0	3	1.1	4.4	0.36	NS
PIP IMGHC-TX-H # 16306	2000	20, 14, 19	17.7	3	1.0	3.2	0.28	NS
PIP IMGHC-TX-H # 16306	6324	16, 14, 20	16.7	3	1.0	3.1	-0.06	NS
PIP IMGHC-TX-H # 16306	20000	24, 16, 13	17.7	3	1.0	5.7	0.21	NS
AAN	5	170, 174, 209	184.3	3	10.8	21.5		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 12: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		19, 13, 8, 6, 13	11.8	5		5.1		
Untreated (DMSO) Controls		11, 9, 18, 9, 20	13.4	5	1.1	5.2		
PIP IMGHC-TX-H # 16306	200	9, 5, 13	9.0	3	0.8	4.0	-0.92	NS
PIP IMGHC-TX-H # 16306	632.4	10, 5, 13	9.3	3	0.8	4.0	-0.80	NS
PIP IMGHC-TX-H # 16306	2000	14, 9, 5	9.3	3	0.8	4.5	-0.82	NS
PIP IMGHC-TX-H # 16306	6324	11, 13, 13	12.3	3	1.0	1.2	0.30	NS
PIP IMGHC-TX-H # 16306	20000	9, 9, 6	8.0	3	0.7	1.7	-1.20	NS
AAC	50	130, 193, 167	163.3	3	13.8	31.7		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 13: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		28, 13, 13, 19, 9	16.4	5		7.4		
Untreated (DMSO) Controls		13, 13, 19, 6, 11	12.4	5	0.8	4.7		
PIP IMGHC-TX-H # 16306	200	9, 9, 15	11.0	3	0.7	3.5	-1.59	NS
PIP IMGHC-TX-H # 16306	632.4	19, 16, 11	15.3	3	0.9	4.0	-0.19	NS
PIP IMGHC-TX-H # 16306	2000	15, 11, 10	12.0	3	0.7	2.6	-1.22	NS
PIP IMGHC-TX-H # 16306	6324	8, 5, 9	7.3	3	0.4	2.1	-3.00	NS
PIP IMGHC-TX-H # 16306	20000	3, 3, 4	3.3	3	0.2	0.6	-5.02	NS
AAN	5	150, 107, 129	128.7	3	7.8	21.5		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 14: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		223, 279, 239, 209, 244	238.8	5		26.4		
Untreated (DMSO) Controls		219, 244, 272, 247, 263	249.0	5	1.0	20.3		
PIP IMGHC-TX-H # 16306	200	242, 249, 248	246.3	3	1.0	3.8	0.52	NS
PIP IMGHC-TX-H # 16306	632.4	217, 277, 236	243.3	3	1.0	30.7	0.29	NS
PIP IMGHC-TX-H # 16306	2000	234, 256, 258	249.3	3	1.0	13.3	0.71	NS
PIP IMGHC-TX-H # 16306	6324	278, 253, 247	259.3	3	1.1	16.4	1.34	NS
PIP IMGHC-TX-H # 16306	20000	266, 253, 227	248.7	3	1.0	19.9	0.66	NS
MMC	0.2	733, 870, 855	819.3	3	3.4	75.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 15: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		202, 194, 252, 229, 217	218.8	5		22.9		
Untreated (DMSO) Controls		207, 197, 214, 222, 233	214.6	5	1.0	13.8		
PIP IMGHC-TX-H # 16306	200	203, 242, 223	222.7	3	1.0	19.5	0.31	NS
PIP IMGHC-TX-H # 16306	632.4	243, 277, 264	261.3	3	1.2	17.2	3.10	*
PIP IMGHC-TX-H # 16306	2000	258, 241, 261	253.3	3	1.2	10.8	2.55	*
PIP IMGHC-TX-H # 16306	6324	244, 241, 222	235.7	3	1.1	11.9	1.28	NS
PIP IMGHC-TX-H # 16306	20000	257, 217, 229	234.3	3	1.1	20.5	1.17	NS
AAN	20	942, 1463, 1103	1169.3	3	5.3	266.8		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 16: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		15, 16, 25, 25, 10	18.2	5		6.6		
Untreated (DMSO) Controls		16, 21, 21, 23, 23	20.8	5	1.1	2.9		
PIP IMGHC-TX-H # 02808	200	21, 29, 29	26.3	3	1.4	4.6	1.72	NS
PIP IMGHC-TX-H # 02808	632.4	16, 13, 28	19.0	3	1.0	7.9	0.17	NS
PIP IMGHC-TX-H # 02808	2000	19, 35, 13	22.3	3	1.2	11.4	0.79	NS
PIP IMGHC-TX-H # 02808	6324	18, 15, 16	16.3	3	0.9	1.5	-0.32	NS
PIP IMGHC-TX-H # 02808	20000	18, 21, 19	19.3	3	1.1	1.5	0.35	NS
2NF	5	728, 856, 950	844.7	3	46.4	111.4		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 17: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA98 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		29, 25, 20, 28, 40	28.4	5		7.4		
Untreated (DMSO) Controls		18, 24, 25, 19, 29	23.0	5	0.8	4.5		
PIP IMGHC-TX-H # 02808	200	23, 25, 35	27.7	3	1.0	6.4	-0.11	NS
PIP IMGHC-TX-H # 02808	632.4	41, 30, 33	34.7	3	1.2	5.7	1.14	NS
PIP IMGHC-TX-H # 02808	2000	35, 18, 25	26.0	3	0.9	8.5	-0.48	NS
PIP IMGHC-TX-H # 02808	6324	21, 30, 35	28.7	3	1.0	7.1	0.06	NS
PIP IMGHC-TX-H # 02808	20000	20, 38, 28	28.7	3	1.0	9.0	0.03	NS
B[a]P	10	303, 314, 289	302.0	3	10.6	12.5		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 18: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		74, 109, 108, 112, 104	101.4	5		15.6		
Untreated (DMSO) Controls		101, 91, 109, 101, 74	95.2	5	0.9	13.5		
PIP IMGHC-TX-H # 02808	200	94, 112, 108	104.7	3	1.0	9.5	0.33	NS
PIP IMGHC-TX-H # 02808	632.4	86, 68, 107	87.0	3	0.9	19.5	-1.39	NS
PIP IMGHC-TX-H # 02808	2000	90, 78, 79	82.3	3	0.8	6.7	-1.79	NS
PIP IMGHC-TX-H # 02808	6324	105, 108, 110	107.7	3	1.1	2.5	0.61	NS
PIP IMGHC-TX-H # 02808	20000	103, 66, 90	86.3	3	0.9	18.8	-1.46	NS
NaN ₃	2	698, 776, 771	748.3	3	7.4	43.7		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 19: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		98, 110, 94, 84, 108	98.8	5		10.6		
Untreated (DMSO) Controls		93, 109, 101, 96, 88	97.4	5	1.0	8.0		
PIP IMGHC-TX-H # 02808	200	79, 88, 103	90.0	3	0.9	12.1	-1.10	NS
PIP IMGHC-TX-H # 02808	632.4	101, 119, 91	103.7	3	1.0	14.2	0.58	NS
PIP IMGHC-TX-H # 02808	2000	107, 108, 139	118.0	3	1.2	18.2	2.21	NS
PIP IMGHC-TX-H # 02808	6324	107, 105, 115	109.0	3	1.1	5.3	1.23	NS
PIP IMGHC-TX-H # 02808	20000	100, 93, 100	97.7	3	1.0	4.0	-0.11	NS
AAN	5	1144, 1284, 1184	1204.0	3	12.2	72.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 20: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		19, 20, 8, 23, 24	18.8	5		6.4		
Untreated (DMSO) Controls		18, 16, 14, 16, 16	16.0	5	0.9	1.4		
PIP IMGHC-TX-H # 02808	200	21, 15, 21	19.0	3	1.0	3.5	0.13	NS
PIP IMGHC-TX-H # 02808	632.4	13, 26, 24	21.0	3	1.1	7.0	0.46	NS
PIP IMGHC-TX-H # 02808	2000	19, 20, 29	22.7	3	1.2	5.5	0.82	NS
PIP IMGHC-TX-H # 02808	6324	26, 15, 8	16.3	3	0.9	9.1	-0.59	NS
PIP IMGHC-TX-H # 02808	20000	28, 25, 16	23.0	3	1.2	6.2	0.86	NS
NaN ₃	2	521, 702, 725	649.3	3	34.5	111.7		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 21: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		21, 11, 14, 18, 21	17.0	5		4.4		
Untreated (DMSO) Controls		24, 21, 9, 14, 19	17.4	5	1.0	5.9		
PIP IMGHC-TX-H # 02808	200	9, 16, 23	16.0	3	0.9	7.0	-0.30	NS
PIP IMGHC-TX-H # 02808	632.4	20, 24, 18	20.7	3	1.2	3.1	0.83	NS
PIP IMGHC-TX-H # 02808	2000	10, 18, 31	19.7	3	1.2	10.6	0.43	NS
PIP IMGHC-TX-H # 02808	6324	16, 23, 16	18.3	3	1.1	4.0	0.32	NS
PIP IMGHC-TX-H # 02808	20000	14, 25, 13	17.3	3	1.0	6.7	0.04	NS
AAN	5	170, 174, 209	184.3	3	10.8	21.5		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 22: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		19, 13, 8, 6, 13	11.8	5		5.1		
Untreated (DMSO) Controls		11, 9, 18, 9, 20	13.4	5	1.1	5.2		
PIP IMGHC-TX-H # 02808	200	13, 8, 5	8.7	3	0.7	4.0	-1.11	NS
PIP IMGHC-TX-H # 02808	632.4	10, 9, 5	8.0	3	0.7	2.6	-1.31	NS
PIP IMGHC-TX-H # 02808	2000	4, 8, 9	7.0	3	0.6	2.6	-1.75	NS
PIP IMGHC-TX-H # 02808	6324	10, 10, 9	9.7	3	0.8	0.6	-0.60	NS
PIP IMGHC-TX-H # 02808	20000	6, 4, 10	6.7	3	0.6	3.1	-1.92	NS
AAC	50	130, 193, 167	163.3	3	13.8	31.7		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 23: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		28, 13, 13, 19, 9	16.4	5		7.4		
Untreated (DMSO) Controls		13, 13, 19, 6, 11	12.4	5	0.8	4.7		
PIP IMGHC-TX-H # 02808	200	15, 13, 10	12.7	3	0.8	2.5	-0.91	NS
PIP IMGHC-TX-H # 02808	632.4	8, 5, 11	8.0	3	0.5	3.0	-2.51	NS
PIP IMGHC-TX-H # 02808	2000	9, 10, 9	9.3	3	0.6	0.6	-1.96	NS
PIP IMGHC-TX-H # 02808	6324	4, 13, 13	10.0	3	0.6	5.2	-1.92	NS
PIP IMGHC-TX-H # 02808	20000	8, 8, 6	7.3	3	0.4	1.2	-2.71	NS
AAN	5	150, 107, 129	128.7	3	7.8	21.5		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 24: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		223, 279, 239, 209, 244	238.8	5		26.4		
Untreated (DMSO) Controls		219, 244, 272, 247, 263	249.0	5	1.0	20.3		
PIP IMGHC-TX-H # 02808	200	271, 258, 269	266.0	3	1.1	7.0	2.00	NS
PIP IMGHC-TX-H # 02808	632.4	271, 253, 242	255.3	3	1.1	14.6	1.24	NS
PIP IMGHC-TX-H # 02808	2000	244, 263, 233	246.7	3	1.0	15.2	0.61	NS
PIP IMGHC-TX-H # 02808	6324	279, 253, 233	255.0	3	1.1	23.1	1.20	NS
PIP IMGHC-TX-H # 02808	20000	241, 234, 251	242.0	3	1.0	8.5	0.27	NS
MMC	0.2	733, 870, 855	819.3	3	3.4	75.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 25: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		202, 194, 252, 229, 217	218.8	5		22.9		
Untreated (DMSO) Controls		207, 197, 214, 222, 233	214.6	5	1.0	13.8		
PIP IMGHC-TX-H # 02808	200	226, 263, 273	254.0	3	1.2	24.8	2.13	NS
PIP IMGHC-TX-H # 02808	632.4	253, 273, 218	248.0	3	1.1	27.8	1.77	NS
PIP IMGHC-TX-H # 02808	2000	229, 241, 291	253.7	3	1.2	32.9	2.10	NS
PIP IMGHC-TX-H # 02808	6324	258, 273, 252	261.0	3	1.2	10.8	2.56	*
PIP IMGHC-TX-H # 02808	20000	252, 241, 256	249.7	3	1.1	7.8	1.90	NS
AAN	20	942, 1463, 1103	1169.3	3	5.3	266.8		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 26: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		15, 16, 25, 25, 10	18.2	5		6.6		
Untreated (DMSO) Controls		16, 21, 21, 23, 23	20.8	5	1.1	2.9		
PIP IMGHC-TX-H # 27609	200	21, 19, 16	18.7	3	1.0	2.5	0.25	NS
PIP IMGHC-TX-H # 27609	632.4	16, 18, 24	19.3	3	1.1	4.2	0.41	NS
PIP IMGHC-TX-H # 27609	2000	28, 19, 19	22.0	3	1.2	5.2	1.10	NS
PIP IMGHC-TX-H # 27609	6324	25, 14, 18	19.0	3	1.0	5.6	0.29	NS
PIP IMGHC-TX-H # 27609	20000	23, 19, 18	20.0	3	1.1	2.6	0.61	NS
2NF	5	728, 856, 950	844.7	3	46.4	111.4		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 27: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA98 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		29, 25, 20, 28, 40	28.4	5		7.4		
Untreated (DMSO) Controls		18, 24, 25, 19, 29	23.0	5	0.8	4.5		
PIP IMGHC-TX-H # 27609	200	39, 24, 33	32.0	3	1.1	7.5	0.80	NS
PIP IMGHC-TX-H # 27609	632.4	38, 26, 23	29.0	3	1.0	7.9	0.14	NS
PIP IMGHC-TX-H # 27609	2000	33, 35, 34	34.0	3	1.2	1.0	1.29	NS
PIP IMGHC-TX-H # 27609	6324	23, 25, 35	27.7	3	1.0	6.4	-0.14	NS
PIP IMGHC-TX-H # 27609	20000	26, 24, 26	25.3	3	0.9	1.2	-0.63	NS
B[a]P	10	303, 314, 289	302.0	3	10.6	12.5		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 28: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		74, 109, 108, 112, 104	101.4	5		15.6		
Untreated (DMSO) Controls		101, 91, 109, 101, 74	95.2	5	0.9	13.5		
PIP IMGHC-TX-H # 27609	200	105, 112, 99	105.3	3	1.0	6.5	0.51	NS
PIP IMGHC-TX-H # 27609	632.4	104, 94, 95	97.7	3	1.0	5.5	-0.39	NS
PIP IMGHC-TX-H # 27609	2000	86, 86, 109	93.7	3	0.9	13.3	-0.90	NS
PIP IMGHC-TX-H # 27609	6324	98, 99, 109	102.0	3	1.0	6.1	0.13	NS
PIP IMGHC-TX-H # 27609	20000	89, 108, 91	96.0	3	0.9	10.4	-0.60	NS
NaN ₃	2	698, 776, 771	748.3	3	7.4	43.7		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 29: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		98, 110, 94, 84, 108	98.8	5		10.6		
Untreated (DMSO) Controls		93, 109, 101, 96, 88	97.4	5	1.0	8.0		
PIP IMGHC-TX-H # 27609	200	85, 91, 112	96.0	3	1.0	14.2	-0.34	NS
PIP IMGHC-TX-H # 27609	632.4	104, 85, 117	102.0	3	1.0	16.1	0.35	NS
PIP IMGHC-TX-H # 27609	2000	101, 83, 88	90.7	3	0.9	9.3	-0.96	NS
PIP IMGHC-TX-H # 27609	6324	95, 105, 80	93.3	3	0.9	12.6	-0.66	NS
PIP IMGHC-TX-H # 27609	20000	89, 93, 93	91.7	3	0.9	2.3	-0.83	NS
AAN	5	1144, 1284, 1184	1204.0	3	12.2	72.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 30: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		19, 20, 8, 23, 24	18.8	5		6.4		
Untreated (DMSO) Controls		18, 16, 14, 16, 16	16.0	5	0.9	1.4		
PIP IMGHC-TX-H # 27609	200	18, 13, 14	15.0	3	0.8	2.6	-1.00	NS
PIP IMGHC-TX-H # 27609	632.4	16, 14, 16	15.3	3	0.8	1.2	-0.87	NS
PIP IMGHC-TX-H # 27609	2000	9, 16, 11	12.0	3	0.6	3.6	-2.04	NS
PIP IMGHC-TX-H # 27609	6324	16, 11, 15	14.0	3	0.7	2.6	-1.32	NS
PIP IMGHC-TX-H # 27609	20000	21, 19, 13	17.7	3	0.9	4.2	-0.22	NS
NaN ₃	2	521, 702, 725	649.3	3	34.5	111.7		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 31: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		21, 11, 14, 18, 21	17.0	5		4.4		
Untreated (DMSO) Controls		24, 21, 9, 14, 19	17.4	5	1.0	5.9		
PIP IMGHC-TX-H # 27609	200	14, 25, 15	18.0	3	1.1	6.1	0.27	NS
PIP IMGHC-TX-H # 27609	632.4	21, 20, 23	21.3	3	1.3	1.5	1.26	NS
PIP IMGHC-TX-H # 27609	2000	20, 15, 25	20.0	3	1.2	5.0	0.86	NS
PIP IMGHC-TX-H # 27609	6324	20, 33, 21	24.7	3	1.5	7.2	2.03	NS
PIP IMGHC-TX-H # 27609	20000	20, 15, 25	20.0	3	1.2	5.0	0.86	NS
AAN	5	170, 174, 209	184.3	3	10.8	21.5		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 32: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		19, 13, 8, 6, 13	11.8	5		5.1		
Untreated (DMSO) Controls		11, 9, 18, 9, 20	13.4	5	1.1	5.2		
PIP IMGHC-TX-H # 27609	200	8, 16, 11	11.7	3	1.0	4.0	0.03	NS
PIP IMGHC-TX-H # 27609	632.4	13, 8, 9	10.0	3	0.8	2.6	-0.47	NS
PIP IMGHC-TX-H # 27609	2000	9, 6, 6	7.0	3	0.6	1.7	-1.53	NS
PIP IMGHC-TX-H # 27609	6324	3, 8, 13	8.0	3	0.7	5.0	-1.34	NS
PIP IMGHC-TX-H # 27609	20000	4, 11, 8	7.7	3	0.6	3.5	-1.36	NS
AAC	50	130, 193, 167	163.3	3	13.8	31.7		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 33: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		28, 13, 13, 19, 9	16.4	5		7.4		
Untreated (DMSO) Controls		13, 13, 19, 6, 11	12.4	5	0.8	4.7		
PIP IMGHC-TX-H # 27609	200	11, 8, 10	9.7	3	0.6	1.5	-1.80	NS
PIP IMGHC-TX-H # 27609	632.4	6, 4, 9	6.3	3	0.4	2.5	-3.09	NS
PIP IMGHC-TX-H # 27609	2000	4, 5, 5	4.7	3	0.3	0.6	-3.76	NS
PIP IMGHC-TX-H # 27609	6324	4, 8, 13	8.3	3	0.5	4.5	-2.41	NS
PIP IMGHC-TX-H # 27609	20000	3, 10, 5	6.0	3	0.4	3.6	-3.31	NS
AAN	5	150, 107, 129	128.7	3	7.8	21.5		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 34: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		223, 279, 239, 209, 244	238.8	5		26.4		
Untreated (DMSO) Controls		219, 244, 272, 247, 263	249.0	5	1.0	20.3		
PIP IMGHC-TX-H # 27609	200	273, 251, 277	267.0	3	1.1	14.0	2.00	NS
PIP IMGHC-TX-H # 27609	632.4	257, 232, 283	257.3	3	1.1	25.5	1.31	NS
PIP IMGHC-TX-H # 27609	2000	283, 256, 251	263.3	3	1.1	17.2	1.74	NS
PIP IMGHC-TX-H # 27609	6324	261, 239, 243	247.7	3	1.0	11.7	0.66	NS
PIP IMGHC-TX-H # 27609	20000	249, 241, 243	244.3	3	1.0	4.2	0.43	NS
MMC	0.2	733, 870, 855	819.3	3	3.4	75.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 35: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		202, 194, 252, 229, 217	218.8	5		22.9		
Untreated (DMSO) Controls		207, 197, 214, 222, 233	214.6	5	1.0	13.8		
PIP IMGHC-TX-H # 27609	200	174, 202, 205	193.7	3	0.9	17.1	-2.13	NS
PIP IMGHC-TX-H # 27609	632.4	238, 208, 218	221.3	3	1.0	15.3	0.23	NS
PIP IMGHC-TX-H # 27609	2000	257, 232, 237	242.0	3	1.1	13.2	1.90	NS
PIP IMGHC-TX-H # 27609	6324	241, 246, 237	241.3	3	1.1	4.5	1.86	NS
PIP IMGHC-TX-H # 27609	20000	234, 213, 232	226.3	3	1.0	11.6	0.65	NS
AAN	20	942, 1463, 1103	1169.3	3	5.3	266.8		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 36: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		15, 16, 25, 25, 10	18.2	5		6.6		
Untreated (DMSO) Controls		16, 21, 21, 23, 23	20.8	5	1.1	2.9		
PIP IMGHC-TX-H # 41609	200	24, 15, 20	19.7	3	1.1	4.5	0.46	NS
PIP IMGHC-TX-H # 41609	632.4	24, 25, 34	27.7	3	1.5	5.5	2.32	NS
PIP IMGHC-TX-H # 41609	2000	26, 20, 23	23.0	3	1.3	3.0	1.30	NS
PIP IMGHC-TX-H # 41609	6324	16, 30, 16	20.7	3	1.1	8.1	0.64	NS
PIP IMGHC-TX-H # 41609	20000	28, 26, 29	27.7	3	1.5	1.5	2.35	NS
2NF	5	728, 856, 950	844.7	3	46.4	111.4		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 37: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA98 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		29, 25, 20, 28, 40	28.4	5		7.4		
Untreated (DMSO) Controls		18, 24, 25, 19, 29	23.0	5	0.8	4.5		
PIP IMGHC-TX-H # 41609	200	30, 35, 24	29.7	3	1.0	5.5	0.27	NS
PIP IMGHC-TX-H # 41609	632.4	30, 30, 41	33.7	3	1.2	6.4	0.99	NS
PIP IMGHC-TX-H # 41609	2000	28, 40, 19	29.0	3	1.0	10.5	0.06	NS
PIP IMGHC-TX-H # 41609	6324	41, 26, 26	31.0	3	1.1	8.7	0.48	NS
PIP IMGHC-TX-H # 41609	20000	25, 35, 26	28.7	3	1.0	5.5	0.09	NS
B[a]P	10	303, 314, 289	302.0	3	10.6	12.5		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 38: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		74, 109, 108, 112, 104	101.4	5		15.6		
Untreated (DMSO) Controls		101, 91, 109, 101, 74	95.2	5	0.9	13.5		
PIP IMGHC-TX-H # 41609	200	99, 85, 95	93.0	3	0.9	7.2	-0.98	NS
PIP IMGHC-TX-H # 41609	632.4	107, 93, 101	100.3	3	1.0	7.0	-0.07	NS
PIP IMGHC-TX-H # 41609	2000	84, 98, 94	92.0	3	0.9	7.2	-1.10	NS
PIP IMGHC-TX-H # 41609	6324	110, 85, 101	98.7	3	1.0	12.7	-0.30	NS
PIP IMGHC-TX-H # 41609	20000	104, 105, 115	108.0	3	1.1	6.1	0.84	NS
NaN ₃	2	698, 776, 771	748.3	3	7.4	43.7		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 39: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		98, 110, 94, 84, 108	98.8	5		10.6		
Untreated (DMSO) Controls		93, 109, 101, 96, 88	97.4	5	1.0	8.0		
PIP IMGHC-TX-H # 41609	200	74, 94, 120	96.0	3	1.0	23.1	-0.37	NS
PIP IMGHC-TX-H # 41609	632.4	129, 110, 135	124.7	3	1.3	13.1	2.57	*
PIP IMGHC-TX-H # 41609	2000	113, 120, 103	112.0	3	1.1	8.5	1.36	NS
PIP IMGHC-TX-H # 41609	6324	99, 129, 117	115.0	3	1.2	15.1	1.63	NS
PIP IMGHC-TX-H # 41609	20000	108, 110, 108	108.7	3	1.1	1.2	1.04	NS
AAN	5	1144, 1284, 1184	1204.0	3	12.2	72.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 40: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		19, 20, 8, 23, 24	18.8	5		6.4		
Untreated (DMSO) Controls		18, 16, 14, 16, 16	16.0	5	0.9	1.4		
PIP IMGHC-TX-H # 41609	200	26, 23, 19	22.7	3	1.2	3.5	1.11	NS
PIP IMGHC-TX-H # 41609	632.4	19, 25, 16	20.0	3	1.1	4.6	0.42	NS
PIP IMGHC-TX-H # 41609	2000	11, 20, 19	16.7	3	0.9	4.9	-0.51	NS
PIP IMGHC-TX-H # 41609	6324	18, 23, 20	20.3	3	1.1	2.5	0.54	NS
PIP IMGHC-TX-H # 41609	20000	26, 18, 20	21.3	3	1.1	4.2	0.77	NS
NaN ₃	2	521, 702, 725	649.3	3	34.5	111.7		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 41: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		21, 11, 14, 18, 21	17.0	5		4.4		
Untreated (DMSO) Controls		24, 21, 9, 14, 19	17.4	5	1.0	5.9		
PIP IMGHC-TX-H # 41609	200	21, 13, 24	19.3	3	1.1	5.7	0.72	NS
PIP IMGHC-TX-H # 41609	632.4	26, 16, 19	20.3	3	1.2	5.1	1.05	NS
PIP IMGHC-TX-H # 41609	2000	15, 21, 18	18.0	3	1.1	3.0	0.37	NS
PIP IMGHC-TX-H # 41609	6324	14, 20, 20	18.0	3	1.1	3.5	0.36	NS
PIP IMGHC-TX-H # 41609	20000	23, 18, 16	19.0	3	1.1	3.6	0.67	NS
AAN	5	170, 174, 209	184.3	3	10.8	21.5		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 42: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		19, 13, 8, 6, 13	11.8	5		5.1		
Untreated (DMSO) Controls		11, 9, 18, 9, 20	13.4	5	1.1	5.2		
PIP IMGHC-TX-H # 41609	200	9, 9, 11	9.7	3	0.8	1.2	-0.48	NS
PIP IMGHC-TX-H # 41609	632.4	16, 9, 5	10.0	3	0.8	5.6	-0.52	NS
PIP IMGHC-TX-H # 41609	2000	8, 6, 19	11.0	3	0.9	7.0	-0.28	NS
PIP IMGHC-TX-H # 41609	6324	16, 9, 10	11.7	3	1.0	3.8	0.03	NS
PIP IMGHC-TX-H # 41609	20000	16, 11, 5	10.7	3	0.9	5.5	-0.33	NS
AAC	50	130, 193, 167	163.3	3	13.8	31.7		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 43: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		28, 13, 13, 19, 9	16.4	5		7.4		
Untreated (DMSO) Controls		13, 13, 19, 6, 11	12.4	5	0.8	4.7		
PIP IMGHC-TX-H # 41609	200	9, 13, 13	11.7	3	0.7	2.3	-1.21	NS
PIP IMGHC-TX-H # 41609	632.4	9, 13, 13	11.7	3	0.7	2.3	-1.21	NS
PIP IMGHC-TX-H # 41609	2000	11, 13, 9	11.0	3	0.7	2.0	-1.41	NS
PIP IMGHC-TX-H # 41609	6324	9, 9, 13	10.3	3	0.6	2.3	-1.64	NS
PIP IMGHC-TX-H # 41609	20000	4, 15, 10	9.7	3	0.6	5.5	-2.04	NS
AAN	5	150, 107, 129	128.7	3	7.8	21.5		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 44: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		223, 279, 239, 209, 244	238.8	5		26.4		
Untreated (DMSO) Controls		219, 244, 272, 247, 263	249.0	5	1.0	20.3		
PIP IMGHC-TX-H # 41609	200	217, 249, 238	234.7	3	1.0	16.3	-0.28	NS
PIP IMGHC-TX-H # 41609	632.4	262, 271, 272	268.3	3	1.1	5.5	2.17	NS
PIP IMGHC-TX-H # 41609	2000	253, 236, 286	258.3	3	1.1	25.4	1.43	NS
PIP IMGHC-TX-H # 41609	6324	256, 249, 238	247.7	3	1.0	9.1	0.69	NS
PIP IMGHC-TX-H # 41609	20000	257, 261, 272	263.3	3	1.1	7.8	1.81	NS
MMC	0.2	733, 870, 855	819.3	3	3.4	75.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 45: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		202, 194, 252, 229, 217	218.8	5		22.9		
Untreated (DMSO) Controls		207, 197, 214, 222, 233	214.6	5	1.0	13.8		
PIP IMGHC-TX-H # 41609	200	172, 202, 184	186.0	3	0.9	15.1	-2.06	NS
PIP IMGHC-TX-H # 41609	632.4	190, 222, 185	199.0	3	0.9	20.1	-1.22	NS
PIP IMGHC-TX-H # 41609	2000	189, 160, 178	175.7	3	0.8	14.6	-2.75	NS
PIP IMGHC-TX-H # 41609	6324	205, 203, 187	198.3	3	0.9	9.9	-1.25	NS
PIP IMGHC-TX-H # 41609	20000	194, 133, 183	170.0	3	0.8	32.5	-3.20	NS
AAN	20	942, 1463, 1103	1169.3	3	5.3	266.8		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 46: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		15, 16, 25, 25, 10	18.2	5		6.6		
Untreated (DMSO) Controls		16, 21, 21, 23, 23	20.8	5	1.1	2.9		
PIP IMGHC-TX-S, #37908	200	25, 24, 20	23.0	3	1.3	2.6	1.49	NS
PIP IMGHC-TX-S, #37908	632.4	28, 30, 26	28.0	3	1.5	2.0	2.77	*
PIP IMGHC-TX-S, #37908	2000	20, 33, 23	25.3	3	1.4	6.8	2.04	NS
PIP IMGHC-TX-S, #37908	6324	23, 23, 18	21.3	3	1.2	2.9	1.03	NS
PIP IMGHC-TX-S, #37908 2NF	20000 5	23, 23, 18 728, 856, 950	21.3 844.7	3 3	1.2 46.4	2.9 111.4	1.03	NS

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 47: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA98 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		29, 25, 20, 28, 40	28.4	5		7.4		
Untreated (DMSO) Controls		18, 24, 25, 19, 29	23.0	5	0.8	4.5		
PIP IMGHC-TX-S, #37908	200	25, 33, 25	27.7	3	1.0	4.6	-0.15	NS
PIP IMGHC-TX-S, #37908	632.4	26, 28, 30	28.0	3	1.0	2.0	-0.02	NS
PIP IMGHC-TX-S, #37908	2000	31, 31, 29	30.3	3	1.1	1.2	0.68	NS
PIP IMGHC-TX-S, #37908	6324	26, 31, 24	27.0	3	1.0	3.6	-0.34	NS
PIP IMGHC-TX-S, #37908	20000	28, 26, 25	26.3	3	0.9	1.5	-0.53	NS
B[a]P	10	303, 314, 289	302.0	3	10.6	12.5		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 48: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		74, 109, 108, 112, 104	101.4	5		15.6		
Untreated (DMSO) Controls		101, 91, 109, 101, 74	95.2	5	0.9	13.5		
PIP IMGHC-TX-S, #37908	200	90, 93, 96	93.0	3	0.9	3.0	-0.90	NS
PIP IMGHC-TX-S, #37908	632.4	107, 105, 74	95.3	3	0.9	18.5	-0.70	NS
PIP IMGHC-TX-S, #37908	2000	100, 109, 104	104.3	3	1.0	4.5	0.38	NS
PIP IMGHC-TX-S, #37908	6324	99, 96, 103	99.3	3	1.0	3.5	-0.17	NS
PIP IMGHC-TX-S, #37908	20000	104, 93, 86	94.3	3	0.9	9.1	-0.76	NS
NaN ₃	2	698, 776, 771	748.3	3	7.4	43.7		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 49: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		98, 110, 94, 84, 108	98.8	5		10.6		
Untreated (DMSO) Controls		93, 109, 101, 96, 88	97.4	5	1.0	8.0		
PIP IMGHC-TX-S, #37908	200	103, 115, 115	111.0	3	1.1	6.9	1.62	NS
PIP IMGHC-TX-S, #37908	632.4	95, 101, 103	99.7	3	1.0	4.2	0.14	NS
PIP IMGHC-TX-S, #37908	2000	117, 113, 99	109.7	3	1.1	9.5	1.44	NS
PIP IMGHC-TX-S, #37908	6324	90, 120, 115	108.3	3	1.1	16.1	1.24	NS
PIP IMGHC-TX-S, #37908	20000	120, 108, 99	109.0	3	1.1	10.5	1.35	NS
AAN	5	1144, 1284, 1184	1204.0	3	12.2	72.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 50: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		19, 20, 8, 23, 24	18.8	5		6.4		
Untreated (DMSO) Controls		18, 16, 14, 16, 16	16.0	5	0.9	1.4		
PIP IMGHC-TX-S, #37908	200	16, 16, 21	17.7	3	0.9	2.9	-0.18	NS
PIP IMGHC-TX-S, #37908	632.4	18, 14, 19	17.0	3	0.9	2.6	-0.38	NS
PIP IMGHC-TX-S, #37908	2000	25, 21, 26	24.0	3	1.3	2.6	1.50	NS
PIP IMGHC-TX-S, #37908	6324	16, 26, 24	22.0	3	1.2	5.3	0.95	NS
PIP IMGHC-TX-S, #37908	20000	15, 23, 21	19.7	3	1.0	4.2	0.35	NS
NaN ₃	2	521, 702, 725	649.3	3	34.5	111.7		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 51: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		21, 11, 14, 18, 21	17.0	5		4.4		
Untreated (DMSO) Controls		24, 21, 9, 14, 19	17.4	5	1.0	5.9		
PIP IMGHC-TX-S, #37908	200	19, 13, 18	16.7	3	1.0	3.2	-0.06	NS
PIP IMGHC-TX-S, #37908	632.4	23, 16, 20	19.7	3	1.2	3.5	0.81	NS
PIP IMGHC-TX-S, #37908	2000	24, 13, 16	17.7	3	1.0	5.7	0.18	NS
PIP IMGHC-TX-S, #37908	6324	18, 19, 13	16.7	3	1.0	3.2	-0.06	NS
PIP IMGHC-TX-S, #37908	20000	16, 21, 9	15.3	3	0.9	6.0	-0.57	NS
AAN	5	170, 174, 209	184.3	3	10.8	21.5		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 52: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		19, 13, 8, 6, 13	11.8	5		5.1		
Untreated (DMSO) Controls		11, 9, 18, 9, 20	13.4	5	1.1	5.2		
PIP IMGHC-TX-S, #37908	200	13, 9, 9	10.3	3	0.9	2.3	-0.32	NS
PIP IMGHC-TX-S, #37908	632.4	10, 13, 10	11.0	3	0.9	1.7	-0.11	NS
PIP IMGHC-TX-S, #37908	2000	13, 4, 5	7.3	3	0.6	4.9	-1.46	NS
PIP IMGHC-TX-S, #37908	6324	6, 13, 6	8.3	3	0.7	4.0	-1.03	NS
PIP IMGHC-TX-S, #37908	20000	5, 16, 5	8.7	3	0.7	6.4	-1.05	NS
AAC	50	130, 193, 167	163.3	3	13.8	31.7		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 53: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		28, 13, 13, 19, 9	16.4	5		7.4		
Untreated (DMSO) Controls		13, 13, 19, 6, 11	12.4	5	0.8	4.7		
PIP IMGHC-TX-S, #37908	200	15, 11, 14	13.3	3	0.8	2.1	-0.53	NS
PIP IMGHC-TX-S, #37908	632.4	13, 8, 3	8.0	3	0.5	5.0	-2.02	NS
PIP IMGHC-TX-S, #37908	2000	5, 9, 13	9.0	3	0.5	4.0	-1.66	NS
PIP IMGHC-TX-S, #37908	6324	8, 9, 15	10.7	3	0.7	3.8	-1.20	NS
PIP IMGHC-TX-S, #37908	20000	5, 13, 1	6.3	3	0.4	6.1	-2.74	NS
AAN	5	150, 107, 129	128.7	3	7.8	21.5		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 54: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		223, 279, 239, 209, 244	238.8	5		26.4		
Untreated (DMSO) Controls		219, 244, 272, 247, 263	249.0	5	1.0	20.3		
PIP IMGHC-TX-S, #37908	200	294, 258, 289	280.3	3	1.2	19.5	2.48	*
PIP IMGHC-TX-S, #37908	632.4	266, 288, 264	272.7	3	1.1	13.3	2.05	NS
PIP IMGHC-TX-S, #37908	2000	284, 302, 306	297.3	3	1.2	11.7	3.45	**
PIP IMGHC-TX-S, #37908	6324	264, 291, 219	258.0	3	1.1	36.4	1.15	NS
PIP IMGHC-TX-S, #37908	20000	266, 282, 299	282.3	3	1.2	16.5	2.60	*
MMC	0.2	733, 870, 855	819.3	3	3.4	75.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 55: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		202, 194, 252, 229, 217	218.8	5		22.9		
Untreated (DMSO) Controls		207, 197, 214, 222, 233	214.6	5	1.0	13.8		
PIP IMGHC-TX-S, #37908	200	194, 217, 248	219.7	3	1.0	27.1	0.05	NS
PIP IMGHC-TX-S, #37908	632.4	249, 216, 252	239.0	3	1.1	20.0	1.21	NS
PIP IMGHC-TX-S, #37908	2000	231, 214, 243	229.3	3	1.0	14.6	0.65	NS
PIP IMGHC-TX-S, #37908	6324	252, 262, 272	262.0	3	1.2	10.0	2.52	*
PIP IMGHC-TX-S, #37908	20000	208, 249, 182	213.0	3	1.0	33.8	-0.38	NS
AAN	20	942, 1463, 1103	1169.3	3	5.3	266.8		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 56: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data - Experiment 1 - DMSO Extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		15, 16, 25, 25, 10	18.2	5		6.6		
Untreated (DMSO) Controls		16, 21, 21, 23, 23	20.8	5	1.1	2.9		
[REDACTED]	200	21, 24, 20	21.7	3	1.2	2.1	0.99	NS
[REDACTED]	632.4	24, 19, 16	19.7	3	1.1	4.0	0.47	NS
[REDACTED]	2000	24, 24, 15	21.0	3	1.2	5.2	0.78	NS
[REDACTED]	6324	20, 23, 26	23.0	3	1.3	3.0	1.30	NS
[REDACTED]	20000	20, 19, 34	24.3	3	1.3	8.4	1.52	NS
2NF	5	728, 856, 950	844.7	3	46.4	111.4		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 57: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data -
Experiment 1 - DMSO Extract, TA98 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		29, 25, 20, 28, 40	28.4	5		7.4		
Untreated (DMSO) Controls		18, 24, 25, 19, 29	23.0	5	0.8	4.5		
[REDACTED]	200	28, 20, 33	27.0	3	1.0	6.6	-0.30	NS
[REDACTED]	632.4	19, 24, 33	25.3	3	0.9	7.1	-0.70	NS
[REDACTED]	2000	26, 21, 24	23.7	3	0.8	2.5	-1.03	NS
[REDACTED]	6324	28, 21, 24	24.3	3	0.9	3.5	-0.88	NS
[REDACTED]	20000	35, 29, 23	29.0	3	1.0	6.0	0.17	NS
B[a]P	10	303, 314, 289	302.0	3	10.6	12.5		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 58: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data -
Experiment 1 - DMSO Extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		74, 109, 108, 112, 104	101.4	5		15.6		
Untreated (DMSO) Controls		101, 91, 109, 101, 74	95.2	5	0.9	13.5		
[REDACTED]	200	108, 100, 78	95.3	3	0.9	15.5	-0.59	NS
[REDACTED]	632.4	107, 108, 94	103.0	3	1.0	7.8	0.20	NS
[REDACTED]	2000	115, 113, 101	109.7	3	1.1	7.6	0.83	NS
[REDACTED]	6324	71, 110, 88	89.7	3	0.9	19.6	-1.20	NS
[REDACTED]	20000	95, 93, 103	97.0	3	1.0	5.3	-0.39	NS
NaN ₃	2	698, 776, 771	748.3	3	7.4	43.7		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 59: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data -
Experiment 1 - DMSO Extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		98, 110, 94, 84, 108	98.8	5		10.6		
Untreated (DMSO) Controls		93, 109, 101, 96, 88	97.4	5	1.0	8.0		
[REDACTED]	200	138, 115, 112	121.7	3	1.2	14.2	2.98	*
[REDACTED]	632.4	115, 104, 103	107.3	3	1.1	6.7	1.17	NS
[REDACTED]	2000	96, 81, 76	84.3	3	0.9	10.4	-2.07	NS
[REDACTED]	6324	99, 94, 79	90.7	3	0.9	10.4	-1.14	NS
[REDACTED]	20000	70, 69, 76	71.7	3	0.7	3.8	-4.00	NS
AAN	5	1144, 1284, 1184	1204.0	3	12.2	72.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 60: ██████████ control silicone gel breast implant ██████████ Raw plate counts and calculated mutagenicity data -
Experiment 1 - DMSO Extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		19, 20, 8, 23, 24	18.8	5		6.4		
Untreated (DMSO) Controls		18, 16, 14, 16, 16	16.0	5	0.9	1.4		
██████████	200	20, 19, 26	21.7	3	1.2	3.8	0.95	NS
██████████	632.4	20, 16, 24	20.0	3	1.1	4.0	0.47	NS
██████████	2000	19, 20, 16	18.3	3	1.0	2.1	0.02	NS
██████████	6324	14, 18, 21	17.7	3	0.9	3.5	-0.21	NS
██████████	20000	15, 15, 13	14.3	3	0.8	1.2	-1.24	NS
NaN ₃	2	521, 702, 725	649.3	3	34.5	111.7		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 61: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data -
Experiment 1 - DMSO Extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		21, 11, 14, 18, 21	17.0	5		4.4		
Untreated (DMSO) Controls		24, 21, 9, 14, 19	17.4	5	1.0	5.9		
[REDACTED]	200	18, 24, 18	20.0	3	1.2	3.5	0.95	NS
[REDACTED]	632.4	20, 24, 14	19.3	3	1.1	5.0	0.72	NS
[REDACTED]	2000	14, 13, 19	15.3	3	0.9	3.2	-0.50	NS
[REDACTED]	6324	13, 23, 15	17.0	3	1.0	5.3	0.00	NS
[REDACTED]	20000	14, 23, 16	17.7	3	1.0	4.7	0.22	NS
AAN	5	170, 174, 209	184.3	3	10.8	21.5		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 62: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data -
Experiment 1 - DMSO Extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		19, 13, 8, 6, 13	11.8	5		5.1		
Untreated (DMSO) Controls		11, 9, 18, 9, 20	13.4	5	1.1	5.2		
[REDACTED]	200	6, 4, 14	8.0	3	0.7	5.3	-1.33	NS
[REDACTED]	632.4	9, 11, 11	10.3	3	0.9	1.2	-0.33	NS
[REDACTED]	2000	11, 15, 11	12.3	3	1.0	2.3	0.28	NS
[REDACTED]	6324	5, 10, 16	10.3	3	0.9	5.5	-0.49	NS
[REDACTED]	20000	6, 8, 11	8.3	3	0.7	2.5	-1.05	NS
AAC	50	130, 193, 167	163.3	3	13.8	31.7		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 63: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data -
Experiment 1 - DMSO Extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		28, 13, 13, 19, 9	16.4	5		7.4		
Untreated (DMSO) Controls		13, 13, 19, 6, 11	12.4	5	0.8	4.7		
[REDACTED]	200	11, 14, 13	12.7	3	0.8	1.5	-1.01	NS
[REDACTED]	632.4	9, 10, 4	7.7	3	0.5	3.2	-3.03	NS
[REDACTED]	2000	6, 8, 9	7.7	3	0.5	1.5	-2.93	NS
[REDACTED]	6324	8, 10, 9	9.0	3	0.5	1.0	-2.36	NS
[REDACTED]	20000	9, 10, 6	8.3	3	0.5	2.1	-2.67	NS
AAN	5	150, 107, 129	128.7	3	7.8	21.5		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 64: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data -
Experiment 1 - DMSO Extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		223, 279, 239, 209, 244	238.8	5		26.4		
Untreated (DMSO) Controls		219, 244, 272, 247, 263	249.0	5	1.0	20.3		
[REDACTED]	200	262, 253, 246	253.7	3	1.1	8.0	0.87	NS
[REDACTED]	632.4	247, 272, 267	262.0	3	1.1	13.2	1.33	NS
[REDACTED]	2000	257, 242, 284	261.0	3	1.1	21.3	1.26	NS
[REDACTED]	6324	273, 236, 248	252.3	3	1.1	18.9	0.78	NS
[REDACTED]	20000	308, 227, 292	275.7	3	1.2	42.9	2.01	NS
MMC	0.2	733, 870, 855	819.3	3	3.4	75.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 65: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data -
Experiment 1 - DMSO Extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		202, 194, 252, 229, 217	218.8	5		22.9		
Untreated (DMSO) Controls		207, 197, 214, 222, 233	214.6	5	1.0	13.8		
[REDACTED]	200	208, 218, 212	212.7	3	1.0	5.0	-0.37	NS
[REDACTED]	632.4	198, 228, 185	203.7	3	0.9	22.1	-0.98	NS
[REDACTED]	2000	238, 213, 277	242.7	3	1.1	32.3	1.48	NS
[REDACTED]	6324	217, 205, 205	209.0	3	1.0	6.9	-0.61	NS
[REDACTED]	20000	167, 180, 138	161.7	3	0.7	21.5	-3.94	NS
AAN	20	942, 1463, 1103	1169.3	3	5.3	266.8		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Appendix 2
Raw plate counts and calculated mutagenicity data Experiment 2 DMSO Extract

Table 66: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		31, 24, 21, 21, 26	24.6	5		4.2		
Untreated (DMSO) Controls		15, 29, 16, 17, 19	19.2	5	0.8	5.7		
PIP IMGHC-TX-H # 16306	1250	21, 16, 17	18.0	3	0.7	2.6	-2.53	NS
PIP IMGHC-TX-H # 16306	2500	16, 22, 21	19.7	3	0.8	3.2	-1.86	NS
PIP IMGHC-TX-H # 16306	5000	20, 19, 21	20.0	3	0.8	1.0	-1.69	NS
PIP IMGHC-TX-H # 16306	10000	16, 14, 17	15.7	3	0.6	1.5	-3.53	NS
PIP IMGHC-TX-H # 16306	20000	14, 11, 21	15.3	3	0.6	5.1	-3.79	NS
2NF	5	1205, 931, 830	988.7	3	40.2	194.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 67: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA98 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		30, 30, 25, 31, 41	31.4	5		5.9		
Untreated (DMSO) Controls		35, 35, 30, 24, 25	29.8	5	0.9	5.3		
PIP IMGHC-TX-H # 16306	1250	26, 24, 51	33.7	3	1.1	15.0	0.20	NS
PIP IMGHC-TX-H # 16306	2500	21, 17, 41	26.3	3	0.8	12.9	-0.87	NS
PIP IMGHC-TX-H # 16306	5000	41, 31, 31	34.3	3	1.1	5.8	0.41	NS
PIP IMGHC-TX-H # 16306	10000	31, 15, 26	24.0	3	0.8	8.2	-1.17	NS
PIP IMGHC-TX-H # 16306	20000	30, 14, 22	22.0	3	0.7	8.0	-1.50	NS
B[a]P	10	537, 526, 530	531.0	3	16.9	5.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 68: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		93, 97, 91, 92, 116	97.8	5		10.4		
Untreated (DMSO) Controls		92, 90, 106, 105, 100	98.6	5	1.0	7.3		
PIP IMGHC-TX-H # 16306	1250	97, 90, 86	91.0	3	0.9	5.6	-0.92	NS
PIP IMGHC-TX-H # 16306	2500	80, 97, 84	87.0	3	0.9	8.9	-1.51	NS
PIP IMGHC-TX-H # 16306	5000	96, 93, 111	100.0	3	1.0	9.6	0.31	NS
PIP IMGHC-TX-H # 16306	10000	101, 77, 96	91.3	3	0.9	12.7	-0.91	NS
PIP IMGHC-TX-H # 16306	20000	85, 101, 105	97.0	3	1.0	10.6	-0.11	NS
NaN ₃	2	592, 642, 614	616.0	3	6.3	25.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 69: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		93, 85, 96, 87, 98	91.8	5		5.6		
Untreated (DMSO) Controls		91, 93, 87, 90, 93	90.8	5	1.0	2.5		
PIP IMGHC-TX-H # 16306	1250	79, 91, 86	85.3	3	0.9	6.0	-0.99	NS
PIP IMGHC-TX-H # 16306	2500	108, 80, 87	91.7	3	1.0	14.6	-0.07	NS
PIP IMGHC-TX-H # 16306	5000	98, 85, 84	89.0	3	1.0	7.8	-0.43	NS
PIP IMGHC-TX-H # 16306	10000	102, 90, 98	96.7	3	1.1	6.1	0.72	NS
PIP IMGHC-TX-H # 16306	20000	70, 81, 95	82.0	3	0.9	12.5	-1.55	NS
AAN	5	1097, 1418, 1731	1415.3	3	15.4	317.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 70: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		19, 21, 12, 22, 15	17.8	5		4.2		
Untreated (DMSO) Controls		14, 14, 11, 14, 14	13.4	5	0.8	1.3		
PIP IMGHC-TX-H # 16306	1250	11, 24, 21	18.7	3	1.0	6.8	0.19	NS
PIP IMGHC-TX-H # 16306	2500	26, 15, 20	20.3	3	1.1	5.5	0.77	NS
PIP IMGHC-TX-H # 16306	5000	24, 20, 19	21.0	3	1.2	2.6	1.02	NS
PIP IMGHC-TX-H # 16306	10000	15, 14, 20	16.3	3	0.9	3.2	-0.44	NS
PIP IMGHC-TX-H # 16306	20000	24, 22, 22	22.7	3	1.3	1.2	1.51	NS
NaN ₃	2	590, 557, 542	563.0	3	31.6	24.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 71: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		21, 21, 20, 16, 21	19.8	5		2.2		
Untreated (DMSO) Controls		12, 10, 20, 7, 16	13.0	5	0.7	5.1		
PIP IMGHC-TX-H # 16306	1250	17, 12, 16	15.0	3	0.8	2.6	-1.67	NS
PIP IMGHC-TX-H # 16306	2500	26, 12, 14	17.3	3	0.9	7.6	-0.98	NS
PIP IMGHC-TX-H # 16306	5000	12, 19, 10	13.7	3	0.7	4.7	-2.24	NS
PIP IMGHC-TX-H # 16306	10000	16, 17, 21	18.0	3	0.9	2.6	-0.60	NS
PIP IMGHC-TX-H # 16306	20000	16, 15, 20	17.0	3	0.9	2.6	-0.94	NS
AAN	5	228, 182, 207	205.7	3	10.4	23.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 72: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		9, 4, 10, 6, 6	7.0	5		2.4		
Untreated (DMSO) Controls		7, 11, 9, 9, 11	9.4	5	1.3	1.7		
PIP IMGHC-TX-H # 16306	1250	10, 10, 9	9.7	3	1.4	0.6	1.66	NS
PIP IMGHC-TX-H # 16306	2500	5, 10, 7	7.3	3	1.0	2.5	0.23	NS
PIP IMGHC-TX-H # 16306	5000	4, 10, 7	7.0	3	1.0	3.0	-0.03	NS
PIP IMGHC-TX-H # 16306	10000	6, 6, 5	5.7	3	0.8	0.6	-0.78	NS
PIP IMGHC-TX-H # 16306	20000	9, 5, 6	6.7	3	1.0	2.1	-0.17	NS
AAC	50	542, 451, 465	486.0	3	69.4	49.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 73: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		7, 6, 9, 5, 10	7.4	5		2.1		
Untreated (DMSO) Controls		9, 9, 12, 7, 5	8.4	5	1.1	2.6		
PIP IMGHC-TX-H # 16306	1250	5, 7, 6	6.0	3	0.8	1.0	-0.58	NS
PIP IMGHC-TX-H # 16306	2500	6, 14, 15	11.7	3	1.6	4.9	1.49	NS
PIP IMGHC-TX-H # 16306	5000	10, 14, 12	12.0	3	1.6	2.0	1.72	NS
PIP IMGHC-TX-H # 16306	10000	4, 10, 16	10.0	3	1.4	6.0	0.81	NS
PIP IMGHC-TX-H # 16306	20000	12, 12, 5	9.7	3	1.3	4.0	0.81	NS
AAN	5	145, 203, 191	179.7	3	24.3	30.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 74: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		265, 264, 293, 269, 260	270.2	5		13.1		
Untreated (DMSO) Controls		258, 288, 263, 259, 295	272.6	5	1.0	17.5		
PIP IMGHC-TX-H # 16306	1250	189, 243, 234	222.0	3	0.8	28.9	-3.70	NS
PIP IMGHC-TX-H # 16306	2500	233, 248, 226	235.7	3	0.9	11.2	-2.58	NS
PIP IMGHC-TX-H # 16306	5000	236, 244, 246	242.0	3	0.9	5.3	-2.09	NS
PIP IMGHC-TX-H # 16306	10000	249, 244, 199	230.7	3	0.9	27.5	-3.00	NS
PIP IMGHC-TX-H # 16306	20000	244, 252, 244	246.7	3	0.9	4.6	-1.73	NS
MMC	0.2	755, 767, 593	705.0	3	2.6	97.2		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 75: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		247, 239, 238, 248, 233	241.0	5		6.4		
Untreated (DMSO) Controls		239, 256, 223, 186, 262	233.2	5	1.0	30.5		
PIP IMGHC-TX-H # 16306	1250	236, 223, 248	235.7	3	1.0	12.5	-0.47	NS
PIP IMGHC-TX-H # 16306	2500	236, 189, 199	208.0	3	0.9	24.8	-2.97	NS
PIP IMGHC-TX-H # 16306	5000	252, 260, 217	243.0	3	1.0	22.9	0.14	NS
PIP IMGHC-TX-H # 16306	10000	228, 244, 253	241.7	3	1.0	12.7	0.05	NS
PIP IMGHC-TX-H # 16306	20000	228, 247, 252	242.3	3	1.0	12.7	0.11	NS
AAN	20	965, 953, 879	932.3	3	3.9	46.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 76: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		31, 24, 21, 21, 26	24.6	5		4.2		
Untreated (DMSO) Controls		15, 29, 16, 17, 19	19.2	5	0.8	5.7		
PIP IMGHC-TX-H # 02808	1250	25, 14, 25	21.3	3	0.9	6.4	-0.64	NS
PIP IMGHC-TX-H # 02808	2500	29, 25, 24	26.0	3	1.1	2.6	0.26	NS
PIP IMGHC-TX-H # 02808	5000	25, 32, 11	22.7	3	0.9	10.7	-0.50	NS
PIP IMGHC-TX-H # 02808	10000	26, 17, 19	20.7	3	0.8	4.7	-0.73	NS
PIP IMGHC-TX-H # 02808	20000	16, 11, 34	20.3	3	0.8	12.1	-0.98	NS
2NF	5	1205, 931, 830	988.7	3	40.2	194.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 77: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA98 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		30, 30, 25, 31, 41	31.4	5		5.9		
Untreated (DMSO) Controls		35, 35, 30, 24, 25	29.8	5	0.9	5.3		
PIP IMGHC-TX-H # 02808	1250	22, 26, 27	25.0	3	0.8	2.6	-1.84	NS
PIP IMGHC-TX-H # 02808	2500	25, 24, 27	25.3	3	0.8	1.5	-1.73	NS
PIP IMGHC-TX-H # 02808	5000	22, 31, 22	25.0	3	0.8	5.2	-1.88	NS
PIP IMGHC-TX-H # 02808	10000	31, 25, 27	27.7	3	0.9	3.1	-1.03	NS
PIP IMGHC-TX-H # 02808	20000	34, 21, 27	27.3	3	0.9	6.5	-1.19	NS
B[a]P	10	537, 526, 530	531.0	3	16.9	5.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 78: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		93, 97, 91, 92, 116	97.8	5		10.4		
Untreated (DMSO) Controls		92, 90, 106, 105, 100	98.6	5	1.0	7.3		
PIP IMGHC-TX-H # 02808	1250	86, 111, 85	94.0	3	1.0	14.7	-0.51	NS
PIP IMGHC-TX-H # 02808	2500	103, 102, 93	99.3	3	1.0	5.5	0.22	NS
PIP IMGHC-TX-H # 02808	5000	95, 98, 90	94.3	3	1.0	4.0	-0.42	NS
PIP IMGHC-TX-H # 02808	10000	75, 97, 105	92.3	3	0.9	15.5	-0.74	NS
PIP IMGHC-TX-H # 02808	20000	87, 100, 102	96.3	3	1.0	8.1	-0.18	NS
NaN ₃	2	592, 642, 614	616.0	3	6.3	25.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 79: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		93, 85, 96, 87, 98	91.8	5		5.6		
Untreated (DMSO) Controls		91, 93, 87, 90, 93	90.8	5	1.0	2.5		
PIP IMGHC-TX-H # 02808	1250	72, 81, 101	84.7	3	0.9	14.8	-0.94	NS
PIP IMGHC-TX-H # 02808	2500	81, 80, 79	80.0	3	0.9	1.0	-1.49	NS
PIP IMGHC-TX-H # 02808	5000	60, 84, 95	79.7	3	0.9	17.9	-1.62	NS
PIP IMGHC-TX-H # 02808	10000	90, 82, 108	93.3	3	1.0	13.3	0.16	NS
PIP IMGHC-TX-H # 02808	20000	106, 97, 102	101.7	3	1.1	4.5	1.18	NS
AAN	5	1097, 1418, 1731	1415.3	3	15.4	317.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 80: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		19, 21, 12, 22, 15	17.8	5		4.2		
Untreated (DMSO) Controls		14, 14, 11, 14, 14	13.4	5	0.8	1.3		
PIP IMGHC-TX-H # 02808	1250	9, 24, 21	18.0	3	1.0	7.9	-0.07	NS
PIP IMGHC-TX-H # 02808	2500	22, 25, 26	24.3	3	1.4	2.1	1.57	NS
PIP IMGHC-TX-H # 02808	5000	16, 24, 21	20.3	3	1.1	4.0	0.64	NS
PIP IMGHC-TX-H # 02808	10000	12, 22, 19	17.7	3	1.0	5.1	-0.05	NS
PIP IMGHC-TX-H # 02808	20000	12, 20, 26	19.3	3	1.1	7.0	0.32	NS
NaN ₃	2	590, 557, 542	563.0	3	31.6	24.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 81: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		21, 21, 20, 16, 21	19.8	5		2.2		
Untreated (DMSO) Controls		12, 10, 20, 7, 16	13.0	5	0.7	5.1		
PIP IMGHC-TX-H # 02808	1250	4, 16, 26	15.3	3	0.8	11.0	-1.28	NS
PIP IMGHC-TX-H # 02808	2500	26, 20, 16	20.7	3	1.0	5.0	0.14	NS
PIP IMGHC-TX-H # 02808	5000	17, 17, 9	14.3	3	0.7	4.6	-1.20	NS
PIP IMGHC-TX-H # 02808	10000	19, 30, 12	20.3	3	1.0	9.1	-0.02	NS
PIP IMGHC-TX-H # 02808	20000	11, 15, 14	13.3	3	0.7	2.1	-1.38	NS
AAN	5	228, 182, 207	205.7	3	10.4	23.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 82: PIP silicone gel breast implantIMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		9, 4, 10, 6, 6	7.0	5		2.4		
Untreated (DMSO) Controls		7, 11, 9, 9, 11	9.4	5	1.3	1.7		
PIP IMGHC-TX-H # 02808	1250	10, 9, 7	8.7	3	1.2	1.5	0.66	NS
PIP IMGHC-TX-H # 02808	2500	11, 4, 2	5.7	3	0.8	4.7	-0.75	NS
PIP IMGHC-TX-H # 02808	5000	6, 14, 12	10.7	3	1.5	4.2	1.23	NS
PIP IMGHC-TX-H # 02808	10000	1, 7, 9	5.7	3	0.8	4.2	-0.81	NS
PIP IMGHC-TX-H # 02808	20000	6, 7, 4	5.7	3	0.8	1.5	-0.50	NS
AAC	50	542, 451, 465	486.0	3	69.4	49.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 83: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		7, 6, 9, 5, 10	7.4	5		2.1		
Untreated (DMSO) Controls		9, 9, 12, 7, 5	8.4	5	1.1	2.6		
PIP IMGHC-TX-H # 02808	1250	14 MB, 11, 6	10.3	3	1.4	4.0	0.96	NS
PIP IMGHC-TX-H # 02808	2500	10, 5, 19	11.3	3	1.5	7.1	1.13	NS
PIP IMGHC-TX-H # 02808	5000	9, 14, 12	11.7	3	1.6	2.5	1.44	NS
PIP IMGHC-TX-H # 02808	10000	12, 16 MB, 20	16.0	3	2.2	4.0	2.61	*
PIP IMGHC-TX-H # 02808	20000	14, 5, 4	7.7	3	1.0	5.5	-0.08	NS
AAN	5	145, 203, 191	179.7	3	24.3	30.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 84: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		265, 264, 293, 269, 260	270.2	5		13.1		
Untreated (DMSO) Controls		258, 288, 263, 259, 295	272.6	5	1.0	17.5		
PIP IMGHC-TX-H # 02808	1250	226, 249, 252	242.3	3	0.9	14.2	-1.87	NS
PIP IMGHC-TX-H # 02808	2500	213, 223, 258	231.3	3	0.9	23.6	-2.65	NS
PIP IMGHC-TX-H # 02808	5000	252, 222, 272	248.7	3	0.9	25.2	-1.45	NS
PIP IMGHC-TX-H # 02808	10000	269, 264, 242	258.3	3	1.0	14.4	-0.78	NS
PIP IMGHC-TX-H # 02808	20000	249, 284, 224	252.3	3	0.9	30.1	-1.22	NS
MMC	0.2	755, 767, 593	705.0	3	2.6	97.2		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 85: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		247, 239, 238, 248, 233	241.0	5		6.4		
Untreated (DMSO) Controls		239, 256, 223, 186, 262	233.2	5	1.0	30.5		
PIP IMGHC-TX-H # 02808	1250	160, 273, 246	226.3	3	0.9	59.0	-0.89	NS
PIP IMGHC-TX-H # 02808	2500	196, 179, 214	196.3	3	0.8	17.5	-2.36	NS
PIP IMGHC-TX-H # 02808	5000	238, 201, 233	224.0	3	0.9	20.1	-0.88	NS
PIP IMGHC-TX-H # 02808	10000	233, 233, 212	226.0	3	0.9	12.1	-0.76	NS
PIP IMGHC-TX-H # 02808	20000	244, 218, 239	233.7	3	1.0	13.8	-0.37	NS
AAN	20	965, 953, 879	932.3	3	3.9	46.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 86: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		31, 24, 21, 21, 26	24.6	5		4.2		
Untreated (DMSO) Controls		15, 29, 16, 17, 19	19.2	5	0.8	5.7		
PIP IMGHC-TX-H # 27609	1250	31, 20, 29	26.7	3	1.1	5.9	0.53	NS
PIP IMGHC-TX-H # 27609	2500	22, 27, 20	23.0	3	0.9	3.6	-0.44	NS
PIP IMGHC-TX-H # 27609	5000	25, 29, 16	23.3	3	0.9	6.7	-0.41	NS
PIP IMGHC-TX-H # 27609	10000	16, 24, 21	20.3	3	0.8	4.0	-1.23	NS
PIP IMGHC-TX-H # 27609	20000	25, 24, 17	22.0	3	0.9	4.4	-0.74	NS
2NF	5	1205, 931, 830	988.7	3	40.2	194.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 87: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA98 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		30, 30, 25, 31, 41	31.4	5		5.9		
Untreated (DMSO) Controls		35, 35, 30, 24, 25	29.8	5	0.9	5.3		
PIP IMGHC-TX-H # 27609	1250	21, 44, 32	32.3	3	1.0	11.5	0.08	NS
PIP IMGHC-TX-H # 27609	2500	29, 20, 26	25.0	3	0.8	4.6	-1.15	NS
PIP IMGHC-TX-H # 27609	5000	26, 25, 46	32.3	3	1.0	11.8	0.08	NS
PIP IMGHC-TX-H # 27609	10000	27, 44, 31	34.0	3	1.1	8.9	0.41	NS
PIP IMGHC-TX-H # 27609	20000	29, 27, 37	31.0	3	1.0	5.3	-0.06	NS
B[a]P	10	537, 526, 530	531.0	3	16.9	5.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 88: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		93, 97, 91, 92, 116	97.8	5		10.4		
Untreated (DMSO) Controls		92, 90, 106, 105, 100	98.6	5	1.0	7.3		
PIP IMGHC-TX-H # 27609	1250	96, 86, 91	91.0	3	0.9	5.0	-0.83	NS
PIP IMGHC-TX-H # 27609	2500	95, 100, 98	97.7	3	1.0	2.5	0.01	NS
PIP IMGHC-TX-H # 27609	5000	90, 82, 111	94.3	3	1.0	15.0	-0.45	NS
PIP IMGHC-TX-H # 27609	10000	116, 88, 96	100.0	3	1.0	14.4	0.25	NS
PIP IMGHC-TX-H # 27609	20000	116, 122, 93	110.3	3	1.1	15.3	1.47	NS
NaN ₃	2	592, 642, 614	616.0	3	6.3	25.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 89: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		93, 85, 96, 87, 98	91.8	5		5.6		
Untreated (DMSO) Controls		91, 93, 87, 90, 93	90.8	5	1.0	2.5		
PIP IMGHC-TX-H # 27609	1250	82, 79, 91	84.0	3	0.9	6.2	-1.20	NS
PIP IMGHC-TX-H # 27609	2500	95, 92, 80	89.0	3	1.0	7.9	-0.43	NS
PIP IMGHC-TX-H # 27609	5000	95, 86, 82	87.7	3	1.0	6.7	-0.63	NS
PIP IMGHC-TX-H # 27609	10000	96, 96, 67	86.3	3	0.9	16.7	-0.91	NS
PIP IMGHC-TX-H # 27609	20000	82, 95, 91	89.3	3	1.0	6.7	-0.38	NS
AAN	5	1097, 1418, 1731	1415.3	3	15.4	317.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 90: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		19, 21, 12, 22, 15	17.8	5		4.2		
Untreated (DMSO) Controls		14, 14, 11, 14, 14	13.4	5	0.8	1.3		
PIP IMGHC-TX-H # 27609	1250	25, 15, 20	20.0	3	1.1	5.0	0.53	NS
PIP IMGHC-TX-H # 27609	2500	14, 6, 15	11.7	3	0.7	4.9	-1.76	NS
PIP IMGHC-TX-H # 27609	5000	19, 20, 12	17.0	3	1.0	4.4	-0.20	NS
PIP IMGHC-TX-H # 27609	10000	14, 14, 10	12.7	3	0.7	2.3	-1.36	NS
PIP IMGHC-TX-H # 27609	20000	11, 12, 27	16.7	3	0.9	9.0	-0.42	NS
NaN ₃	2	590, 557, 542	563.0	3	31.6	24.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 91: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		21, 21, 20, 16, 21	19.8	5		2.2		
Untreated (DMSO) Controls		12, 10, 20, 7, 16	13.0	5	0.7	5.1		
PIP IMGHC-TX-H # 27609	1250	10, 21, 20	17.0	3	0.9	6.1	-1.04	NS
PIP IMGHC-TX-H # 27609	2500	19, 19, 17	18.3	3	0.9	1.2	-0.46	NS
PIP IMGHC-TX-H # 27609	5000	22, 11, 21	18.0	3	0.9	6.1	-0.69	NS
PIP IMGHC-TX-H # 27609	10000	21, 15, 14	16.7	3	0.8	3.8	-1.05	NS
PIP IMGHC-TX-H # 27609	20000	11, 15, 16	14.0	3	0.7	2.6	-1.99	NS
AAN	5	228, 182, 207	205.7	3	10.4	23.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 92: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		9, 4, 10, 6, 6	7.0	5		2.4		
Untreated (DMSO) Controls		7, 11, 9, 9, 11	9.4	5	1.3	1.7		
PIP IMGHC-TX-H # 27609	1250	1, 9, 9	6.3	3	0.9	4.6	-0.57	NS
PIP IMGHC-TX-H # 27609	2500	19, 9, 7	11.7	3	1.7	6.4	1.47	NS
PIP IMGHC-TX-H # 27609	5000	9, 9, 11	9.7	3	1.4	1.2	1.00	NS
PIP IMGHC-TX-H # 27609	10000	4, 5, 2	3.7	3	0.5	1.5	-1.48	NS
PIP IMGHC-TX-H # 27609	20000	5, 5, 11	7.0	3	1.0	3.5	-0.03	NS
AAC	50	542, 451, 465	486.0	3	69.4	49.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 93: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		7, 6, 9, 5, 10	7.4	5		2.1		
Untreated (DMSO) Controls		9, 9, 12, 7, 5	8.4	5	1.1	2.6		
PIP IMGHC-TX-H # 27609	1250	11, 11, 11	11.0	3	1.5	0.0	1.85	NS
PIP IMGHC-TX-H # 27609	2500	14, 15, 7	12.0	3	1.6	4.4	2.16	NS
PIP IMGHC-TX-H # 27609	5000	9, 9, 15	11.0	3	1.5	3.5	1.77	NS
PIP IMGHC-TX-H # 27609	10000	12, 9, 6	9.0	3	1.2	3.0	0.82	NS
PIP IMGHC-TX-H # 27609	20000	6, 11, 7	8.0	3	1.1	2.6	0.31	NS
AAN	5	145, 203, 191	179.7	3	24.3	30.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 94: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		265, 264, 293, 269, 260	270.2	5		13.1		
Untreated (DMSO) Controls		258, 288, 263, 259, 295	272.6	5	1.0	17.5		
PIP IMGHC-TX-H # 27609	1250	247, 264, 238	249.7	3	0.9	13.2	-1.72	NS
PIP IMGHC-TX-H # 27609	2500	242, 272, 231	248.3	3	0.9	21.2	-1.85	NS
PIP IMGHC-TX-H # 27609	5000	265, 267, 288	273.3	3	1.0	12.7	0.26	NS
PIP IMGHC-TX-H # 27609	10000	244, 282, 280	268.7	3	1.0	21.4	-0.14	NS
PIP IMGHC-TX-H # 27609	20000	265, 233, 258	252.0	3	0.9	16.8	-1.53	NS
MMC	0.2	755, 767, 593	705.0	3	2.6	97.2		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 95: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		247, 239, 238, 248, 233	241.0	5		6.4		
Untreated (DMSO) Controls		239, 256, 223, 186, 262	233.2	5	1.0	30.5		
PIP IMGHC-TX-H # 27609	1250	218, 239, 209	222.0	3	0.9	15.4	-1.98	NS
PIP IMGHC-TX-H # 27609	2500	186, 224, 227	212.3	3	0.9	22.9	-3.04	NS
PIP IMGHC-TX-H # 27609	5000	227, 223, 221	223.7	3	0.9	3.1	-1.79	NS
PIP IMGHC-TX-H # 27609	10000	227, 218, 214	219.7	3	0.9	6.7	-2.21	NS
PIP IMGHC-TX-H # 27609	20000	209, 201, 231	213.7	3	0.9	15.5	-2.87	NS
AAN	20	965, 953, 879	932.3	3	3.9	46.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 96: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		31, 24, 21, 21, 26	24.6	5		4.2		
Untreated (DMSO) Controls		15, 29, 16, 17, 19	19.2	5	0.8	5.7		
PIP IMGHC-TX-H # 41609	1250	20, 32, 25	25.7	3	1.0	6.0	0.20	NS
PIP IMGHC-TX-H # 41609	2500	29, 17, 30	25.3	3	1.0	7.2	0.10	NS
PIP IMGHC-TX-H # 41609	5000	12, 14, 25	17.0	3	0.7	7.0	-1.83	NS
PIP IMGHC-TX-H # 41609	10000	25, 29, 20	24.7	3	1.0	4.5	0.01	NS
PIP IMGHC-TX-H # 41609	20000	14, 31, 25	23.3	3	0.9	8.6	-0.37	NS
2NF	5	1205, 931, 830	988.7	3	40.2	194.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 97: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA98 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		30, 30, 25, 31, 41	31.4	5		5.9		
Untreated (DMSO) Controls		35, 35, 30, 24, 25	29.8	5	0.9	5.3		
PIP IMGHC-TX-H # 41609	1250	24, 35, 35	31.3	3	1.0	6.4	-0.02	NS
PIP IMGHC-TX-H # 41609	2500	26, 31, 37	31.3	3	1.0	5.5	0.00	NS
PIP IMGHC-TX-H # 41609	5000	31, 26, 30	29.0	3	0.9	2.6	-0.50	NS
PIP IMGHC-TX-H # 41609	10000	24, 35, 34	31.0	3	1.0	6.1	-0.09	NS
PIP IMGHC-TX-H # 41609	20000	27, 44, 45	38.7	3	1.2	10.1	1.45	NS
B[a]P	10	537, 526, 530	531.0	3	16.9	5.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 98: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		93, 97, 91, 92, 116	97.8	5		10.4		
Untreated (DMSO) Controls		92, 90, 106, 105, 100	98.6	5	1.0	7.3		
PIP IMGHC-TX-H # 41609	1250	107, 82, 95	94.7	3	1.0	12.5	-0.43	NS
PIP IMGHC-TX-H # 41609	2500	91, 107, 115	104.3	3	1.1	12.2	0.86	NS
PIP IMGHC-TX-H # 41609	5000	74, 84, 74	77.3	3	0.8	5.8	-2.89	NS
PIP IMGHC-TX-H # 41609	10000	103, 102, 95	100.0	3	1.0	4.4	0.32	NS
PIP IMGHC-TX-H # 41609	20000	110, 95, 85	96.7	3	1.0	12.6	-0.16	NS
NaN ₃	2	592, 642, 614	616.0	3	6.3	25.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 99: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		93, 85, 96, 87, 98	91.8	5		5.6		
Untreated (DMSO) Controls		91, 93, 87, 90, 93	90.8	5	1.0	2.5		
PIP IMGHC-TX-H # 41609	1250	95, 106, 128	109.7	3	1.2	16.8	2.76	*
PIP IMGHC-TX-H # 41609	2500	98 MB, 120, 105	107.7	3	1.2	11.2	2.49	*
PIP IMGHC-TX-H # 41609	5000	121, 115, 113	116.3	3	1.3	4.2	3.81	**
PIP IMGHC-TX-H # 41609	10000	105 MB, 118, 112	111.7	3	1.2	6.5	3.11	*
PIP IMGHC-TX-H # 41609	20000	106, 108, 118	110.7	3	1.2	6.4	2.96	*
AAN	5	1097, 1418, 1731	1415.3	3	15.4	317.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 100: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		19, 21, 12, 22, 15	17.8	5		4.2		
Untreated (DMSO) Controls		14, 14, 11, 14, 14	13.4	5	0.8	1.3		
PIP IMGHC-TX-H # 41609	1250	7, 16, 10	11.0	3	0.6	4.6	-1.61	NS
PIP IMGHC-TX-H # 41609	2500	7, 21, 16	14.7	3	0.8	7.1	-0.79	NS
PIP IMGHC-TX-H # 41609	5000	6, 16, 12	11.3	3	0.6	5.0	-1.55	NS
PIP IMGHC-TX-H # 41609	10000	16, 24, 14	18.0	3	1.0	5.3	0.03	NS
PIP IMGHC-TX-H # 41609	20000	12, 30, 12	18.0	3	1.0	10.4	-0.10	NS
NaN ₃	2	590, 557, 542	563.0	3	31.6	24.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 101: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		21, 21, 20, 16, 21	19.8	5		2.2		
Untreated (DMSO) Controls		12, 10, 20, 7, 16	13.0	5	0.7	5.1		
PIP IMGHC-TX-H # 41609	1250	19, 17, 22	19.3	3	1.0	2.5	-0.19	NS
PIP IMGHC-TX-H # 41609	2500	16, 21, 15	17.3	3	0.9	3.2	-1.03	NS
PIP IMGHC-TX-H # 41609	5000	11, 22, 21	18.0	3	0.9	6.1	-0.87	NS
PIP IMGHC-TX-H # 41609	10000	20, 19, 17	18.7	3	0.9	1.5	-0.44	NS
PIP IMGHC-TX-H # 41609	20000	16, 17, 21	18.0	3	0.9	2.6	-0.73	NS
AAN	5	228, 182, 207	205.7	3	10.4	23.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 102: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		9, 4, 10, 6, 6	7.0	5		2.4		
Untreated (DMSO) Controls		7, 11, 9, 9, 11	9.4	5	1.3	1.7		
PIP IMGHC-TX-H # 41609	1250	7, 4, 7	6.0	3	0.9	1.7	-0.45	NS
PIP IMGHC-TX-H # 41609	2500	10, 9, 15	11.3	3	1.6	3.2	1.82	NS
PIP IMGHC-TX-H # 41609	5000	11, 15, 6	10.7	3	1.5	4.5	1.49	NS
PIP IMGHC-TX-H # 41609	10000	16, 6, 9	10.3	3	1.5	5.1	1.33	NS
PIP IMGHC-TX-H # 41609	20000	7, 11, 6	8.0	3	1.1	2.6	0.48	NS
AAC	50	542, 451, 465	486.0	3	69.4	49.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 103: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		7, 6, 9, 5, 10	7.4	5		2.1		
Untreated (DMSO) Controls		9, 9, 12, 7, 5	8.4	5	1.1	2.6		
PIP IMGHC-TX-H # 41609	1250	12, 10, 7	9.7	3	1.3	2.5	1.26	NS
PIP IMGHC-TX-H # 41609	2500	11, 7, 9	9.0	3	1.2	2.0	0.93	NS
PIP IMGHC-TX-H # 41609	5000	17, 14, 11	14.0	3	1.9	3.0	3.31	*
PIP IMGHC-TX-H # 41609	10000	16, 12, 12	13.3	3	1.8	2.3	3.04	*
PIP IMGHC-TX-H # 41609	20000	6, 14, 11	10.3	3	1.4	4.0	1.51	NS
AAN	5	145, 203, 191	179.7	3	24.3	30.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 104: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		265, 264, 293, 269, 260	270.2	5		13.1		
Untreated (DMSO) Controls		258, 288, 263, 259, 295	272.6	5	1.0	17.5		
PIP IMGHC-TX-H # 41609	1250	267, 283, 292	280.7	3	1.0	12.7	1.07	NS
PIP IMGHC-TX-H # 41609	2500	257, 256, 270	261.0	3	1.0	7.8	-0.94	NS
PIP IMGHC-TX-H # 41609	5000	274, 257, 244	258.3	3	1.0	15.0	-1.23	NS
PIP IMGHC-TX-H # 41609	10000	217, 256, 239	237.3	3	0.9	19.6	-3.50	NS
PIP IMGHC-TX-H # 41609	20000	257, 249, 251	252.3	3	0.9	4.2	-1.85	NS
MMC	0.2	755, 767, 593	705.0	3	2.6	97.2		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 105: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		247, 239, 238, 248, 233	241.0	5		6.4		
Untreated (DMSO) Controls		239, 256, 223, 186, 262	233.2	5	1.0	30.5		
PIP IMGHC-TX-H # 41609	1250	167, 228, 172	189.0	3	0.8	33.9	-3.61	NS
PIP IMGHC-TX-H # 41609	2500	211, 224, 221	218.7	3	0.9	6.8	-1.47	NS
PIP IMGHC-TX-H # 41609	5000	231, 257, 186	224.7	3	0.9	35.9	-1.13	NS
PIP IMGHC-TX-H # 41609	10000	227, 241, 229	232.3	3	1.0	7.6	-0.56	NS
PIP IMGHC-TX-H # 41609	20000	238, 213, 222	224.3	3	0.9	12.7	-1.09	NS
AAN	20	965, 953, 879	932.3	3	3.9	46.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 106: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		31, 24, 21, 21, 26	24.6	5		4.2		
Untreated (DMSO) Controls		15, 29, 16, 17, 19	19.2	5	0.8	5.7		
PIP IMGHC-TX-S, #37908	1250	17, 21, 20	19.3	3	0.8	2.1	-1.40	NS
PIP IMGHC-TX-S, #37908	2500	24, 14, 22	20.0	3	0.8	5.3	-1.27	NS
PIP IMGHC-TX-S, #37908	5000	24, 17, 26	22.3	3	0.9	4.7	-0.61	NS
PIP IMGHC-TX-S, #37908	10000	24, 34, 15	24.3	3	1.0	9.5	-0.20	NS
PIP IMGHC-TX-S, #37908	20000	24, 20, 22	22.0	3	0.9	2.0	-0.66	NS
2NF	5	1205, 931, 830	988.7	3	40.2	194.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 107: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA98 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		30, 30, 25, 31, 41	31.4	5		5.9		
Untreated (DMSO) Controls		35, 35, 30, 24, 25	29.8	5	0.9	5.3		
PIP IMGHC-TX-S, #37908	1250	32, 26, 37	31.7	3	1.0	5.5	0.07	NS
PIP IMGHC-TX-S, #37908	2500	32, 29, 29	30.0	3	1.0	1.7	-0.26	NS
PIP IMGHC-TX-S, #37908	5000	35, 22, 20	25.7	3	0.8	8.1	-1.34	NS
PIP IMGHC-TX-S, #37908	10000	36, 44, 32	37.3	3	1.2	6.1	1.23	NS
PIP IMGHC-TX-S, #37908	20000	21, 37, 34	30.7	3	1.0	8.5	-0.21	NS
B[a]P	10	537, 526, 530	531.0	3	16.9	5.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 108: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		93, 97, 91, 92, 116	97.8	5		10.4		
Untreated (DMSO) Controls		92, 90, 106, 105, 100	98.6	5	1.0	7.3		
PIP IMGHC-TX-S, #37908	1250	86, 110, 101	99.0	3	1.0	12.1	0.15	NS
PIP IMGHC-TX-S, #37908	2500	90, 88, 98	92.0	3	0.9	5.3	-0.74	NS
PIP IMGHC-TX-S, #37908	5000	105, 95, 98	99.3	3	1.0	5.1	0.22	NS
PIP IMGHC-TX-S, #37908	10000	75, 101, 105	93.7	3	1.0	16.3	-0.58	NS
PIP IMGHC-TX-S, #37908	20000	92, 97, 80	89.7	3	0.9	8.7	-1.07	NS
NaN ₃	2	592, 642, 614	616.0	3	6.3	25.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 109: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		93, 85, 96, 87, 98	91.8	5		5.6		
Untreated (DMSO) Controls		91, 93, 87, 90, 93	90.8	5	1.0	2.5		
PIP IMGHC-TX-S, #37908	1250	75, 96, 113	94.7	3	1.0	19.0	0.28	NS
PIP IMGHC-TX-S, #37908	2500	105, 102, 91	99.3	3	1.1	7.4	0.92	NS
PIP IMGHC-TX-S, #37908	5000	95, 115, 82	97.3	3	1.1	16.6	0.64	NS
PIP IMGHC-TX-S, #37908	10000	107, 115, 112	111.3	3	1.2	4.0	2.34	NS
PIP IMGHC-TX-S, #37908	20000	118, 98, 111	109.0	3	1.2	10.1	2.06	NS
AAN	5	1097, 1418, 1731	1415.3	3	15.4	317.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 110: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		19, 21, 12, 22, 15	17.8	5		4.2		
Untreated (DMSO) Controls		14, 14, 11, 14, 14	13.4	5	0.8	1.3		
PIP IMGHC-TX-S, #37908	1250	15, 15, 22	17.3	3	1.0	4.0	-0.17	NS
PIP IMGHC-TX-S, #37908	2500	19, 24, 17	20.0	3	1.1	3.6	0.91	NS
PIP IMGHC-TX-S, #37908	5000	19, 20, 25	21.3	3	1.2	3.2	1.43	NS
PIP IMGHC-TX-S, #37908	10000	22, 19, 19	20.0	3	1.1	1.7	0.94	NS
PIP IMGHC-TX-S, #37908	20000	12, 15, 15	14.0	3	0.8	1.7	-1.56	NS
NaN ₃	2	590, 557, 542	563.0	3	31.6	24.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 111: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		21, 21, 20, 16, 21	19.8	5		2.2		
Untreated (DMSO) Controls		12, 10, 20, 7, 16	13.0	5	0.7	5.1		
PIP IMGHC-TX-S, #37908	1250	15, 15, 22	17.3	3	0.9	4.0	-0.75	NS
PIP IMGHC-TX-S, #37908	2500	21, 16, 17	18.0	3	0.9	2.6	-0.52	NS
PIP IMGHC-TX-S, #37908	5000	26, 16, 10	17.3	3	0.9	8.1	-0.89	NS
PIP IMGHC-TX-S, #37908	10000	16, 17, 24	19.0	3	1.0	4.4	-0.26	NS
PIP IMGHC-TX-S, #37908	20000	21, 11, 12	14.7	3	0.7	5.5	-1.64	NS
AAN	5	228, 182, 207	205.7	3	10.4	23.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 112: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		9, 4, 10, 6, 6	7.0	5		2.4		
Untreated (DMSO) Controls		7, 11, 9, 9, 11	9.4	5	1.3	1.7		
PIP IMGHC-TX-S, #37908	1250	4, 2, 14	6.7	3	1.0	6.4	-0.45	NS
PIP IMGHC-TX-S, #37908	2500	16, 4, 7	9.0	3	1.3	6.2	0.53	NS
PIP IMGHC-TX-S, #37908	5000	7, 7, 6	6.7	3	1.0	0.6	-0.06	NS
PIP IMGHC-TX-S, #37908	10000	7, 6, 11	8.0	3	1.1	2.6	0.38	NS
PIP IMGHC-TX-S, #37908	20000	6, 10, 10	8.7	3	1.2	2.3	0.62	NS
AAC	50	542, 451, 465	486.0	3	69.4	49.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 113: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		7, 6, 9, 5, 10	7.4	5		2.1		
Untreated (DMSO) Controls		9, 9, 12, 7, 5	8.4	5	1.1	2.6		
PIP IMGHC-TX-S, #37908	1250	4, 12, 11	9.0	3	1.2	4.4	0.52	NS
PIP IMGHC-TX-S, #37908	2500	16, 20, 9	15.0	3	2.0	5.6	2.55	*
PIP IMGHC-TX-S, #37908	5000	17, 11, 21	16.3	3	2.2	5.0	2.96	*
PIP IMGHC-TX-S, #37908	10000	7, 16, 12	11.7	3	1.6	4.5	1.52	NS
PIP IMGHC-TX-S, #37908	20000	14, 14, 20	16.0	3	2.2	3.5	2.91	*
AAN	5	145, 203, 191	179.7	3	24.3	30.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 114: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		265, 264, 293, 269, 260	270.2	5		13.1		
Untreated (DMSO) Controls		258, 288, 263, 259, 295	272.6	5	1.0	17.5		
PIP IMGHC-TX-S, #37908	1250	267, 263, 279	269.7	3	1.0	8.3	-0.05	NS
PIP IMGHC-TX-S, #37908	2500	283, 265, 273	273.7	3	1.0	9.0	0.42	NS
PIP IMGHC-TX-S, #37908	5000	289, 262, 278	276.3	3	1.0	13.6	0.73	NS
PIP IMGHC-TX-S, #37908	10000	260, 287, 269	272.0	3	1.0	13.7	0.21	NS
PIP IMGHC-TX-S, #37908	20000	290, 273, 277	280.0	3	1.0	8.9	1.16	NS
MMC	0.2	755, 767, 593	705.0	3	2.6	97.2		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 115: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		247, 239, 238, 248, 233	241.0	5		6.4		
Untreated (DMSO) Controls		239, 256, 223, 186, 262	233.2	5	1.0	30.5		
PIP IMGHC-TX-S, #37908	1250	232, 233, 236	233.7	3	1.0	2.1	-0.63	NS
PIP IMGHC-TX-S, #37908	2500	209, 238, 208	218.3	3	0.9	17.0	-2.02	NS
PIP IMGHC-TX-S, #37908	5000	259, 254, 221	244.7	3	1.0	20.6	0.29	NS
PIP IMGHC-TX-S, #37908	10000	226, 256, 212	231.3	3	1.0	22.5	-0.87	NS
PIP IMGHC-TX-S, #37908	20000	257, 242, 217	238.7	3	1.0	20.2	-0.22	NS
AAN	20	965, 953, 879	932.3	3	3.9	46.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 116: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		31, 24, 21, 21, 26	24.6	5		4.2		
Untreated (DMSO) Controls		15, 29, 16, 17, 19	19.2	5	0.8	5.7		
[REDACTED]	1250	21, 29, 27	25.7	3	1.0	4.2	0.35	NS
[REDACTED]	2500	24, 34, 24	27.3	3	1.1	5.8	0.86	NS
[REDACTED]	5000	22, 21, 16	19.7	3	0.8	3.2	-1.70	NS
[REDACTED]	10000	24, 19, 17	20.0	3	0.8	3.6	-1.58	NS
[REDACTED]	20000	25, 25, 19	23.0	3	0.9	3.5	-0.52	NS
2NF	5	1205, 931, 830	988.7	3	40.2	194.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 117: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA98 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		30, 30, 25, 31, 41	31.4	5		5.9		
Untreated (DMSO) Controls		35, 35, 30, 24, 25	29.8	5	0.9	5.3		
[REDACTED]	1250	29, 41, 36	35.3	3	1.1	6.0	0.89	NS
[REDACTED]	2500	35, 36, 34	35.0	3	1.1	1.0	0.86	NS
[REDACTED]	5000	26, 24, 40	30.0	3	1.0	8.7	-0.37	NS
[REDACTED]	10000	34, 24, 25	27.7	3	0.9	5.5	-0.89	NS
[REDACTED]	20000	32, 22, 22	25.3	3	0.8	5.8	-1.48	NS
B[a]P	10	537, 526, 530	531.0	3	16.9	5.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 118: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		93, 97, 91, 92, 116	97.8	5		10.4		
Untreated (DMSO) Controls		92, 90, 106, 105, 100	98.6	5	1.0	7.3		
[REDACTED]	1250	97, 96, 100	97.7	3	1.0	2.1	0.01	NS
[REDACTED]	2500	111, 88, 88	95.7	3	1.0	13.3	-0.33	NS
[REDACTED]	5000	88, 77, 85	83.3	3	0.9	5.7	-2.18	NS
[REDACTED]	10000	84, 72, 87	81.0	3	0.8	7.9	-2.57	NS
[REDACTED]	20000	92, 91, 110	97.7	3	1.0	10.7	-0.02	NS
NaN ₃	2	592, 642, 614	616.0	3	6.3	25.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 119: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data -
Experiment 2 – DMSO Extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		93, 85, 96, 87, 98	91.8	5		5.6		
Untreated (DMSO) Controls		91, 93, 87, 90, 93	90.8	5	1.0	2.5		
[REDACTED]	1250	97, 97, 80	91.3	3	1.0	9.8	-0.07	NS
[REDACTED]	2500	100, 93, 69	87.3	3	1.0	16.3	-0.63	NS
[REDACTED]	5000	84, 85, 101	90.0	3	1.0	9.5	-0.24	NS
[REDACTED]	10000	82, 100, 84	88.7	3	1.0	9.9	-0.41	NS
[REDACTED]	20000	111, 84, 105	100.0	3	1.1	14.2	0.97	NS
AAN	5	1097, 1418, 1731	1415.3	3	15.4	317.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 120: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data -
Experiment 2 – DMSO Extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		19, 21, 12, 22, 15	17.8	5		4.2		
Untreated (DMSO) Controls		14, 14, 11, 14, 14	13.4	5	0.8	1.3		
[REDACTED]	1250	15, 20, 11	15.3	3	0.9	4.5	-0.68	NS
[REDACTED]	2500	11, 11, 22	14.7	3	0.8	6.4	-0.93	NS
[REDACTED]	5000	24, 24, 12	20.0	3	1.1	6.9	0.50	NS
[REDACTED]	10000	14, 9, 17	13.3	3	0.7	4.0	-1.26	NS
[REDACTED]	20000	17, 12, 11	13.3	3	0.7	3.2	-1.24	NS
NaN ₃	2	590, 557, 542	563.0	3	31.6	24.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 121: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data -
Experiment 2 – DMSO Extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		21, 21, 20, 16, 21	19.8	5		2.2		
Untreated (DMSO) Controls		12, 10, 20, 7, 16	13.0	5	0.7	5.1		
[REDACTED]	1250	17, 25, 7	16.3	3	0.8	9.0	-1.08	NS
[REDACTED]	2500	15, 11, 21	15.7	3	0.8	5.0	-1.08	NS
[REDACTED]	5000	29, 16, 17	20.7	3	1.0	7.2	0.12	NS
[REDACTED]	10000	16, 21, 22	19.7	3	1.0	3.2	-0.04	NS
[REDACTED]	20000	24, 14, 21	19.7	3	1.0	5.1	-0.08	NS
AAN	5	228, 182, 207	205.7	3	10.4	23.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 122: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		9, 4, 10, 6, 6	7.0	5		2.4		
Untreated (DMSO) Controls		7, 11, 9, 9, 11	9.4	5	1.3	1.7		
[REDACTED]	1250	7, 4, 9	6.7	3	1.0	2.5	-0.14	NS
[REDACTED]	2500	10, 9, 6	8.3	3	1.2	2.1	0.58	NS
[REDACTED]	5000	10, 5, 15	10.0	3	1.4	5.0	1.07	NS
[REDACTED]	10000	10, 5, 4	6.3	3	0.9	3.2	-0.33	NS
[REDACTED]	20000	5, 7, 15	9.0	3	1.3	5.3	0.69	NS
AAC	50	542, 451, 465	486.0	3	69.4	49.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 123: ██████████ control silicone gel breast implant ██████████ Raw plate counts and calculated mutagenicity data -
Experiment 2 – DMSO Extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		7, 6, 9, 5, 10	7.4	5		2.1		
Untreated (DMSO) Controls		9, 9, 12, 7, 5	8.4	5	1.1	2.6		
██████████	1250	15, 15, 7	12.3	3	1.7	4.6	2.00	NS
██████████	2500	10, 15, 19	14.7	3	2.0	4.5	2.88	*
██████████	5000	7, 14, 5	8.7	3	1.2	4.7	0.46	NS
██████████	10000	15, 20, 17	17.3	3	2.3	2.5	3.82	**
██████████	20000	11, 11, 14	12.0	3	1.6	1.7	1.99	NS
AAN	5	145, 203, 191	179.7	3	24.3	30.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 124: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		265, 264, 293, 269, 260	270.2	5		13.1		
Untreated (DMSO) Controls		258, 288, 263, 259, 295	272.6	5	1.0	17.5		
[REDACTED]	1250	236, 234, 224	231.3	3	0.9	6.4	-4.20	NS
[REDACTED]	2500	243, 212, 243	232.7	3	0.9	17.9	-4.07	NS
[REDACTED]	5000	263, 256, 284	267.7	3	1.0	14.6	-0.27	NS
[REDACTED]	10000	263, 263, 287	271.0	3	1.0	13.9	0.08	NS
[REDACTED]	20000	273, 268, 260	267.0	3	1.0	6.6	-0.32	NS
MMC	0.2	755, 767, 593	705.0	3	2.6	97.2		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 125: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data - Experiment 2 – DMSO Extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank DMSO Extract		247, 239, 238, 248, 233	241.0	5		6.4		
Untreated (DMSO) Controls		239, 256, 223, 186, 262	233.2	5	1.0	30.5		
[REDACTED]	1250	206, 213, 184	201.0	3	0.8	15.1	-4.09	NS
[REDACTED]	2500	217, 182, 202	200.3	3	0.8	17.6	-4.17	NS
[REDACTED]	5000	214, 219, 226	219.7	3	0.9	6.0	-2.12	NS
[REDACTED]	10000	193, 231, 229	217.7	3	0.9	21.4	-2.36	NS
[REDACTED]	20000	234, 216, 227	225.7	3	0.9	9.1	-1.52	NS
AAN	20	965, 953, 879	932.3	3	3.9	46.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Appendix 3

Raw plate counts and calculated mutagenicity data Experiment 1 Water Extract

Table 126: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		34, 40, 17, 26, 24	28.2	5		9.0		
Untreated (Water) Controls		22, 25, 20, 15, 15	19.4	5	0.7	4.4		
PIP IMGHC-TX-H # 16306	1000	31, 21, 27	26.3	3	0.9	5.0	-0.30	NS
PIP IMGHC-TX-H # 16306	3162	27, 30, 22	26.3	3	0.9	4.0	-0.28	NS
PIP IMGHC-TX-H # 16306	10000	19, 24, 31	24.7	3	0.9	6.0	-0.66	NS
PIP IMGHC-TX-H # 16306	31620	19, 30, 21	23.3	3	0.8	5.9	-0.95	NS
PIP IMGHC-TX-H # 16306	100000	30, 19, 21	23.3	3	0.8	5.9	-0.95	NS
2NF	5	899, 794, 900	864.3	3	30.7	60.9		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 127: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA98+S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		36, 19, 31, 27, 34	29.4	5		6.7		
Untreated (Water) Controls		25, 29, 25, 17, 26	24.4	5	0.8	4.4		
PIP IMGHC-TX-H # 16306	1000	40, 31, 34	35.0	3	1.2	4.6	1.32	NS
PIP IMGHC-TX-H # 16306	3162	32, 42, 42	38.7	3	1.3	5.8	2.07	NS
PIP IMGHC-TX-H # 16306	10000	45, 44, 35	41.3	3	1.4	5.5	2.62	*
PIP IMGHC-TX-H # 16306	31620	40, 41, 54	45.0	3	1.5	7.8	3.31	*
PIP IMGHC-TX-H # 16306	100000	52, 40, 39	43.7	3	1.5	7.2	3.06	*
B[a]P	10	314, 351, 388	351.0	3	11.9	37.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 128: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		84, 88, 98, 93, 86	89.8	5		5.7		
Untreated (Water) Controls		97, 96, 71, 105, 97	93.2	5	1.0	12.9		
PIP IMGHC-TX-H # 16306	1000	100, 113, 112	108.3	3	1.2	7.2	2.42	NS
PIP IMGHC-TX-H # 16306	3162	97, 95, 90	94.0	3	1.0	3.6	0.58	NS
PIP IMGHC-TX-H # 16306	10000	93, 87, 108	96.0	3	1.1	10.8	0.82	NS
PIP IMGHC-TX-H # 16306	31620	93, 76, 107	92.0	3	1.0	15.5	0.25	NS
PIP IMGHC-TX-H # 16306	100000	113, 82, 102	99.0	3	1.1	15.7	1.19	NS
NaN ₃	2	755, 752, 790	765.7	3	8.5	21.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 129: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		132, 122, 138, 107, 135	126.8	5		12.6		
Untreated (Water) Controls		120, 135, 125, 123, 122	125.0	5	1.0	5.9		
PIP IMGHC-TX-H # 16306	1000	103, 151, 132	128.7	3	1.0	24.2	0.11	NS
PIP IMGHC-TX-H # 16306	3162	115, 112, 81	102.7	3	0.8	18.8	-2.05	NS
PIP IMGHC-TX-H # 16306	10000	116, 100, 95	103.7	3	0.8	11.0	-1.92	NS
PIP IMGHC-TX-H # 16306	31620	95, 88, 98	93.7	3	0.7	5.1	-2.81	NS
PIP IMGHC-TX-H # 16306	100000	97, 98, 66	87.0	3	0.7	18.2	-3.50	NS
AAN	5	1296, 1099, 1206	1200.3	3	9.5	98.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 130: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		10, 15, 21, 15, 12	14.6	5		4.2		
Untreated (Water) Controls		16, 21, 6, 15, 12	14.0	5	1.0	5.5		
PIP IMGHC-TX-H # 16306	1000	17, 10, 19	15.3	3	1.1	4.7	0.21	NS
PIP IMGHC-TX-H # 16306	3162	19, 11, 9	13.0	3	0.9	5.3	-0.55	NS
PIP IMGHC-TX-H # 16306	10000	14, 12, 16	14.0	3	1.0	2.0	-0.13	NS
PIP IMGHC-TX-H # 16306	31620	11, 11, 14	12.0	3	0.8	1.7	-0.79	NS
PIP IMGHC-TX-H # 16306	100000	16, 22, 9	15.7	3	1.1	6.5	0.25	NS
NaN ₃	2	715, 722, 683	706.7	3	48.4	20.8		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 131: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		22, 15, 22, 20, 11	18.0	5		4.8		
Untreated (Water) Controls		21, 24, 21, 10, 16	18.4	5	1.0	5.5		
PIP IMGHC-TX-H # 16306	1000	21, 21, 12	18.0	3	1.0	5.2	0.00	NS
PIP IMGHC-TX-H # 16306	3162	25, 19, 19	21.0	3	1.2	3.5	0.93	NS
PIP IMGHC-TX-H # 16306	10000	22, 16, 19	19.0	3	1.1	3.0	0.36	NS
PIP IMGHC-TX-H # 16306	31620	19, 11, 20	16.7	3	0.9	4.9	-0.41	NS
PIP IMGHC-TX-H # 16306	100000	22, 17, 14	17.7	3	1.0	4.0	-0.06	NS
AAN	5	181, 238, 221	213.3	3	11.9	29.3		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 132: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		6, 5, 14, 4, 4	6.6	5		4.2		
Untreated (Water) Controls		10, 9, 4, 10, 7	8.0	5	1.2	2.5		
PIP IMGHC-TX-H # 16306	1000	11, 4, 2	5.7	3	0.9	4.7	-0.36	NS
PIP IMGHC-TX-H # 16306	3162	7, 5, 9	7.0	3	1.1	2.0	0.21	NS
PIP IMGHC-TX-H # 16306	10000	1, 15, 2	6.0	3	0.9	7.8	-0.58	NS
PIP IMGHC-TX-H # 16306	31620	1, 10, 7	6.0	3	0.9	4.6	-0.32	NS
PIP IMGHC-TX-H # 16306	100000	7, 6, 5	6.0	3	0.9	1.0	-0.06	NS
AAC	50	177, 130, 126	144.3	3	21.9	28.4		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 133: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		15, 16, 6, 15, 11	12.6	5		4.2		
Untreated (Water) Controls		9, 16, 14, 17, 14	14.0	5	1.1	3.1		
PIP IMGHC-TX-H # 16306	1000	12, 12, 11	11.7	3	0.9	0.6	-0.20	NS
PIP IMGHC-TX-H # 16306	3162	19, 20, 9	16.0	3	1.3	6.1	1.00	NS
PIP IMGHC-TX-H # 16306	10000	9, 17, 21	15.7	3	1.2	6.1	0.91	NS
PIP IMGHC-TX-H # 16306	31620	11, 10, 14	11.7	3	0.9	2.1	-0.22	NS
PIP IMGHC-TX-H # 16306	100000	19, 11, 14	14.7	3	1.2	4.0	0.69	NS
AAN	5	155, 145, 158	152.7	3	12.1	6.8		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 134: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		269, 273, 265, 288, 287	276.4	5		10.5		
Untreated (Water) Controls		278, 280, 265, 283, 279	277.0	5	1.0	7.0		
PIP IMGHC-TX-H # 16306	1000	273, 277, 280	276.7	3	1.0	3.5	0.05	NS
PIP IMGHC-TX-H # 16306	3162	280, 278, 278	278.7	3	1.0	1.2	0.33	NS
PIP IMGHC-TX-H # 16306	10000	262, 278, 272	270.7	3	1.0	8.1	-0.81	NS
PIP IMGHC-TX-H # 16306	31620	268, 270, 290	276.0	3	1.0	12.2	-0.06	NS
PIP IMGHC-TX-H # 16306	100000	295, 273, 268	278.7	3	1.0	14.4	0.32	NS
MMC	0.2	823, 870, 889	860.7	3	3.1	34.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 135: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		239, 238, 248, 227, 222	234.8	5		10.3		
Untreated (Water) Controls		172, 191, 201, 229, 223	203.2	5	0.9	23.4		
PIP IMGHC-TX-H # 16306	1000	241, 212, 226	226.3	3	1.0	14.5	-0.68	NS
PIP IMGHC-TX-H # 16306	3162	208, 219, 269	232.0	3	1.0	32.5	-0.27	NS
PIP IMGHC-TX-H # 16306	10000	280, 252, 285	272.3	3	1.2	17.8	2.84	*
PIP IMGHC-TX-H # 16306	31620	222, 217, 217	218.7	3	0.9	2.9	-1.29	NS
PIP IMGHC-TX-H # 16306	100000	229, 217, 194	213.3	3	0.9	17.8	-1.75	NS
AAN	20	1029, 834, 1115	992.7	3	4.2	144.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 136: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		34, 40, 17, 26, 24	28.2	5		9.0		
Untreated (Water) Controls		22, 25, 20, 15, 15	19.4	5	0.7	4.4		
PIP IMGHC-TX-H # 02808	1000	26, 24, 26	25.3	3	0.9	1.2	-0.51	NS
PIP IMGHC-TX-H # 02808	3162	29, 19, 30	26.0	3	0.9	6.1	-0.42	NS
PIP IMGHC-TX-H # 02808	10000	25, 29, 32	28.7	3	1.0	3.5	0.21	NS
PIP IMGHC-TX-H # 02808	31620	24, 22, 32	26.0	3	0.9	5.3	-0.40	NS
PIP IMGHC-TX-H # 02808	100000	29, 31, 21	27.0	3	1.0	5.3	-0.18	NS
2NF	5	899, 794, 900	864.3	3	30.7	60.9		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 137: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA98+S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		36, 19, 31, 27, 34	29.4	5		6.7		
Untreated (Water) Controls		25, 29, 25, 17, 26	24.4	5	0.8	4.4		
PIP IMGHC-TX-H # 02808	1000	30, 40, 31	33.7	3	1.1	5.5	0.81	NS
PIP IMGHC-TX-H # 02808	3162	29, 39, 42	36.7	3	1.2	6.8	1.30	NS
PIP IMGHC-TX-H # 02808	10000	36, 36, 42	38.0	3	1.3	3.5	1.55	NS
PIP IMGHC-TX-H # 02808	31620	14, 36, 35	28.3	3	1.0	12.4	-0.35	NS
PIP IMGHC-TX-H # 02808	100000	42, 37, 34	37.7	3	1.3	4.0	1.50	NS
B[a]P	10	314, 351, 388	351.0	3	11.9	37.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 138: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		84, 88, 98, 93, 86	89.8	5		5.7		
Untreated (Water) Controls		97, 96, 71, 105, 97	93.2	5	1.0	12.9		
PIP IMGHC-TX-H # 02808	1000	106, 103, 102	103.7	3	1.2	2.1	2.01	NS
PIP IMGHC-TX-H # 02808	3162	103, 97, 108	102.7	3	1.1	5.5	1.87	NS
PIP IMGHC-TX-H # 02808	10000	112, 117, 105	111.3	3	1.2	6.0	3.05	*
PIP IMGHC-TX-H # 02808	31620	88, 101, 115	101.3	3	1.1	13.5	1.64	NS
PIP IMGHC-TX-H # 02808	100000	95, 131, 125	117.0	3	1.3	19.3	3.74	**
NaN ₃	2	755, 752, 790	765.7	3	8.5	21.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 139: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		132, 122, 138, 107, 135	126.8	5		12.6		
Untreated (Water) Controls		120, 135, 125, 123, 122	125.0	5	1.0	5.9		
PIP IMGHC-TX-H # 02808	1000	100, 106, 118	108.0	3	0.9	9.2	-2.37	NS
PIP IMGHC-TX-H # 02808	3162	82, 88, 105	91.7	3	0.7	11.9	-4.64	NS
PIP IMGHC-TX-H # 02808	10000	102, 95, 96	97.7	3	0.8	3.8	-3.76	NS
PIP IMGHC-TX-H # 02808	31620	102, 85, 100	95.7	3	0.8	9.3	-4.06	NS
PIP IMGHC-TX-H # 02808	100000	120, 102, 120	114.0	3	0.9	10.4	-1.59	NS
AAN	5	1296, 1099, 1206	1200.3	3	9.5	98.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 140: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		10, 15, 21, 15, 12	14.6	5		4.2		
Untreated (Water) Controls		16, 21, 6, 15, 12	14.0	5	1.0	5.5		
PIP IMGHC-TX-H # 02808	1000	16, 16, 19	17.0	3	1.2	1.7	0.69	NS
PIP IMGHC-TX-H # 02808	3162	21, 21, 21	21.0	3	1.4	0.0	1.67	NS
PIP IMGHC-TX-H # 02808	10000	10, 17, 21	16.0	3	1.1	5.6	0.35	NS
PIP IMGHC-TX-H # 02808	31620	6, 12, 24	14.0	3	1.0	9.2	-0.39	NS
PIP IMGHC-TX-H # 02808	100000	15, 24, 17	18.7	3	1.3	4.7	1.07	NS
NaN ₃	2	715, 722, 683	706.7	3	48.4	20.8		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 141: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		22, 15, 22, 20, 11	18.0	5		4.8		
Untreated (Water) Controls		21, 24, 21, 10, 16	18.4	5	1.0	5.5		
PIP IMGHC-TX-H # 02808	1000	17, 21, 16	18.0	3	1.0	2.6	0.07	NS
PIP IMGHC-TX-H # 02808	3162	30, 19, 22	23.7	3	1.3	5.7	1.58	NS
PIP IMGHC-TX-H # 02808	10000	27, 15, 16	19.3	3	1.1	6.7	0.37	NS
PIP IMGHC-TX-H # 02808	31620	12, 14, 21	15.7	3	0.9	4.7	-0.69	NS
PIP IMGHC-TX-H # 02808	100000	21, 25, 19	21.7	3	1.2	3.1	1.09	NS
AAN	5	181, 238, 221	213.3	3	11.9	29.3		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 142: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		6, 5, 14, 4, 4	6.6	5		4.2		
Untreated (Water) Controls		10, 9, 4, 10, 7	8.0	5	1.2	2.5		
PIP IMGHC-TX-H # 02808	1000	7, 2, 7	5.3	3	0.8	2.9	-0.52	NS
PIP IMGHC-TX-H # 02808	3162	1, 7, 7	5.0	3	0.8	3.5	-0.80	NS
PIP IMGHC-TX-H # 02808	10000	9, 10, 6	8.3	3	1.3	2.1	0.80	NS
PIP IMGHC-TX-H # 02808	31620	2, 7, 5	4.7	3	0.7	2.5	-0.80	NS
PIP IMGHC-TX-H # 02808	100000	4, 4, 6	4.7	3	0.7	1.2	-0.69	NS
AAC	50	177, 130, 126	144.3	3	21.9	28.4		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 143: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		15, 16, 6, 15, 11	12.6	5		4.2		
Untreated (Water) Controls		9, 16, 14, 17, 14	14.0	5	1.1	3.1		
PIP IMGHC-TX-H # 02808	1000	15, 9, 12	12.0	3	1.0	3.0	-0.10	NS
PIP IMGHC-TX-H # 02808	3162	6, 22, 17	15.0	3	1.2	8.2	0.45	NS
PIP IMGHC-TX-H # 02808	10000	11, 16, 5	10.7	3	0.8	5.5	-0.57	NS
PIP IMGHC-TX-H # 02808	31620	17, 11, 9	12.3	3	1.0	4.2	-0.04	NS
PIP IMGHC-TX-H # 02808	100000	9, 9, 19	12.3	3	1.0	5.8	-0.09	NS
AAN	5	155, 145, 158	152.7	3	12.1	6.8		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 144: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		269, 273, 265, 288, 287	276.4	5		10.5		
Untreated (Water) Controls		278, 280, 265, 283, 279	277.0	5	1.0	7.0		
PIP IMGHC-TX-H # 02808	1000	244, 243, 233	240.0	3	0.9	6.1	-4.21	NS
PIP IMGHC-TX-H # 02808	3162	246, 282, 244	257.3	3	0.9	21.4	-2.19	NS
PIP IMGHC-TX-H # 02808	10000	251, 236, 257	248.0	3	0.9	10.8	-3.26	NS
PIP IMGHC-TX-H # 02808	31620	259, 256, 258	257.7	3	0.9	1.5	-2.12	NS
PIP IMGHC-TX-H # 02808	100000	213, 236, 229	226.0	3	0.8	11.8	-5.92	NS
MMC	0.2	823, 870, 889	860.7	3	3.1	34.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 145: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		239, 238, 248, 227, 222	234.8	5		10.3		
Untreated (Water) Controls		172, 191, 201, 229, 223	203.2	5	0.9	23.4		
PIP IMGHC-TX-H # 02808	1000	186, 197, 228	203.7	3	0.9	21.8	-2.17	NS
PIP IMGHC-TX-H # 02808	3162	184, 229, 236	216.3	3	0.9	28.2	-1.30	NS
PIP IMGHC-TX-H # 02808	10000	219, 207, 231	219.0	3	0.9	12.0	-1.07	NS
PIP IMGHC-TX-H # 02808	31620	173, 196, 171	180.0	3	0.8	13.9	-3.91	NS
PIP IMGHC-TX-H # 02808	100000	197, 147, 162	168.7	3	0.7	25.7	-4.82	NS
AAN	20	1029, 834, 1115	992.7	3	4.2	144.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 146: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		34, 40, 17, 26, 24	28.2	5		9.0		
Untreated (Water) Controls		22, 25, 20, 15, 15	19.4	5	0.7	4.4		
PIP IMGHC-TX-H # 27609	1000	22, 26, 29	25.7	3	0.9	3.5	-0.37	NS
PIP IMGHC-TX-H # 27609	3162	34, 27, 25	28.7	3	1.0	4.7	0.16	NS
PIP IMGHC-TX-H # 27609	10000	25, 26, 27	26.0	3	0.9	1.0	-0.30	NS
PIP IMGHC-TX-H # 27609	31620	34, 10, 26	23.3	3	0.8	12.2	-1.05	NS
PIP IMGHC-TX-H # 27609	100000	31, 30, 29	30.0	3	1.1	1.0	0.42	NS
2NF	5	899, 794, 900	864.3	3	30.7	60.9		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 147: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA98+S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		36, 19, 31, 27, 34	29.4	5		6.7		
Untreated (Water) Controls		25, 29, 25, 17, 26	24.4	5	0.8	4.4		
PIP IMGHC-TX-H # 27609	1000	26, 30, 49	35.0	3	1.2	12.3	0.91	NS
PIP IMGHC-TX-H # 27609	3162	21, 15, 24	20.0	3	0.7	4.6	-1.83	NS
PIP IMGHC-TX-H # 27609	10000	29, 29, 47	35.0	3	1.2	10.4	0.94	NS
PIP IMGHC-TX-H # 27609	31620	32, 21, 22	25.0	3	0.9	6.1	-0.81	NS
PIP IMGHC-TX-H # 27609	100000	25, 36, 30	30.3	3	1.0	5.5	0.20	NS
B[a]P	10	314, 351, 388	351.0	3	11.9	37.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 148: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		84, 88, 98, 93, 86	89.8	5		5.7		
Untreated (Water) Controls		97, 96, 71, 105, 97	93.2	5	1.0	12.9		
PIP IMGHC-TX-H # 27609	1000	106, 100, 102	102.7	3	1.1	3.1	2.34	NS
PIP IMGHC-TX-H # 27609	3162	116, 103, 98	105.7	3	1.2	9.3	2.84	*
PIP IMGHC-TX-H # 27609	10000	98, 91, 111	100.0	3	1.1	10.1	1.84	NS
PIP IMGHC-TX-H # 27609	31620	106, 101, 101	102.7	3	1.1	2.9	2.34	NS
PIP IMGHC-TX-H # 27609	100000	98, 91, 115	101.3	3	1.1	12.3	2.06	NS
NaN ₃	2	755, 752, 790	765.7	3	8.5	21.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 149: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		132, 122, 138, 107, 135	126.8	5		12.6		
Untreated (Water) Controls		120, 135, 125, 123, 122	125.0	5	1.0	5.9		
PIP IMGHC-TX-H # 27609	1000	115, 120, 130	121.7	3	1.0	7.6	-0.57	NS
PIP IMGHC-TX-H # 27609	3162	147, 115, 131	131.0	3	1.0	16.0	0.47	NS
PIP IMGHC-TX-H # 27609	10000	103, 111, 113	109.0	3	0.9	5.3	-2.09	NS
PIP IMGHC-TX-H # 27609	31620	107, 103, 121	110.3	3	0.9	9.5	-1.94	NS
PIP IMGHC-TX-H # 27609	100000	102, 130, 121	117.7	3	0.9	14.3	-1.07	NS
AAN	5	1296, 1099, 1206	1200.3	3	9.5	98.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 150: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		10, 15, 21, 15, 12	14.6	5		4.2		
Untreated (Water) Controls		16, 21, 6, 15, 12	14.0	5	1.0	5.5		
PIP IMGHC-TX-H # 27609	1000	16, 14, 7	12.3	3	0.8	4.7	-0.71	NS
PIP IMGHC-TX-H # 27609	3162	7, 15, 19	13.7	3	0.9	6.1	-0.36	NS
PIP IMGHC-TX-H # 27609	10000	19, 12, 12	14.3	3	1.0	4.0	-0.06	NS
PIP IMGHC-TX-H # 27609	31620	22, 12, 14	16.0	3	1.1	5.3	0.38	NS
PIP IMGHC-TX-H # 27609	100000	15, 24, 19	19.3	3	1.3	4.5	1.27	NS
NaN ₃	2	715, 722, 683	706.7	3	48.4	20.8		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 151: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		22, 15, 22, 20, 11	18.0	5		4.8		
Untreated (Water) Controls		21, 24, 21, 10, 16	18.4	5	1.0	5.5		
PIP IMGHC-TX-H # 27609	1000	20, 16, 14	16.7	3	0.9	3.1	-0.31	NS
PIP IMGHC-TX-H # 27609	3162	22, 17, 7	15.3	3	0.9	7.6	-0.89	NS
PIP IMGHC-TX-H # 27609	10000	12, 12, 20	14.7	3	0.8	4.6	-0.94	NS
PIP IMGHC-TX-H # 27609	31620	17, 14, 11	14.0	3	0.8	3.0	-1.10	NS
PIP IMGHC-TX-H # 27609	100000	17, 15, 17	16.3	3	0.9	1.2	-0.39	NS
AAN	5	181, 238, 221	213.3	3	11.9	29.3		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 152: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		6, 5, 14, 4, 4	6.6	5		4.2		
Untreated (Water) Controls		10, 9, 4, 10, 7	8.0	5	1.2	2.5		
PIP IMGHC-TX-H # 27609	1000	10, 5, 5	6.7	3	1.0	2.9	0.14	NS
PIP IMGHC-TX-H # 27609	3162	9, 5, 9	7.7	3	1.2	2.3	0.62	NS
PIP IMGHC-TX-H # 27609	10000	7, 5, 9	7.0	3	1.1	2.0	0.34	NS
PIP IMGHC-TX-H # 27609	31620	6, 5, 11	7.3	3	1.1	3.2	0.43	NS
PIP IMGHC-TX-H # 27609	100000	5, 6, 11	7.3	3	1.1	3.2	0.43	NS
AAC	50	177, 130, 126	144.3	3	21.9	28.4		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 153: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		15, 16, 6, 15, 11	12.6	5		4.2		
Untreated (Water) Controls		9, 16, 14, 17, 14	14.0	5	1.1	3.1		
PIP IMGHC-TX-H # 27609	1000	10, 15, 12	12.3	3	1.0	2.5	-0.01	NS
PIP IMGHC-TX-H # 27609	3162	12, 11, 11	11.3	3	0.9	0.6	-0.37	NS
PIP IMGHC-TX-H # 27609	10000	16, 10, 15	13.7	3	1.1	3.2	0.48	NS
PIP IMGHC-TX-H # 27609	31620	10, 6, 6	7.3	3	0.6	2.3	-2.23	NS
PIP IMGHC-TX-H # 27609	100000	9, 9, 17	11.7	3	0.9	4.6	-0.35	NS
AAN	5	155, 145, 158	152.7	3	12.1	6.8		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 154: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		269, 273, 265, 288, 287	276.4	5		10.5		
Untreated (Water) Controls		278, 280, 265, 283, 279	277.0	5	1.0	7.0		
PIP IMGHC-TX-H # 27609	1000	223, 228, 246	232.3	3	0.8	12.1	-4.58	NS
PIP IMGHC-TX-H # 27609	3162	251, 222, 252	241.7	3	0.9	17.0	-3.59	NS
PIP IMGHC-TX-H # 27609	10000	243, 257, 226	242.0	3	0.9	15.5	-3.55	NS
PIP IMGHC-TX-H # 27609	31620	264, 265, 242	257.0	3	0.9	13.0	-1.97	NS
PIP IMGHC-TX-H # 27609	100000	260, 241, 260	253.7	3	0.9	11.0	-2.31	NS
MMC	0.2	823, 870, 889	860.7	3	3.1	34.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 155: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		239, 238, 248, 227, 222	234.8	5		10.3		
Untreated (Water) Controls		172, 191, 201, 229, 223	203.2	5	0.9	23.4		
PIP IMGHC-TX-H # 27609	1000	193, 199, 229	207.0	3	0.9	19.3	-1.67	NS
PIP IMGHC-TX-H # 27609	3162	197, 198, 202	199.0	3	0.8	2.6	-2.15	NS
PIP IMGHC-TX-H # 27609	10000	222, 214, 213	216.3	3	0.9	4.9	-1.09	NS
PIP IMGHC-TX-H # 27609	31620	219, 198, 203	206.7	3	0.9	11.0	-1.68	NS
PIP IMGHC-TX-H # 27609	100000	173, 120, 91	128.0	3	0.5	41.6	-7.29	NS
AAN	20	1029, 834, 1115	992.7	3	4.2	144.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 156: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		34, 40, 17, 26, 24	28.2	5		9.0		
Untreated (Water) Controls		22, 25, 20, 15, 15	19.4	5	0.7	4.4		
PIP IMGHC-TX-H # 41609	1000	24, 29, 22	25.0	3	0.9	3.6	-0.66	NS
PIP IMGHC-TX-H # 41609	3162	27, 26, 32	28.3	3	1.0	3.2	0.16	NS
PIP IMGHC-TX-H # 41609	10000	24, 22, 19	21.7	3	0.8	2.5	-1.52	NS
PIP IMGHC-TX-H # 41609	31620	16, 22, 21	19.7	3	0.7	3.2	-2.09	NS
PIP IMGHC-TX-H # 41609	100000	25, 22, 17	21.3	3	0.8	4.0	-1.63	NS
2NF	5	899, 794, 900	864.3	3	30.7	60.9		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 157: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA98+S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		36, 19, 31, 27, 34	29.4	5		6.7		
Untreated (Water) Controls		25, 29, 25, 17, 26	24.4	5	0.8	4.4		
PIP IMGHC-TX-H # 41609	1000	42, 27, 49	39.3	3	1.3	11.2	1.71	NS
PIP IMGHC-TX-H # 41609	3162	25, 32, 32	29.7	3	1.0	4.0	0.10	NS
PIP IMGHC-TX-H # 41609	10000	26, 36 MB, 17	26.3	3	0.9	9.5	-0.65	NS
PIP IMGHC-TX-H # 41609	31620	24, 24, 22	23.3	3	0.8	1.2	-1.15	NS
PIP IMGHC-TX-H # 41609	100000	39, 37, 26	34.0	3	1.2	7.0	0.86	NS
B[a]P	10	314, 351, 388	351.0	3	11.9	37.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 158: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		84, 88, 98, 93, 86	89.8	5		5.7		
Untreated (Water) Controls		97, 96, 71, 105, 97	93.2	5	1.0	12.9		
PIP IMGHC-TX-H # 41609	1000	96, 107, 91	98.0	3	1.1	8.2	1.81	NS
PIP IMGHC-TX-H # 41609	3162	101, 92, 92	95.0	3	1.1	5.2	1.17	NS
PIP IMGHC-TX-H # 41609	10000	93, 91, 87	90.3	3	1.0	3.1	0.13	NS
PIP IMGHC-TX-H # 41609	31620	102, 91, 84	92.3	3	1.0	9.1	0.55	NS
PIP IMGHC-TX-H # 41609	100000	92, 100, 98	96.7	3	1.1	4.2	1.54	NS
NaN ₃	2	755, 752, 790	765.7	3	8.5	21.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 159: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		132, 122, 138, 107, 135	126.8	5		12.6		
Untreated (Water) Controls		120, 135, 125, 123, 122	125.0	5	1.0	5.9		
PIP IMGHC-TX-H # 41609	1000	131, 111, 100	114.0	3	0.9	15.7	-1.12	NS
PIP IMGHC-TX-H # 41609	3162	92, 117, 113	107.3	3	0.8	13.4	-1.71	NS
PIP IMGHC-TX-H # 41609	10000	125, 116, 93	111.3	3	0.9	16.5	-1.36	NS
PIP IMGHC-TX-H # 41609	31620	121, 118, 90	109.7	3	0.9	17.1	-1.52	NS
PIP IMGHC-TX-H # 41609	100000	123, 132, 98	117.7	3	0.9	17.6	-0.80	NS
AAN	5	1296, 1099, 1206	1200.3	3	9.5	98.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 160: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		10, 15, 21, 15, 12	14.6	5		4.2		
Untreated (Water) Controls		16, 21, 6, 15, 12	14.0	5	1.0	5.5		
PIP IMGHC-TX-H # 41609	1000	22, 20, 11	17.7	3	1.2	5.9	0.88	NS
PIP IMGHC-TX-H # 41609	3162	14, 16, 19	16.3	3	1.1	2.5	0.58	NS
PIP IMGHC-TX-H # 41609	10000	22, 11, 17	16.7	3	1.1	5.5	0.60	NS
PIP IMGHC-TX-H # 41609	31620	20, 16, 9	15.0	3	1.0	5.6	0.08	NS
PIP IMGHC-TX-H # 41609	100000	16, 19, 19	18.0	3	1.2	1.7	1.07	NS
NaN ₃	2	715, 722, 683	706.7	3	48.4	20.8		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 161: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		22, 15, 22, 20, 11	18.0	5		4.8		
Untreated (Water) Controls		21, 24, 21, 10, 16	18.4	5	1.0	5.5		
PIP IMGHC-TX-H # 41609	1000	17, 21, 24	20.7	3	1.1	3.5	0.57	NS
PIP IMGHC-TX-H # 41609	3162	35, 12, 12	19.7	3	1.1	13.3	0.13	NS
PIP IMGHC-TX-H # 41609	10000	12, 21, 14	15.7	3	0.9	4.7	-0.49	NS
PIP IMGHC-TX-H # 41609	31620	14, 15, 30	19.7	3	1.1	9.0	0.27	NS
PIP IMGHC-TX-H # 41609	100000	17, 16, 21	18.0	3	1.0	2.6	0.05	NS
AAN	5	181, 238, 221	213.3	3	11.9	29.3		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 162: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		6, 5, 14, 4, 4	6.6	5		4.2		
Untreated (Water) Controls		10, 9, 4, 10, 7	8.0	5	1.2	2.5		
PIP IMGHC-TX-H # 41609	1000	7, 5, 7	6.3	3	1.0	1.2	0.05	NS
PIP IMGHC-TX-H # 41609	3162	7, 9, 7	7.7	3	1.2	1.2	0.64	NS
PIP IMGHC-TX-H # 41609	10000	14, 6, 7	9.0	3	1.4	4.4	1.06	NS
PIP IMGHC-TX-H # 41609	31620	2, 10, 7	6.3	3	1.0	4.0	-0.18	NS
PIP IMGHC-TX-H # 41609	100000	6, 5, 4	5.0	3	0.8	1.0	-0.59	NS
AAC	50	177, 130, 126	144.3	3	21.9	28.4		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 163: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		15, 16, 6, 15, 11	12.6	5		4.2		
Untreated (Water) Controls		9, 16, 14, 17, 14	14.0	5	1.1	3.1		
PIP IMGHC-TX-H # 41609	1000	15, 10, 14	13.0	3	1.0	2.6	0.20	NS
PIP IMGHC-TX-H # 41609	3162	15, 14, 17	15.3	3	1.2	1.5	0.89	NS
PIP IMGHC-TX-H # 41609	10000	10, 10, 2	7.3	3	0.6	4.6	-2.01	NS
PIP IMGHC-TX-H # 41609	31620	12, 17, 6	11.7	3	0.9	5.5	-0.34	NS
PIP IMGHC-TX-H # 41609	100000	11, 9, 11	10.3	3	0.8	1.2	-0.63	NS
AAN	5	155, 145, 158	152.7	3	12.1	6.8		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 164: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		269, 273, 265, 288, 287	276.4	5		10.5		
Untreated (Water) Controls		278, 280, 265, 283, 279	277.0	5	1.0	7.0		
PIP IMGHC-TX-H # 41609	1000	254, 249, 265	256.0	3	0.9	8.2	-2.16	NS
PIP IMGHC-TX-H # 41609	3162	258, 262, 246	255.3	3	0.9	8.3	-2.24	NS
PIP IMGHC-TX-H # 41609	10000	260, 232, 243	245.0	3	0.9	14.1	-3.38	NS
PIP IMGHC-TX-H # 41609	31620	238, 278, 244	253.3	3	0.9	21.6	-2.48	NS
PIP IMGHC-TX-H # 41609	100000	269, 248, 259	258.7	3	0.9	10.5	-1.88	NS
MMC	0.2	823, 870, 889	860.7	3	3.1	34.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 165: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		239, 238, 248, 227, 222	234.8	5		10.3		
Untreated (Water) Controls		172, 191, 201, 229, 223	203.2	5	0.9	23.4		
PIP IMGHC-TX-H # 41609	1000	187, 275, 280	247.3	3	1.1	52.3	0.53	NS
PIP IMGHC-TX-H # 41609	3162	272, 202, 264	246.0	3	1.0	38.3	0.51	NS
PIP IMGHC-TX-H # 41609	10000	270, 260, 224	251.3	3	1.1	24.2	0.80	NS
PIP IMGHC-TX-H # 41609	31620	241, 258, 242	247.0	3	1.1	9.5	0.60	NS
PIP IMGHC-TX-H # 41609	100000	234, 256, 243	244.3	3	1.0	11.1	0.47	NS
AAN	20	1029, 834, 1115	992.7	3	4.2	144.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 166: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		34, 40, 17, 26, 24	28.2	5		9.0		
Untreated (Water) Controls		22, 25, 20, 15, 15	19.4	5	0.7	4.4		
PIP IMGHC-TX-S, #37908	1000	27, 21, 31	26.3	3	0.9	5.0	-0.29	NS
PIP IMGHC-TX-S, #37908	3162	24, 26, 27	25.7	3	0.9	1.5	-0.39	NS
PIP IMGHC-TX-S, #37908	10000	17, 36, 31	28.0	3	1.0	9.8	-0.05	NS
PIP IMGHC-TX-S, #37908	31620	29, 24, 25	26.0	3	0.9	2.6	-0.33	NS
PIP IMGHC-TX-S, #37908	100000	22, 30, 19	23.7	3	0.8	5.7	-0.85	NS
2NF	5	899, 794, 900	864.3	3	30.7	60.9		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 167: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA98+S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		36, 19, 31, 27, 34	29.4	5		6.7		
Untreated (Water) Controls		25, 29, 25, 17, 26	24.4	5	0.8	4.4		
PIP IMGHC-TX-S, #37908	1000	39, 41, 42	40.7	3	1.4	1.5	2.06	NS
PIP IMGHC-TX-S, #37908	3162	35, 30, 35	33.3	3	1.1	2.9	0.79	NS
PIP IMGHC-TX-S, #37908	10000	37, 24, 36	32.3	3	1.1	7.2	0.57	NS
PIP IMGHC-TX-S, #37908	31620	36, 32, 47	38.3	3	1.3	7.8	1.63	NS
PIP IMGHC-TX-S, #37908	100000	52, 34, 25	37.0	3	1.3	13.7	1.31	NS
B[a]P	10	314, 351, 388	351.0	3	11.9	37.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 168: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		84, 88, 98, 93, 86	89.8	5		5.7		
Untreated (Water) Controls		97, 96, 71, 105, 97	93.2	5	1.0	12.9		
PIP IMGHC-TX-S, #37908	1000	110, 98, 97	101.7	3	1.1	7.2	1.95	NS
PIP IMGHC-TX-S, #37908	3162	98, 91, 103	97.3	3	1.1	6.0	1.26	NS
PIP IMGHC-TX-S, #37908	10000	108, 102, 92	100.7	3	1.1	8.1	1.79	NS
PIP IMGHC-TX-S, #37908	31620	105, 121, 91	105.7	3	1.2	15.0	2.54	*
PIP IMGHC-TX-S, #37908	100000	98, 106, 115	106.3	3	1.2	8.5	2.69	*
NaN ₃	2	755, 752, 790	765.7	3	8.5	21.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 169: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		132, 122, 138, 107, 135	126.8	5		12.6		
Untreated (Water) Controls		120, 135, 125, 123, 122	125.0	5	1.0	5.9		
PIP IMGHC-TX-S, #37908	1000	136, 146, 131	137.7	3	1.1	7.6	1.11	NS
PIP IMGHC-TX-S, #37908	3162	137, 151, 128	138.7	3	1.1	11.6	1.20	NS
PIP IMGHC-TX-S, #37908	10000	106, 92, 122	106.7	3	0.8	15.0	-2.17	NS
PIP IMGHC-TX-S, #37908	31620	110, 102, 108	106.7	3	0.8	4.2	-2.14	NS
PIP IMGHC-TX-S, #37908	100000	117, 95, 80	97.3	3	0.8	18.6	-3.27	NS
AAN	5	1296, 1099, 1206	1200.3	3	9.5	98.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 170: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		10, 15, 21, 15, 12	14.6	5		4.2		
Untreated (Water) Controls		16, 21, 6, 15, 12	14.0	5	1.0	5.5		
PIP IMGHC-TX-S, #37908	1000	16, 16, 7	13.0	3	0.9	5.2	-0.55	NS
PIP IMGHC-TX-S, #37908	3162	16, 16, 15	15.7	3	1.1	0.6	0.38	NS
PIP IMGHC-TX-S, #37908	10000	16, 7, 21	14.7	3	1.0	7.1	-0.11	NS
PIP IMGHC-TX-S, #37908	31620	19, 17, 14	16.7	3	1.1	2.5	0.64	NS
PIP IMGHC-TX-S, #37908	100000	16, 12, 21	16.3	3	1.1	4.5	0.51	NS
NaN ₃	2	715, 722, 683	706.7	3	48.4	20.8		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 171: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		22, 15, 22, 20, 11	18.0	5		4.8		
Untreated (Water) Controls		21, 24, 21, 10, 16	18.4	5	1.0	5.5		
PIP IMGHC-TX-S, #37908	1000	19, 17, 9	15.0	3	0.8	5.3	-0.85	NS
PIP IMGHC-TX-S, #37908	3162	7, 12, 11	10.0	3	0.6	2.6	-2.38	NS
PIP IMGHC-TX-S, #37908	10000	21, 12, 17	16.7	3	0.9	4.5	-0.34	NS
PIP IMGHC-TX-S, #37908	31620	30, 14, 23 M B	22.3	3	1.2	8.0	1.04	NS
PIP IMGHC-TX-S, #37908	100000	17, 17, 22	18.7	3	1.0	2.9	0.23	NS
AAN	5	181, 238, 221	213.3	3	11.9	29.3		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 172: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		6, 5, 14, 4, 4	6.6	5		4.2		
Untreated (Water) Controls		10, 9, 4, 10, 7	8.0	5	1.2	2.5		
PIP IMGHC-TX-S, #37908	1000	2, 14, 12	9.3	3	1.4	6.4	0.76	NS
PIP IMGHC-TX-S, #37908	3162	10, 10, 6	8.7	3	1.3	2.3	0.86	NS
PIP IMGHC-TX-S, #37908	10000	7, 7, 5	6.3	3	1.0	1.2	0.05	NS
PIP IMGHC-TX-S, #37908	31620	6, 9, 6	7.0	3	1.1	1.7	0.29	NS
PIP IMGHC-TX-S, #37908	100000	5, 7, 12	8.0	3	1.2	3.6	0.58	NS
AAC	50	177, 130, 126	144.3	3	21.9	28.4		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 173: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		15, 16, 6, 15, 11	12.6	5		4.2		
Untreated (Water) Controls		9, 16, 14, 17, 14	14.0	5	1.1	3.1		
PIP IMGHC-TX-S, #37908	1000	15, 17, 19	17.0	3	1.3	2.0	1.86	NS
PIP IMGHC-TX-S, #37908	3162	17, 17, 17	17.0	3	1.3	0.0	1.87	NS
PIP IMGHC-TX-S, #37908	10000	17, 26, 20	21.0	3	1.7	4.6	3.20	*
PIP IMGHC-TX-S, #37908	31620	20, 14, 12	15.3	3	1.2	4.2	1.18	NS
PIP IMGHC-TX-S, #37908	100000	15, 14, 17	15.3	3	1.2	1.5	1.24	NS
AAN	5	155, 145, 158	152.7	3	12.1	6.8		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 174: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		269, 273, 265, 288, 287	276.4	5		10.5		
Untreated (Water) Controls		278, 280, 265, 283, 279	277.0	5	1.0	7.0		
PIP IMGHC-TX-S, #37908	1000	272, 268, 282	274.0	3	1.0	7.2	-0.23	NS
PIP IMGHC-TX-S, #37908	3162	270, 263, 279	270.7	3	1.0	8.0	-0.56	NS
PIP IMGHC-TX-S, #37908	10000	243, 269, 241	251.0	3	0.9	15.6	-2.54	NS
PIP IMGHC-TX-S, #37908	31620	262, 280, 267	269.7	3	1.0	9.3	-0.66	NS
PIP IMGHC-TX-S, #37908	100000	258, 251, 213	240.7	3	0.9	24.2	-3.64	NS
MMC	0.2	823, 870, 889	860.7	3	3.1	34.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 175: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		239, 238, 248, 227, 222	234.8	5		10.3		
Untreated (Water) Controls		172, 191, 201, 229, 223	203.2	5	0.9	23.4		
PIP IMGHC-TX-S, #37908	1000	239, 263, 264	255.3	3	1.1	14.2	1.35	NS
PIP IMGHC-TX-S, #37908	3162	265, 231, 242	246.0	3	1.0	17.3	0.74	NS
PIP IMGHC-TX-S, #37908	10000	263, 233, 199	231.7	3	1.0	32.0	-0.26	NS
PIP IMGHC-TX-S, #37908	31620	217, 233, 199	216.3	3	0.9	17.0	-1.28	NS
PIP IMGHC-TX-S, #37908	100000	208, 201, 254	221.0	3	0.9	28.8	-0.98	NS
AAN	20	1029, 834, 1115	992.7	3	4.2	144.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 176: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		34, 40, 17, 26, 24	28.2	5		9.0		
Untreated (Water) Controls		22, 25, 20, 15, 15	19.4	5	0.7	4.4		
[REDACTED]	1000	24, 35, 19	26.0	3	0.9	8.2	-0.40	NS
[REDACTED]	3162	26, 26, 27	26.3	3	0.9	0.6	-0.25	NS
[REDACTED]	10000	19, 37, 21	25.7	3	0.9	9.9	-0.50	NS
[REDACTED]	31620	25, 21, 24	23.3	3	0.8	2.1	-0.87	NS
[REDACTED]	100000	27, 24, 19	23.3	3	0.8	4.0	-0.89	NS
2NF	5	899, 794, 900	864.3	3	30.7	60.9		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 177: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA98+S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		36, 19, 31, 27, 34	29.4	5		6.7		
Untreated (Water) Controls		25, 29, 25, 17, 26	24.4	5	0.8	4.4		
[REDACTED]	1000	39, 35, 32	35.3	3	1.2	3.5	1.38	NS
[REDACTED]	3162	41, 27, 27	31.7	3	1.1	8.1	0.52	NS
[REDACTED]	10000	37, 34, 27	32.7	3	1.1	5.1	0.79	NS
[REDACTED]	31620	24, 25, 35	28.0	3	1.0	6.1	-0.30	NS
[REDACTED]	100000	27, 21, 21	23.0	3	0.8	3.5	-1.52	NS
B[a]P	10	314, 351, 388	351.0	3	11.9	37.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 178: ██████████ control silicone gel breast implant ██████████ Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		84, 88, 98, 93, 86	89.8	5		5.7		
Untreated (Water) Controls		97, 96, 71, 105, 97	93.2	5	1.0	12.9		
██████████	1000	111, 112, 107	110.0	3	1.2	2.6	2.94	*
██████████	3162	82, 96, 106	94.7	3	1.1	12.1	0.71	NS
██████████	10000	96, 80, 75	83.7	3	0.9	11.0	-0.98	NS
██████████	31620	105, 93, 82	93.3	3	1.0	11.5	0.51	NS
██████████	100000	86, 70, 86	80.7	3	0.9	9.2	-1.45	NS
NaN ₃	2	755, 752, 790	765.7	3	8.5	21.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 179: ██████████ control silicone gel breast implant ██████████ Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		132, 122, 138, 107, 135	126.8	5		12.6		
Untreated (Water) Controls		120, 135, 125, 123, 122	125.0	5	1.0	5.9		
██████████	1000	107, 70, 76	84.3	3	0.7	19.9	-2.89	NS
██████████	3162	82, 103, 91	92.0	3	0.7	10.5	-2.29	NS
██████████	10000	127, 51, 108	95.3	3	0.8	39.6	-2.26	NS
██████████	31620	108, 106, 97	103.7	3	0.8	5.9	-1.47	NS
██████████	100000	103, 90, 95	96.0	3	0.8	6.6	-1.99	NS
AAN	5	1296, 1099, 1206	1200.3	3	9.5	98.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 180: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		10, 15, 21, 15, 12	14.6	5		4.2		
Untreated (Water) Controls		16, 21, 6, 15, 12	14.0	5	1.0	5.5		
[REDACTED]	1000	14, 10, 21	15.0	3	1.0	5.6	0.09	NS
[REDACTED]	3162	16, 15, 15	15.3	3	1.1	0.6	0.30	NS
[REDACTED]	10000	24, 16, 17	19.0	3	1.3	4.4	1.32	NS
[REDACTED]	31620	12, 10, 17	13.0	3	0.9	3.6	-0.50	NS
[REDACTED]	100000	9, 11, 21	13.7	3	0.9	6.4	-0.38	NS
NaN ₃	2	715, 722, 683	706.7	3	48.4	20.8		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 181: ██████████ control silicone gel breast implant ██████████ Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		22, 15, 22, 20, 11	18.0	5		4.8		
Untreated (Water) Controls		21, 24, 21, 10, 16	18.4	5	1.0	5.5		
██████████	1000	35, 21, 24	26.7	3	1.5	7.4	1.52	NS
██████████	3162	26, 17, 22	21.7	3	1.2	4.5	0.70	NS
██████████	10000	21, 17, 17	18.3	3	1.0	2.3	0.11	NS
██████████	31620	9, 19, 29	19.0	3	1.1	10.0	0.06	NS
██████████	100000	12, 27, 6	15.0	3	0.8	10.8	-0.83	NS
AAN	5	181, 238, 221	213.3	3	11.9	29.3		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 182: ██████████ control silicone gel breast implant ██████████ Raw plate counts and calculated mutagenicity data -
Experiment 1 – Water Extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		6, 5, 14, 4, 4	6.6	5		4.2		
Untreated (Water) Controls		10, 9, 4, 10, 7	8.0	5	1.2	2.5		
██████████	1000	2, 5, 9	5.3	3	0.8	3.5	-0.68	NS
██████████	3162	9, 7, 6	7.3	3	1.1	1.5	0.54	NS
██████████	10000	7, 9, 5	7.0	3	1.1	2.0	0.36	NS
██████████	31620	5, 5, 7	5.7	3	0.9	1.2	-0.29	NS
██████████	100000	12, 10, 9	10.3	3	1.6	1.5	1.84	NS
AAC	50	177, 130, 126	144.3	3	21.9	28.4		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 183: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data -
Experiment 1 – Water Extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		15, 16, 6, 15, 11	12.6	5		4.2		
Untreated (Water) Controls		9, 16, 14, 17, 14	14.0	5	1.1	3.1		
[REDACTED]	1000	10, 7, 7	8.0	3	0.6	1.7	-1.23	NS
[REDACTED]	3162	7, 21, 15	14.3	3	1.1	7.0	0.36	NS
[REDACTED]	10000	15, 15, 7	12.3	3	1.0	4.6	-0.07	NS
[REDACTED]	31620	16, 5, 10	10.3	3	0.8	5.5	-0.66	NS
[REDACTED]	100000	4, 15, 7	8.7	3	0.7	5.7	-1.19	NS
AAN	5	155, 145, 158	152.7	3	12.1	6.8		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 184: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		269, 273, 265, 288, 287	276.4	5		10.5		
Untreated (Water) Controls		278, 280, 265, 283, 279	277.0	5	1.0	7.0		
[REDACTED]	1000	247, 254, 275	258.7	3	0.9	14.6	-1.99	NS
[REDACTED]	3162	251, 272, 262	261.7	3	0.9	10.5	-1.64	NS
[REDACTED]	10000	273, 307, 270	283.3	3	1.0	20.6	0.74	NS
[REDACTED]	31620	268, 260, 254	260.7	3	0.9	7.0	-1.75	NS
[REDACTED]	100000	249, 258, 265	257.3	3	0.9	8.0	-2.13	NS
MMC	0.2	823, 870, 889	860.7	3	3.1	34.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 185: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data - Experiment 1 – Water Extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		239, 238, 248, 227, 222	234.8	5		10.3		
Untreated (Water) Controls		172, 191, 201, 229, 223	203.2	5	0.9	23.4		
[REDACTED]	1000	213, 229, 232	224.7	3	1.0	10.2	-0.59	NS
[REDACTED]	3162	247, 228, 269	248.0	3	1.1	20.5	0.75	NS
[REDACTED]	10000	248, 275, 219	247.3	3	1.1	28.0	0.69	NS
[REDACTED]	31620	258, 244, 202	234.7	3	1.0	29.1	-0.04	NS
[REDACTED]	100000	222, 233, 166	207.0	3	0.9	35.9	-1.73	NS
AAN	20	1029, 834, 1115	992.7	3	4.2	144.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Appendix 4
Raw plate counts and calculated mutagenicity data Experiment 2 Water Extract

Table 186: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		17, 20, 27, 15, 20	19.8	5		4.5		
Untreated (Water) Controls		19, 26, 21, 27, 16	21.8	5	1.1	4.7		
PIP IMGHC-TX-H # 16306	6250	26, 25, 21	24.0	3	1.2	2.6	1.14	NS
PIP IMGHC-TX-H # 16306	12500	17, 27, 15	19.7	3	1.0	6.4	-0.07	NS
PIP IMGHC-TX-H # 16306	25000	20, 15, 15	16.7	3	0.8	2.9	-0.86	NS
PIP IMGHC-TX-H # 16306	50000	24, 22, 16	20.7	3	1.0	4.2	0.25	NS
PIP IMGHC-TX-H # 16306	100000	11, 26, 19	18.7	3	0.9	7.5	-0.41	NS
2NF	5	561, 577, 570	569.3	3	28.8	8.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 187: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA98 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		24, 20, 27, 41, 39	30.2	5		9.3		
Untreated (Water) Controls		29, 29, 22, 25, 17	24.4	5	0.8	5.1		
PIP IMGHC-TX-H # 16306	6250	37, 35, 27	33.0	3	1.1	5.3	0.65	NS
PIP IMGHC-TX-H # 16306	12500	29, 31, 25	28.3	3	0.9	3.1	-0.28	NS
PIP IMGHC-TX-H # 16306	25000	32, 34, 30	32.0	3	1.1	2.0	0.47	NS
PIP IMGHC-TX-H # 16306	50000	20, 34, 19	24.3	3	0.8	8.4	-1.25	NS
PIP IMGHC-TX-H # 16306	100000	35, 26, 32	31.0	3	1.0	4.6	0.26	NS
B[a]P	10	391, 401, 511	434.3	3	14.4	66.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 188: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		108, 91, 113, 97, 101	102.0	5		8.7		
Untreated (Water) Controls		100, 100, 105, 122, 105	106.4	5	1.0	9.1		
PIP IMGHC-TX-H # 16306	6250	118, 148, 105	123.7	3	1.2	22.1	1.73	NS
PIP IMGHC-TX-H # 16306	12500	115, 100, 131	115.3	3	1.1	15.5	1.09	NS
PIP IMGHC-TX-H # 16306	25000	123, 145, 96	121.3	3	1.2	24.5	1.53	NS
PIP IMGHC-TX-H # 16306	50000	110, 130, 91	110.3	3	1.1	19.5	0.66	NS
PIP IMGHC-TX-H # 16306	100000	90, 115, 97	100.7	3	1.0	12.9	-0.12	NS
NaN ₃	2	561, 546, 571	559.3	3	5.5	12.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 189: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		130, 143, 140, 102, 123	127.6	5		16.4		
Untreated (Water) Controls		116, 142, 133, 140, 115	129.2	5	1.0	12.9		
PIP IMGHC-TX-H # 16306	6250	95, 118, 110	107.7	3	0.8	11.7	-2.03	NS
PIP IMGHC-TX-H # 16306	12500	120, 133, 111	121.3	3	1.0	11.1	-0.60	NS
PIP IMGHC-TX-H # 16306	25000	117, 122, 105	114.7	3	0.9	8.7	-1.28	NS
PIP IMGHC-TX-H # 16306	50000	105, 101, 97	101.0	3	0.8	4.0	-2.74	NS
PIP IMGHC-TX-H # 16306	100000	136, 108, 100	114.7	3	0.9	18.9	-1.32	NS
AAN	5	587, 739, 636	654.0	3	5.1	77.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 190: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		16, 20, 24, 25, 22	21.4	5		3.6		
Untreated (Water) Controls		20, 21, 24, 14, 27	21.2	5	1.0	4.9		
PIP IMGHC-TX-H # 16306	6250	17, 21, 21	19.7	3	0.9	2.3	-0.49	NS
PIP IMGHC-TX-H # 16306	12500	15, 17, 15	15.7	3	0.7	1.2	-1.75	NS
PIP IMGHC-TX-H # 16306	25000	20, 12, 25	19.0	3	0.9	6.6	-0.80	NS
PIP IMGHC-TX-H # 16306	50000	7, 14, 14	11.7	3	0.5	4.0	-3.30	NS
PIP IMGHC-TX-H # 16306	100000	17, 26, 15	19.3	3	0.9	5.9	-0.66	NS
NaN ₃	2	484, 518, 469	490.3	3	22.9	25.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 191: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		19, 19, 20, 22, 26	21.2	5		2.9		
Untreated (Water) Controls		35, 20, 30, 19, 22	25.2	5	1.2	7.0		
PIP IMGHC-TX-H # 16306	6250	19, 12, 16	15.7	3	0.7	3.5	-2.39	NS
PIP IMGHC-TX-H # 16306	12500	19, 20, 17	18.7	3	0.9	1.5	-1.02	NS
PIP IMGHC-TX-H # 16306	25000	17, 16, 10	14.3	3	0.7	3.8	-3.05	NS
PIP IMGHC-TX-H # 16306	50000	19, 20, 22	20.3	3	1.0	1.5	-0.32	NS
PIP IMGHC-TX-H # 16306	100000	25, 16, 20	20.3	3	1.0	4.5	-0.38	NS
AAN	5	178, 196, 202	192.0	3	9.1	12.5		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 192: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		9, 5, 9, 7, 6	7.2	5		1.8		
Untreated (Water) Controls		6, 5, 7, 4, 9	6.2	5	0.9	1.9		
PIP IMGHC-TX-H # 16306	6250	5, 6, 6	5.7	3	0.8	0.6	-0.84	NS
PIP IMGHC-TX-H # 16306	12500	7, 6, 5	6.0	3	0.8	1.0	-0.65	NS
PIP IMGHC-TX-H # 16306	25000	1, 4, 5	3.3	3	0.5	2.1	-2.70	NS
PIP IMGHC-TX-H # 16306	50000	7, 1, 5	4.3	3	0.6	3.1	-2.07	NS
PIP IMGHC-TX-H # 16306	100000	6, 9, 7	7.3	3	1.0	1.5	0.09	NS
AAC	50	107, 156, 120	127.7	3	17.7	25.4		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 193: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		20, 21, 10, 15, 15	16.2	5		4.4		
Untreated (Water) Controls		19, 10, 12, 17, 5	12.6	5	0.8	5.6		
PIP IMGHC-TX-H # 16306	6250	9, 11, 9	9.7	3	0.6	1.2	-2.17	NS
PIP IMGHC-TX-H # 16306	12500	20, 27, 11	19.3	3	1.2	8.0	0.82	NS
PIP IMGHC-TX-H # 16306	25000	5, 11, 9	8.3	3	0.5	3.1	-2.79	NS
PIP IMGHC-TX-H # 16306	50000	11, 11, 14	12.0	3	0.7	1.7	-1.31	NS
PIP IMGHC-TX-H # 16306	100000	11, 6, 11	9.3	3	0.6	2.9	-2.36	NS
AAN	5	151, 121, 110	127.3	3	7.9	21.2		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 194: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		267, 302, 283, 316 M B, 297	293.0	5		18.7		
Untreated (Water) Controls		299, 308, 294, 302, 293	299.2	5	1.0	6.1		
PIP IMGHC-TX-H # 16306	6250	259, 241, 232	244.0	3	0.8	13.7	-2.95	NS
PIP IMGHC-TX-H # 16306	12500	287, 254, 262	267.7	3	0.9	17.2	-1.49	NS
PIP IMGHC-TX-H # 16306	25000	270, 213, 211	231.3	3	0.8	33.5	-3.80	NS
PIP IMGHC-TX-H # 16306	50000	219, 259, 232	236.7	3	0.8	20.4	-3.43	NS
PIP IMGHC-TX-H # 16306	100000	219, 270, 253	247.3	3	0.8	26.0	-2.76	NS
MMC	0.2	815, 804, 805	808.0	3	2.8	6.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 195: PIP silicone gel breast implant IMGHC-TX-H, batch 16306 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		268, 244, 272, 253, 248	257.0	5		12.4		
Untreated (Water) Controls		265, 246, 280, 217, 241	249.8	5	1.0	24.0		
PIP IMGHC-TX-H # 16306	6250	219, 248, 222	229.7	3	0.9	15.9	-1.43	NS
PIP IMGHC-TX-H # 16306	12500	252, 248, 253	251.0	3	1.0	2.6	-0.30	NS
PIP IMGHC-TX-H # 16306	25000	187, 248, 283	239.3	3	0.9	48.6	-0.99	NS
PIP IMGHC-TX-H # 16306	50000	229, 170, 221	206.7	3	0.8	32.0	-2.73	NS
PIP IMGHC-TX-H # 16306	100000	233, 274, 234	247.0	3	1.0	23.4	-0.52	NS
AAN	20	1167, 1182, 1169	1172.7	3	4.6	8.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 196: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		17, 20, 27, 15, 20	19.8	5		4.5		
Untreated (Water) Controls		19, 26, 21, 27, 16	21.8	5	1.1	4.7		
PIP IMGHC-TX-H # 02808	6250	16, 30, 20	22.0	3	1.1	7.2	0.67	NS
PIP IMGHC-TX-H # 02808	12500	22, 19, 16	19.0	3	1.0	3.0	-0.23	NS
PIP IMGHC-TX-H # 02808	25000	25, 20, 20	21.7	3	1.1	2.9	0.67	NS
PIP IMGHC-TX-H # 02808	50000	15, 21, 20	18.7	3	0.9	3.2	-0.36	NS
PIP IMGHC-TX-H # 02808	100000	19, 20, 20	19.7	3	1.0	0.6	0.02	NS
2NF	5	561, 577, 570	569.3	3	28.8	8.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 197: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA98 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		24, 20, 27, 41, 39	30.2	5		9.3		
Untreated (Water) Controls		29, 29, 22, 25, 17	24.4	5	0.8	5.1		
PIP IMGHC-TX-H # 02808	6250	35, 30, 32	32.3	3	1.1	2.5	0.57	NS
PIP IMGHC-TX-H # 02808	12500	37, 32, 30	33.0	3	1.1	3.6	0.70	NS
PIP IMGHC-TX-H # 02808	25000	36, 39, 39	38.0	3	1.3	1.7	1.70	NS
PIP IMGHC-TX-H # 02808	50000	30, 36, 37	34.3	3	1.1	3.8	0.97	NS
PIP IMGHC-TX-H # 02808	100000	26, 22, 39	29.0	3	1.0	8.9	-0.23	NS
B[a]P	10	391, 401, 511	434.3	3	14.4	66.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 198: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		108, 91, 113, 97, 101	102.0	5		8.7		
Untreated (Water) Controls		100, 100, 105, 122, 105	106.4	5	1.0	9.1		
PIP IMGHC-TX-H # 02808	6250	137, 105, 113	118.3	3	1.2	16.7	2.24	NS
PIP IMGHC-TX-H # 02808	12500	123, 111, 111	115.0	3	1.1	6.9	1.83	NS
PIP IMGHC-TX-H # 02808	25000	116, 127, 106	116.3	3	1.1	10.5	2.00	NS
PIP IMGHC-TX-H # 02808	50000	105, 101, 115	107.0	3	1.0	7.2	0.72	NS
PIP IMGHC-TX-H # 02808	100000	106, 122, 113	113.7	3	1.1	8.0	1.65	NS
NaN ₃	2	561, 546, 571	559.3	3	5.5	12.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 199: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		130, 143, 140, 102, 123	127.6	5		16.4		
Untreated (Water) Controls		116, 142, 133, 140, 115	129.2	5	1.0	12.9		
PIP IMGHC-TX-H # 02808	6250	130, 110, 100	113.3	3	0.9	15.3	-1.25	NS
PIP IMGHC-TX-H # 02808	12500	103, 110, 95	102.7	3	0.8	7.5	-2.21	NS
PIP IMGHC-TX-H # 02808	25000	115, 101, 97	104.3	3	0.8	9.5	-2.06	NS
PIP IMGHC-TX-H # 02808	50000	130, 96, 103	109.7	3	0.9	18.0	-1.59	NS
PIP IMGHC-TX-H # 02808	100000	117, 105, 81	101.0	3	0.8	18.3	-2.42	NS
AAN	5	587, 739, 636	654.0	3	5.1	77.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 200: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		16, 20, 24, 25, 22	21.4	5		3.6		
Untreated (Water) Controls		20, 21, 24, 14, 27	21.2	5	1.0	4.9		
PIP IMGHC-TX-H # 02808	6250	16, 21, 19	18.7	3	0.9	2.5	-0.84	NS
PIP IMGHC-TX-H # 02808	12500	21, 29, 16	22.0	3	1.0	6.6	0.12	NS
PIP IMGHC-TX-H # 02808	25000	16, 22, 16	18.0	3	0.8	3.5	-1.08	NS
PIP IMGHC-TX-H # 02808	50000	19, 25, 14	19.3	3	0.9	5.5	-0.69	NS
PIP IMGHC-TX-H # 02808	100000	12, 19, 14	15.0	3	0.7	3.6	-2.14	NS
NaN ₃	2	484, 518, 469	490.3	3	22.9	25.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 201: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		19, 19, 20, 22, 26	21.2	5		2.9		
Untreated (Water) Controls		35, 20, 30, 19, 22	25.2	5	1.2	7.0		
PIP IMGHC-TX-H # 02808	6250	34, 15, 29	26.0	3	1.2	9.8	1.30	NS
PIP IMGHC-TX-H # 02808	12500	24, 21, 22	22.3	3	1.1	1.5	0.38	NS
PIP IMGHC-TX-H # 02808	25000	21, 25, 24	23.3	3	1.1	2.1	0.69	NS
PIP IMGHC-TX-H # 02808	50000	22, 19, 17	19.3	3	0.9	2.5	-0.61	NS
PIP IMGHC-TX-H # 02808	100000	17, 20, 16	17.7	3	0.8	2.1	-1.19	NS
AAN	5	178, 196, 202	192.0	3	9.1	12.5		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 202: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		9, 5, 9, 7, 6	7.2	5		1.8		
Untreated (Water) Controls		6, 5, 7, 4, 9	6.2	5	0.9	1.9		
PIP IMGHC-TX-H # 02808	6250	7, 12, 6	8.3	3	1.2	3.2	0.33	NS
PIP IMGHC-TX-H # 02808	12500	10, 4, 14	9.3	3	1.3	5.0	0.53	NS
PIP IMGHC-TX-H # 02808	25000	7, 11, 1	6.3	3	0.9	5.0	-0.61	NS
PIP IMGHC-TX-H # 02808	50000	7, 10, 1	6.0	3	0.8	4.6	-0.70	NS
PIP IMGHC-TX-H # 02808	100000	6, 11, 6	7.7	3	1.1	2.9	0.13	NS
AAC	50	107, 156, 120	127.7	3	17.7	25.4		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 203: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		20, 21, 10, 15, 15	16.2	5		4.4		
Untreated (Water) Controls		19, 10, 12, 17, 5	12.6	5	0.8	5.6		
PIP IMGHC-TX-H # 02808	6250	15, 16, 6	12.3	3	0.8	5.5	-1.30	NS
PIP IMGHC-TX-H # 02808	12500	10, 12, 16	12.7	3	0.8	3.1	-1.06	NS
PIP IMGHC-TX-H # 02808	25000	14, 12, 9	11.7	3	0.7	2.5	-1.40	NS
PIP IMGHC-TX-H # 02808	50000	24, 11, 16	17.0	3	1.0	6.6	0.19	NS
PIP IMGHC-TX-H # 02808	100000	7, 7, 6	6.7	3	0.4	0.6	-3.34	NS
AAN	5	151, 121, 110	127.3	3	7.9	21.2		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 204: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		267, 302, 283, 316 M B, 297	293.0	5		18.7		
Untreated (Water) Controls		299, 308, 294, 302, 293	299.2	5	1.0	6.1		
PIP IMGHC-TX-H # 02808	6250	247, 256, 274	259.0	3	0.9	13.7	-2.79	NS
PIP IMGHC-TX-H # 02808	12500	270, 293, 298	287.0	3	1.0	14.9	-0.47	NS
PIP IMGHC-TX-H # 02808	25000	300, 259, 264	274.3	3	0.9	22.4	-1.52	NS
PIP IMGHC-TX-H # 02808	50000	269, 260, 239	256.0	3	0.9	15.4	-3.05	NS
PIP IMGHC-TX-H # 02808	100000	268, 249, 254	257.0	3	0.9	9.8	-2.96	NS
MMC	0.2	815, 804, 805	808.0	3	2.8	6.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 205: PIP silicone gel breast implant IMGHC-TX-H, batch 02808 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		268, 244, 272, 253, 248	257.0	5		12.4		
Untreated (Water) Controls		265, 246, 280, 217, 241	249.8	5	1.0	24.0		
PIP IMGHC-TX-H # 02808	6250	244, 227, 243	238.0	3	0.9	9.5	-1.59	NS
PIP IMGHC-TX-H # 02808	12500	224, 207, 194	208.3	3	0.8	15.0	-4.22	NS
PIP IMGHC-TX-H # 02808	25000	219, 226, 254	233.0	3	0.9	18.5	-2.03	NS
PIP IMGHC-TX-H # 02808	50000	243, 278, 254	258.3	3	1.0	17.9	0.10	NS
PIP IMGHC-TX-H # 02808	100000	237, 194, 208	213.0	3	0.8	21.9	-3.81	NS
AAN	20	1167, 1182, 1169	1172.7	3	4.6	8.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 206: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		17, 20, 27, 15, 20	19.8	5		4.5		
Untreated (Water) Controls		19, 26, 21, 27, 16	21.8	5	1.1	4.7		
PIP IMGHC-TX-H # 27609	6250	27, 11, 16	18.0	3	0.9	8.2	-0.54	NS
PIP IMGHC-TX-H # 27609	12500	20, 9, 11	13.3	3	0.7	5.9	-1.74	NS
PIP IMGHC-TX-H # 27609	25000	12, 22, 22	18.7	3	0.9	5.8	-0.31	NS
PIP IMGHC-TX-H # 27609	50000	14, 17, 17	16.0	3	0.8	1.7	-0.91	NS
PIP IMGHC-TX-H # 27609	100000	22, 20, 12	18.0	3	0.9	5.3	-0.46	NS
2NF	5	561, 577, 570	569.3	3	28.8	8.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 207: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA98 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		24, 20, 27, 41, 39	30.2	5		9.3		
Untreated (Water) Controls		29, 29, 22, 25, 17	24.4	5	0.8	5.1		
PIP IMGHC-TX-H # 27609	6250	31, 19, 31	27.0	3	0.9	6.9	-0.45	NS
PIP IMGHC-TX-H # 27609	12500	37, 20, 9	22.0	3	0.7	14.1	-1.50	NS
PIP IMGHC-TX-H # 27609	25000	31, 25, 25	27.0	3	0.9	3.5	-0.41	NS
PIP IMGHC-TX-H # 27609	50000	20, 20, 31	23.7	3	0.8	6.4	-0.99	NS
PIP IMGHC-TX-H # 27609	100000	27, 20, 21	22.7	3	0.8	3.8	-1.13	NS
B[a]P	10	391, 401, 511	434.3	3	14.4	66.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 208: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		108, 91, 113, 97, 101	102.0	5		8.7		
Untreated (Water) Controls		100, 100, 105, 122, 105	106.4	5	1.0	9.1		
PIP IMGHC-TX-H # 27609	6250	82, 107, 111	100.0	3	1.0	15.7	-0.32	NS
PIP IMGHC-TX-H # 27609	12500	116, 113, 95	108.0	3	1.1	11.4	0.81	NS
PIP IMGHC-TX-H # 27609	25000	103, 108, 120	110.3	3	1.1	8.7	1.13	NS
PIP IMGHC-TX-H # 27609	50000	110, 115, 125	116.7	3	1.1	7.6	1.96	NS
PIP IMGHC-TX-H # 27609	100000	126, 116, 115	119.0	3	1.2	6.1	2.26	NS
NaN ₃	2	561, 546, 571	559.3	3	5.5	12.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 209: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		130, 143, 140, 102, 123	127.6	5		16.4		
Untreated (Water) Controls		116, 142, 133, 140, 115	129.2	5	1.0	12.9		
PIP IMGHC-TX-H # 27609	6250	116, 132, 131	126.3	3	1.0	9.0	-0.10	NS
PIP IMGHC-TX-H # 27609	12500	108, 97, 118	107.7	3	0.8	10.5	-2.08	NS
PIP IMGHC-TX-H # 27609	25000	116, 121, 103	113.3	3	0.9	9.3	-1.46	NS
PIP IMGHC-TX-H # 27609	50000	88, 118, 108	104.7	3	0.8	15.3	-2.44	NS
PIP IMGHC-TX-H # 27609	100000	90, 103, 107	100.0	3	0.8	8.9	-2.94	NS
AAN	5	587, 739, 636	654.0	3	5.1	77.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 210: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		16, 20, 24, 25, 22	21.4	5		3.6		
Untreated (Water) Controls		20, 21, 24, 14, 27	21.2	5	1.0	4.9		
PIP IMGHC-TX-H # 27609	6250	17, 11, 16	14.7	3	0.7	3.2	-2.20	NS
PIP IMGHC-TX-H # 27609	12500	16, 14, 15	15.0	3	0.7	1.0	-2.04	NS
PIP IMGHC-TX-H # 27609	25000	25, 22, 12	19.7	3	0.9	6.8	-0.63	NS
PIP IMGHC-TX-H # 27609	50000	24, 21, 15	20.0	3	0.9	4.6	-0.44	NS
PIP IMGHC-TX-H # 27609	100000	14, 19, 11	14.7	3	0.7	4.0	-2.22	NS
NaN ₃	2	484, 518, 469	490.3	3	22.9	25.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 211: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		19, 19, 20, 22, 26	21.2	5		2.9		
Untreated (Water) Controls		35, 20, 30, 19, 22	25.2	5	1.2	7.0		
PIP IMGHC-TX-H # 27609	6250	25, 20, 11	18.7	3	0.9	7.1	-0.78	NS
PIP IMGHC-TX-H # 27609	12500	17, 14, 14	15.0	3	0.7	1.7	-1.71	NS
PIP IMGHC-TX-H # 27609	25000	15, 16, 17	16.0	3	0.8	1.0	-1.40	NS
PIP IMGHC-TX-H # 27609	50000	11, 32, 19	20.7	3	1.0	10.6	-0.36	NS
PIP IMGHC-TX-H # 27609	100000	16, 17, 17	16.7	3	0.8	0.6	-1.21	NS
AAN	5	178, 196, 202	192.0	3	9.1	12.5		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 212: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		9, 5, 9, 7, 6	7.2	5		1.8		
Untreated (Water) Controls		6, 5, 7, 4, 9	6.2	5	0.9	1.9		
PIP IMGHC-TX-H # 27609	6250	4, 5, 6	5.0	3	0.7	1.0	-1.44	NS
PIP IMGHC-TX-H # 27609	12500	5, 7, 9	7.0	3	1.0	2.0	-0.13	NS
PIP IMGHC-TX-H # 27609	25000	6, 9, 4	6.3	3	0.9	2.5	-0.60	NS
PIP IMGHC-TX-H # 27609	50000	10, 5, 6	7.0	3	1.0	2.6	-0.17	NS
PIP IMGHC-TX-H # 27609	100000	6, 2, 5	4.3	3	0.6	2.1	-2.09	NS
AAC	50	107, 156, 120	127.7	3	17.7	25.4		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 213: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		20, 21, 10, 15, 15	16.2	5		4.4		
Untreated (Water) Controls		19, 10, 12, 17, 5	12.6	5	0.8	5.6		
PIP IMGHC-TX-H # 27609	6250	10, 21, 19	16.7	3	1.0	5.9	0.10	NS
PIP IMGHC-TX-H # 27609	12500	14, 16, 11	13.7	3	0.8	2.5	-0.73	NS
PIP IMGHC-TX-H # 27609	25000	22, 12, 12	15.3	3	0.9	5.8	-0.29	NS
PIP IMGHC-TX-H # 27609	50000	7, 9, 9	8.3	3	0.5	1.2	-2.66	NS
PIP IMGHC-TX-H # 27609	100000	10, 4, 9	7.7	3	0.5	3.2	-3.05	NS
AAN	5	151, 121, 110	127.3	3	7.9	21.2		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 214: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		267, 302, 283, 316 M B, 297	293.0	5		18.7		
Untreated (Water) Controls		299, 308, 294, 302, 293	299.2	5	1.0	6.1		
PIP IMGHC-TX-H # 27609	6250	256, 279, 278	271.0	3	0.9	13.0	-1.87	NS
PIP IMGHC-TX-H # 27609	12500	247, 272, 259	259.3	3	0.9	12.5	-2.90	NS
PIP IMGHC-TX-H # 27609	25000	278, 252, 272	267.3	3	0.9	13.6	-2.20	NS
PIP IMGHC-TX-H # 27609	50000	262, 256, 289	269.0	3	0.9	17.6	-2.06	NS
PIP IMGHC-TX-H # 27609	100000	241, 268, 265	258.0	3	0.9	14.8	-3.03	NS
MMC	0.2	815, 804, 805	808.0	3	2.8	6.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 215: PIP silicone gel breast implant IMGHC-TX-H, batch 27609 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		268, 244, 272, 253, 248	257.0	5		12.4		
Untreated (Water) Controls		265, 246, 280, 217, 241	249.8	5	1.0	24.0		
PIP IMGHC-TX-H # 27609	6250	208, 270, 168	215.3	3	0.8	51.4	-2.42	NS
PIP IMGHC-TX-H # 27609	12500	192, 206, 223	207.0	3	0.8	15.5	-2.80	NS
PIP IMGHC-TX-H # 27609	25000	171, 181, 182	178.0	3	0.7	6.1	-4.57	NS
PIP IMGHC-TX-H # 27609	50000	201, 194, 227	207.3	3	0.8	17.4	-2.79	NS
PIP IMGHC-TX-H # 27609	100000	249, 234, 207	230.0	3	0.9	21.3	-1.49	NS
AAN	20	1167, 1182, 1169	1172.7	3	4.6	8.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 216: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		18, 20, 16, 21, 23	19.6	5		2.7		
Untreated (Water) Controls		26, 13, 20, 16, 14	17.8	5	0.9	5.3		
PIP IMGHC-TX-H # 41609	6250	29, 28, 19	25.3	3	1.3	5.5	2.04	NS
PIP IMGHC-TX-H # 41609	12500	13, 15, 19	15.7	3	0.8	3.1	-1.63	NS
PIP IMGHC-TX-H # 41609	25000	21, 23, 25	23.0	3	1.2	2.0	1.29	NS
PIP IMGHC-TX-H # 41609	50000	26, 21, 16	21.0	3	1.1	5.0	0.49	NS
PIP IMGHC-TX-H # 41609	100000	18, 23, 18	19.7	3	1.0	2.9	0.03	NS
2NF	5	1554, 1164, 1042	1253.3	3	63.9	267.4		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 217: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA98 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		25, 23, 25, 28, 26	25.4	5		1.8		
Untreated (Water) Controls		16, 33, 18, 23, 24	22.8	5	0.9	6.6		
PIP IMGHC-TX-H # 41609	6250	34, 31, 33	32.7	3	1.3	1.5	1.65	NS
PIP IMGHC-TX-H # 41609	12500	28, 40, 36	34.7	3	1.4	6.1	2.04	NS
PIP IMGHC-TX-H # 41609	25000	36, 40, 26	34.0	3	1.3	7.2	1.88	NS
PIP IMGHC-TX-H # 41609	50000	31, 25, 51	35.7	3	1.4	13.6	2.11	NS
PIP IMGHC-TX-H # 41609	100000	44, 33, 36	37.7	3	1.5	5.7	2.66	*
B[a]P	10	535, 548, 545	542.7	3	21.4	6.8		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 218: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		115, 115, 107, 90, 109	107.2	5		10.3		
Untreated (Water) Controls		109, 109, 110, 113, 104	109.0	5	1.0	3.2		
PIP IMGHC-TX-H # 41609	6250	112, 112, 99	107.7	3	1.0	7.5	0.08	NS
PIP IMGHC-TX-H # 41609	12500	125, 122, 110	119.0	3	1.1	7.9	1.59	NS
PIP IMGHC-TX-H # 41609	25000	125, 110, 99	111.3	3	1.0	13.1	0.56	NS
PIP IMGHC-TX-H # 41609	50000	115, 101, 112	109.3	3	1.0	7.4	0.31	NS
PIP IMGHC-TX-H # 41609	100000	99, 101, 81	93.7	3	0.9	11.0	-1.92	NS
NaN ₃	2	922, 752, 841	838.3	3	7.8	85.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 219: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		118, 89, 101, 76, 110	98.8	5		16.7		
Untreated (Water) Controls		95, 109, 120, 142, 117	116.6	5	1.2	17.2		
PIP IMGHC-TX-H # 41609	6250	112, 112, 157	127.0	3	1.3	26.0	1.67	NS
PIP IMGHC-TX-H # 41609	12500	85, 94, 105	94.7	3	1.0	10.0	-0.24	NS
PIP IMGHC-TX-H # 41609	25000	109, 85, 124	106.0	3	1.1	19.7	0.45	NS
PIP IMGHC-TX-H # 41609	50000	118, 84, 153	118.3	3	1.2	34.5	1.12	NS
PIP IMGHC-TX-H # 41609	100000	90, 103, 144	112.3	3	1.1	28.2	0.80	NS
AAN	5	1204, 662, 915	927.0	3	9.4	271.2		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 220: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		15, 20, 21, 24, 15	19.0	5		3.9		
Untreated (Water) Controls		8, 14, 20, 19, 21	16.4	5	0.9	5.4		
PIP IMGHC-TX-H # 41609	6250	20, 9, 15	14.7	3	0.8	5.5	-1.45	NS
PIP IMGHC-TX-H # 41609	12500	16, 15, 23	18.0	3	0.9	4.4	-0.30	NS
PIP IMGHC-TX-H # 41609	25000	13, 24, 16	17.7	3	0.9	5.7	-0.45	NS
PIP IMGHC-TX-H # 41609	50000	16, 18, 15	16.3	3	0.9	1.5	-0.78	NS
PIP IMGHC-TX-H # 41609	100000	15, 20, 24	19.7	3	1.0	4.5	0.19	NS
NaN ₃	2	739, 616, 653	669.3	3	35.2	63.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 221: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		19, 19, 10, 29, 26	20.6	5		7.4		
Untreated (Water) Controls		16, 15, 21, 28, 11	18.2	5	0.9	6.5		
PIP IMGHC-TX-H # 41609	6250	21, 23, 28	24.0	3	1.2	3.6	0.65	NS
PIP IMGHC-TX-H # 41609	12500	26, 13, 24	21.0	3	1.0	7.0	0.10	NS
PIP IMGHC-TX-H # 41609	25000	24, 8, 24	18.7	3	0.9	9.2	-0.41	NS
PIP IMGHC-TX-H # 41609	50000	31, 23, 11	21.7	3	1.1	10.1	0.14	NS
PIP IMGHC-TX-H # 41609	100000	15, 26, 25	22.0	3	1.1	6.1	0.29	NS
AAN	5	204, 261, 229	231.3	3	11.2	28.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 222: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		5, 6, 15, 11, 5	8.4	5		4.4		
Untreated (Water) Controls		8, 6, 14, 4, 3	7.0	5	0.8	4.4		
PIP IMGHC-TX-H # 41609	6250	5, 8, 5	6.0	3	0.7	1.7	-0.89	NS
PIP IMGHC-TX-H # 41609	12500	4, 4, 9	5.7	3	0.7	2.9	-1.12	NS
PIP IMGHC-TX-H # 41609	25000	6, 6, 5	5.7	3	0.7	0.6	-1.02	NS
PIP IMGHC-TX-H # 41609	50000	8, 3, 1	4.0	3	0.5	3.6	-2.22	NS
PIP IMGHC-TX-H # 41609	100000	6, 5, 8	6.3	3	0.8	1.5	-0.73	NS
AAC	50	150, 187, 132	156.3	3	18.6	28.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 223: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		19, 15, 18, 11, 18	16.2	5		3.3		
Untreated (Water) Controls		4, 15, 8, 5, 6	7.6	5	0.5	4.4		
PIP IMGHC-TX-H # 41609	6250	10, 8, 13	10.3	3	0.6	2.5	-1.87	NS
PIP IMGHC-TX-H # 41609	12500	13, 6, 6	8.3	3	0.5	4.0	-2.71	NS
PIP IMGHC-TX-H # 41609	25000	14, 14, 20	16.0	3	1.0	3.5	-0.05	NS
PIP IMGHC-TX-H # 41609	50000	20, 6, 11	12.3	3	0.8	7.1	-1.37	NS
PIP IMGHC-TX-H # 41609	100000	5, 5, 10	6.7	3	0.4	2.9	-3.38	NS
AAN	5	167, 130, 125	140.7	3	8.7	22.9		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 224: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		312, 268, 302, 251, 263	279.2	5		26.4		
Untreated (Water) Controls		205, 160, 219, 214, 244	208.4	5	0.7	30.7		
PIP IMGHC-TX-H # 41609	6250	321, 256, 322	299.7	3	1.1	37.8	1.06	NS
PIP IMGHC-TX-H # 41609	12500	232, 266, 281	259.7	3	0.9	25.1	-1.06	NS
PIP IMGHC-TX-H # 41609	25000	289, 316, 294	299.7	3	1.1	14.4	1.09	NS
PIP IMGHC-TX-H # 41609	50000	299, 286, 293	292.7	3	1.0	6.5	0.73	NS
PIP IMGHC-TX-H # 41609	100000	320, 289, 258	289.0	3	1.0	31.0	0.52	NS
MMC	0.2	764, 655, 704	707.7	3	2.5	54.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 225: PIP silicone gel breast implant IMGHC-TX-H, batch 41609 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		262, 170, 226, 214, 150	204.4	5		44.8		
Untreated (Water) Controls		226, 218, 224, 214, 194	215.2	5	1.1	12.8		
PIP IMGHC-TX-H # 41609	6250	238, 143, 118	166.3	3	0.8	63.3	-1.46	NS
PIP IMGHC-TX-H # 41609	12500	122, 147, 182	150.3	3	0.7	30.1	-1.99	NS
PIP IMGHC-TX-H # 41609	25000	189, 193, 217	199.7	3	1.0	15.1	-0.10	NS
PIP IMGHC-TX-H # 41609	50000	178, 223, 187	196.0	3	1.0	23.8	-0.24	NS
PIP IMGHC-TX-H # 41609	100000	217, 236, 210	221.0	3	1.1	13.5	0.63	NS
AAN	20	694, 739, 1021	818.0	3	4.0	177.2		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 226: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		17, 20, 27, 15, 20	19.8	5		4.5		
Untreated (Water) Controls		19, 26, 21, 27, 16	21.8	5	1.1	4.7		
PIP IMGHC-TX-S, #37908	6250	24, 19, 24	22.3	3	1.1	2.9	0.73	NS
PIP IMGHC-TX-S, #37908	12500	14, 27, 21	20.7	3	1.0	6.5	0.20	NS
PIP IMGHC-TX-S, #37908	25000	17, 15, 24	18.7	3	0.9	4.7	-0.32	NS
PIP IMGHC-TX-S, #37908	50000	20, 24, 14	19.3	3	1.0	5.0	-0.14	NS
PIP IMGHC-TX-S, #37908	100000	20, 12, 20	17.3	3	0.9	4.6	-0.73	NS
2NF	5	561, 577, 570	569.3	3	28.8	8.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 227: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA98 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		24, 20, 27, 41, 39	30.2	5		9.3		
Untreated (Water) Controls		29, 29, 22, 25, 17	24.4	5	0.8	5.1		
PIP IMGHC-TX-S, #37908	6250	32, 20, 37	29.7	3	1.0	8.7	-0.08	NS
PIP IMGHC-TX-S, #37908	12500	27, 20, 22	23.0	3	0.8	3.6	-1.27	NS
PIP IMGHC-TX-S, #37908	25000	26, 40, 26	30.7	3	1.0	8.1	0.12	NS
PIP IMGHC-TX-S, #37908	50000	26, 35, 29	30.0	3	1.0	4.6	0.05	NS
PIP IMGHC-TX-S, #37908	100000	37, 22, 34	31.0	3	1.0	7.9	0.18	NS
B[a]P	10	391, 401, 511	434.3	3	14.4	66.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 228: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		108, 91, 113, 97, 101	102.0	5		8.7		
Untreated (Water) Controls		100, 100, 105, 122, 105	106.4	5	1.0	9.1		
PIP IMGHC-TX-S, #37908	6250	100, 102, 91	97.7	3	1.0	5.9	-0.64	NS
PIP IMGHC-TX-S, #37908	12500	90, 102, 103	98.3	3	1.0	7.2	-0.54	NS
PIP IMGHC-TX-S, #37908	25000	98, 106, 111	105.0	3	1.0	6.6	0.45	NS
PIP IMGHC-TX-S, #37908	50000	118, 100, 88	102.0	3	1.0	15.1	-0.03	NS
PIP IMGHC-TX-S, #37908	100000	126, 110, 128	121.3	3	1.2	9.9	2.75	*
NaN ₃	2	561, 546, 571	559.3	3	5.5	12.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 229: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		130, 143, 140, 102, 123	127.6	5		16.4		
Untreated (Water) Controls		116, 142, 133, 140, 115	129.2	5	1.0	12.9		
PIP IMGHC-TX-S, #37908	6250	93, 113, 95	100.3	3	0.8	11.0	-2.67	NS
PIP IMGHC-TX-S, #37908	12500	113, 122, 122	119.0	3	0.9	5.2	-0.78	NS
PIP IMGHC-TX-S, #37908	25000	126, 116, 125	122.3	3	1.0	5.5	-0.46	NS
PIP IMGHC-TX-S, #37908	50000	122, 108, 115	115.0	3	0.9	7.0	-1.17	NS
PIP IMGHC-TX-S, #37908	100000	137, 113, 88	112.7	3	0.9	24.5	-1.48	NS
AAN	5	587, 739, 636	654.0	3	5.1	77.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 230: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		16, 20, 24, 25, 22	21.4	5		3.6		
Untreated (Water) Controls		20, 21, 24, 14, 27	21.2	5	1.0	4.9		
PIP IMGHC-TX-S, #37908	6250	20, 16, 24	20.0	3	0.9	4.0	-0.37	NS
PIP IMGHC-TX-S, #37908	12500	12, 16, 10	12.7	3	0.6	3.1	-2.55	NS
PIP IMGHC-TX-S, #37908	25000	11, 16, 24	17.0	3	0.8	6.6	-1.29	NS
PIP IMGHC-TX-S, #37908	50000	9, 20, 22	17.0	3	0.8	7.0	-1.33	NS
PIP IMGHC-TX-S, #37908	100000	20, 26, 26	24.0	3	1.1	3.5	0.66	NS
NaN ₃	2	484, 518, 469	490.3	3	22.9	25.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 231: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		19, 19, 20, 22, 26	21.2	5		2.9		
Untreated (Water) Controls		35, 20, 30, 19, 22	25.2	5	1.2	7.0		
PIP IMGHC-TX-S, #37908	6250	27, 27, 11	21.7	3	1.0	9.2	-0.05	NS
PIP IMGHC-TX-S, #37908	12500	29, 20, 14	21.0	3	1.0	7.5	-0.11	NS
PIP IMGHC-TX-S, #37908	25000	26, 26, 20	24.0	3	1.1	3.5	0.53	NS
PIP IMGHC-TX-S, #37908	50000	10, 17, 30	19.0	3	0.9	10.1	-0.62	NS
PIP IMGHC-TX-S, #37908	100000	17, 30, 25	24.0	3	1.1	6.6	0.49	NS
AAN	5	178, 196, 202	192.0	3	9.1	12.5		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 232: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		9, 5, 9, 7, 6	7.2	5		1.8		
Untreated (Water) Controls		6, 5, 7, 4, 9	6.2	5	0.9	1.9		
PIP IMGHC-TX-S, #37908	6250	2, 10, 4	5.3	3	0.7	4.2	-1.15	NS
PIP IMGHC-TX-S, #37908	12500	7, 9, 4	6.7	3	0.9	2.5	-0.29	NS
PIP IMGHC-TX-S, #37908	25000	1, 7, 5	4.3	3	0.6	3.1	-1.71	NS
PIP IMGHC-TX-S, #37908	50000	9, 6, 11	8.7	3	1.2	2.5	0.62	NS
PIP IMGHC-TX-S, #37908	100000	12, 10, 10	10.7	3	1.5	1.2	1.45	NS
AAC	50	107, 156, 120	127.7	3	17.7	25.4		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 233: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		20, 21, 10, 15, 15	16.2	5		4.4		
Untreated (Water) Controls		19, 10, 12, 17, 5	12.6	5	0.8	5.6		
PIP IMGHC-TX-S, #37908	6250	6, 6, 16	9.3	3	0.6	5.8	-2.48	NS
PIP IMGHC-TX-S, #37908	12500	11, 4, 9	8.0	3	0.5	3.6	-2.94	NS
PIP IMGHC-TX-S, #37908	25000	4, 4, 7	5.0	3	0.3	1.7	-4.29	NS
PIP IMGHC-TX-S, #37908	50000	12, 9, 14	11.7	3	0.7	2.5	-1.42	NS
PIP IMGHC-TX-S, #37908	100000	10, 9, 12	10.3	3	0.6	1.5	-1.89	NS
AAN	5	151, 121, 110	127.3	3	7.9	21.2		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 234: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		267, 302, 283, 316 M B, 297	293.0	5		18.7		
Untreated (Water) Controls		299, 308, 294, 302, 293	299.2	5	1.0	6.1		
PIP IMGHC-TX-S, #37908	6250	233, 269, 272	258.0	3	0.9	21.7	-2.71	NS
PIP IMGHC-TX-S, #37908	12500	263, 275, 242	260.0	3	0.9	16.7	-2.54	NS
PIP IMGHC-TX-S, #37908	25000	305, 295, 269	289.7	3	1.0	18.6	-0.25	NS
PIP IMGHC-TX-S, #37908	50000	287, 253, 259	266.3	3	0.9	18.1	-2.04	NS
PIP IMGHC-TX-S, #37908	100000	258, 258, 270	262.0	3	0.9	6.9	-2.37	NS
MMC	0.2	815, 804, 805	808.0	3	2.8	6.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 235: PIP silicone gel breast implant IMGHC-TX-S, batch 37908 Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		268, 244, 272, 253, 248	257.0	5		12.4		
Untreated (Water) Controls		265, 246, 280, 217, 241	249.8	5	1.0	24.0		
PIP IMGHC-TX-S, #37908	6250	167, 216, 238	207.0	3	0.8	36.3	-2.62	NS
PIP IMGHC-TX-S, #37908	12500	243, 244, 242	243.0	3	0.9	1.0	-0.69	NS
PIP IMGHC-TX-S, #37908	25000	265, 259, 263	262.3	3	1.0	3.1	0.26	NS
PIP IMGHC-TX-S, #37908	50000	267, 238, 253	252.7	3	1.0	14.5	-0.21	NS
PIP IMGHC-TX-S, #37908	100000	206, 277, 172	218.3	3	0.8	53.6	-2.07	NS
AAN	20	1167, 1182, 1169	1172.7	3	4.6	8.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 236: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA98 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		17, 20, 27, 15, 20	19.8	5		4.5		
Untreated (Water) Controls		19, 26, 21, 27, 16	21.8	5	1.1	4.7		
[REDACTED]	6250	17, 17, 19	17.7	3	0.9	1.2	-0.74	NS
[REDACTED]	12500	27, 17, 16	20.0	3	1.0	6.1	0.04	NS
[REDACTED]	25000	17, 20, 20	19.0	3	1.0	1.7	-0.24	NS
[REDACTED]	50000	15, 19, 12	15.3	3	0.8	3.5	-1.74	NS
[REDACTED]	100000	15, 15, 17	15.7	3	0.8	1.2	-1.55	NS
2NF	5	561, 577, 570	569.3	3	28.8	8.0		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 237: ██████████ control silicone gel breast implant ██████████ Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA98 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		24, 20, 27, 41, 39	30.2	5		9.3		
Untreated (Water) Controls		29, 29, 22, 25, 17	24.4	5	0.8	5.1		
██████████	6250	30, 36, 35	33.7	3	1.1	3.2	0.81	NS
██████████	12500	27, 37, 47	37.0	3	1.2	10.0	1.37	NS
██████████	25000	25, 24, 31	26.7	3	0.9	3.8	-0.66	NS
██████████	50000	36, 42, 35	37.7	3	1.2	3.8	1.57	NS
██████████	100000	30, 24, 25	26.3	3	0.9	3.2	-0.73	NS
B[a]P	10	391, 401, 511	434.3	3	14.4	66.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 238: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA100 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		108, 91, 113, 97, 101	102.0	5		8.7		
Untreated (Water) Controls		100, 100, 105, 122, 105	106.4	5	1.0	9.1		
[REDACTED]	6250	112, 108, 112	110.7	3	1.1	2.3	1.63	NS
[REDACTED]	12500	111, 88, 103	100.7	3	1.0	11.7	-0.27	NS
[REDACTED]	25000	96, 111, 103	103.3	3	1.0	7.5	0.26	NS
[REDACTED]	50000	112, 113, 115	113.3	3	1.1	1.5	2.11	NS
[REDACTED]	100000	96, 98, 103	99.0	3	1.0	3.6	-0.55	NS
NaN ₃	2	561, 546, 571	559.3	3	5.5	12.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 239: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data -
Experiment 2 – Water extract, TA100 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		130, 143, 140, 102, 123	127.6	5		16.4		
Untreated (Water) Controls		116, 142, 133, 140, 115	129.2	5	1.0	12.9		
[REDACTED]	6250	106, 118, 135	119.7	3	0.9	14.6	-0.77	NS
[REDACTED]	12500	116, 121, 121	119.3	3	0.9	2.9	-0.78	NS
[REDACTED]	25000	128, 122, 113	121.0	3	0.9	7.5	-0.62	NS
[REDACTED]	50000	131, 125, 128	128.0	3	1.0	3.0	0.08	NS
[REDACTED]	100000	126, 108, 85	106.3	3	0.8	20.6	-2.19	NS
AAN	5	587, 739, 636	654.0	3	5.1	77.6		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 240: ██████████ control silicone gel breast implant ██████████ Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1535 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		16, 20, 24, 25, 22	21.4	5		3.6		
Untreated (Water) Controls		20, 21, 24, 14, 27	21.2	5	1.0	4.9		
██████████	6250	26, 10, 14	16.7	3	0.8	8.3	-1.26	NS
██████████	12500	16, 26, 35	25.7	3	1.2	9.5	0.81	NS
██████████	25000	24, 15, 16	18.3	3	0.9	4.9	-0.73	NS
██████████	50000	24, 27, 19	23.3	3	1.1	4.0	0.42	NS
██████████	100000	21, 20, 12	17.7	3	0.8	4.9	-0.90	NS
NaN ₃	2	484, 518, 469	490.3	3	22.9	25.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 241: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1535 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		19, 19, 20, 22, 26	21.2	5		2.9		
Untreated (Water) Controls		35, 20, 30, 19, 22	25.2	5	1.2	7.0		
[REDACTED]	6250	16, 17, 11	14.7	3	0.7	3.2	-2.74	NS
[REDACTED]	12500	20, 17, 10	15.7	3	0.7	5.1	-2.37	NS
[REDACTED]	25000	14, 19, 14	15.7	3	0.7	2.9	-2.27	NS
[REDACTED]	50000	17, 17, 19	17.7	3	0.8	1.2	-1.38	NS
[REDACTED]	100000	12, 15, 16	14.3	3	0.7	2.1	-2.86	NS
AAN	5	178, 196, 202	192.0	3	9.1	12.5		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 242: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1537 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		9, 5, 9, 7, 6	7.2	5		1.8		
Untreated (Water) Controls		6, 5, 7, 4, 9	6.2	5	0.9	1.9		
[REDACTED]	6250	6, 6, 11	7.7	3	1.1	2.9	0.13	NS
[REDACTED]	12500	2, 9, 2	4.3	3	0.6	4.0	-1.30	NS
[REDACTED]	25000	5, 14, 6	8.3	3	1.2	4.9	0.26	NS
[REDACTED]	50000	4, 7, 12	7.7	3	1.1	4.0	0.07	NS
[REDACTED]	100000	1, 6, 12	6.3	3	0.9	5.5	-0.65	NS
AAC	50	107, 156, 120	127.7	3	17.7	25.4		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 243: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA1537 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		20, 21, 10, 15, 15	16.2	5		4.4		
Untreated (Water) Controls		19, 10, 12, 17, 5	12.6	5	0.8	5.6		
[REDACTED]	6250	14, 7, 10	10.3	3	0.6	3.5	-2.42	NS
[REDACTED]	12500	15, 9, 10	11.3	3	0.7	3.2	-1.94	NS
[REDACTED]	25000	9, 5, 10	8.0	3	0.5	2.6	-3.57	NS
[REDACTED]	50000	11, 12, 12	11.7	3	0.7	0.6	-1.73	NS
[REDACTED]	100000	14, 11, 12	12.3	3	0.8	1.5	-1.45	NS
AAN	5	151, 121, 110	127.3	3	7.9	21.2		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 244: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA102 -S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		267, 302, 283, 316 M B, 297	293.0	5		18.7		
Untreated (Water) Controls		299, 308, 294, 302, 293	299.2	5	1.0	6.1		
[REDACTED]	6250	289, 325, 275	296.3	3	1.0	25.8	0.27	NS
[REDACTED]	12500	248, 265, 237	250.0	3	0.9	14.1	-3.76	NS
[REDACTED]	25000	277, 268, 260	268.3	3	0.9	8.5	-2.11	NS
[REDACTED]	50000	264, 248, 246	252.7	3	0.9	9.9	-3.51	NS
[REDACTED]	100000	263, 268, 279	270.0	3	0.9	8.2	-1.96	NS
MMC	0.2	815, 804, 805	808.0	3	2.8	6.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Table 245: [REDACTED] control silicone gel breast implant [REDACTED] Raw plate counts and calculated mutagenicity data - Experiment 2 – Water extract, TA102 +S-9

Compound	Concentration (µg/plate)	Revertant numbers/plate	Mean	N	Fold Increase	Standard Deviation	Dunnett's t-value	Significance
Blank Water Extract		268, 244, 272, 253, 248	257.0	5		12.4		
Untreated (Water) Controls		265, 246, 280, 217, 241	249.8	5	1.0	24.0		
[REDACTED]	6250	152, 186, 248	195.3	3	0.8	48.7	-3.57	NS
[REDACTED]	12500	221, 221, 228	223.3	3	0.9	4.0	-1.82	NS
[REDACTED]	25000	217, 234, 234	228.3	3	0.9	9.8	-1.55	NS
[REDACTED]	50000	249, 204, 212	221.7	3	0.9	24.0	-1.94	NS
[REDACTED]	100000	233, 206, 188	209.0	3	0.8	22.6	-2.67	NS
AAN	20	1167, 1182, 1169	1172.7	3	4.6	8.1		

For key to abbreviations, postfixes and significance values refer to [Appendix 5](#)

Appendix 5
Key to abbreviations, postfixes and significance values

Dunnett's t-test significance values

NS	Not significant
*	$p \leq 0.05$
**	$p \leq 0.01$

Positive controls

2NF	2-Nitrofluorene
NaN ₃	Sodium azide
AAC	9-Aminoacridine
MMC	Mitomycin C
B[a]P	Benzo[a]pyrene
AAN	2-Aminoanthracene

Table Postfixes

B	Bubbles or split in agar
M	Plate counted manually

Appendix 6
Historical negative (vehicle) control values for *S. typhimurium* strains

Table 246: Historical negative (vehicle) control values for *S. typhimurium* strains

Strain	S-9	No. of studies	Revertant numbers for individual plates			99% confidence interval for group mean of:		
			No. of plates	Mean	99% reference range ⁽¹⁾	4 values ⁽²⁾	5 values ⁽²⁾	6 values ⁽²⁾
TA98	-	51	525	25	9.0-44.0	16.0-34.3	16.8-33.1	17.4-32.3
TA98	+	51	538	35	16.0-58.0	25.0-46.6	26.0-45.3	26.7-44.4
TA100	-	51	600	111	73.0-156.5	88.7-133.5	90.8-130.9	92.4-129.0
TA100	+	51	604	117	71.0-168.0	91.8-144.3	94.3-141.2	96.2-139.0
TA1535	-	50	520	17	5.0-30.0	10.8-24.8	11.4-23.9	11.8-23.3
TA1535	+	50	525	17	6.0-32.0	10.8-24.5	11.4-23.6	11.8-23.0
TA1537	-	51	530	13	3.0-30.0	6.3-20.1	6.9-19.2	7.3-18.5
TA1537	+	51	523	18	4.0-30.0	10.4-25.6	11.0-24.6	11.5-23.9
TA102	-	50	520	270	184.0-350.0	227.7-313.3	231.9-308.5	235.0-304.9
TA102	+	50	528	233	153.0-328.0	191.5-275.2	195.6-270.4	198.6-266.9

⁽¹⁾ Reference ranges are calculated from percentiles of the observed distributions.

⁽²⁾ Calculated from square-root transformed data.

Ranges calculated in January 2011 by CLEH Statistics, using data selected without bias from studies[#] started during the periods given below:

S. typhimurium strains

Feb 08 to Jul 09

All studies had been audited prior to data collection.

Appendix 8
Quality control statements for S-9

MOLTOX POST MITOCHONDRIAL SUPERNATANT (S-9)
QUALITY CONTROL & PRODUCTION CERTIFICATE

LOT NO.: 2920	SPECIES: Rat	PREPARATION DATE: April 04, 2012
PART NO.: 11-101	STRAIN: Sprague Dawley	EXPIRATION DATE: April 04, 2014
VOLUME: 5mL	SEX: Male	BUFFER: 0.154 M KCl
	TISSUE: Liver	INDUCING AGENT(s): Aroclor 1254 (Monsanto KL615), 500 mg/kg i.p.
REFERENCE: Maron, D & Ames, B, <i>Mutat Res</i> 113:173, 1983		
STORAGE: At or below -70°C		

For Research Purposes Only

BIOCHEMISTRY:

- PROTEIN

35.8 mg/ml

Assayed according to the method of Lowry et al., *JBC* 193:265, 1951 using bovine serum albumin as the standard.

- ALKOXYRESORUFIN-0-DEALKYLASE ACTIVITIES

		Fold -
Activity	P450	Induction
EROD	1A1, 1A2	136.0
PROD	2B1, 2B2	38.8
BROD	2B1, 2B2	57.5
MROD	1A1, 1A2	59.5

Assays for ethoxyresorufin-0-deethylase (EROD), pentoxy-, benzyl- and methoxyresorufin-0-dealkylases (PROD, BROD, & MROD) were conducted using a modification of the methods of Burke, et al., *Biochem Pharm* 34:3337, 1985. Fold-inductions were calculated as the ratio of the sample vs. uninduced specific activities (SA's). Control SA's (pmoles/min/mg protein) were 72.8, 23.7, 95.7, & 44.2 for EROD, PROD, BROD and MROD, respectively.

BIOASSAY:

- TEST FOR THE PRESENCE OF ADVENTITIOUS AGENTS

Samples of S-9 were assayed for the presence of contaminating microflora by plating 1.0 ml volumes on Nutrient Agar and Minimal Glucose (Vogel-Bonner E, supplemented with 0.05 mM L-histidine and D-biotin) media. Triplicate plates were read after 40 - 48 h incubation at 35 ± 2°C. The tested samples met acceptance criteria.

- PROMUTAGEN ACTIVATION

No. His+ Revertants	
TA98	TA1535
184.4	1098

The ability of the sample to activate ethidium (EtBr) EtBr/CPA/and cyclophosphamide (CPA) to intermediates mutagenic to TA98 and TA1535, respectively, was determined according to Lesca, et al., *Mutation Res* 129:299, 1984. Data were expressed as revertants per µg EtBr or per mg CPA.

Dilutions of the sample S9, ranging from 0.2 - 10% in S9 mix, were tested for their ability to activate benzo(a)pyrene (BP) and 2-aminoanthracene (2-AA) to intermediates mutagenic to TA100. Assays were conducted as described by Maron & Ames, (*Mutat Res* 113:173, 1983).

µl S9 per plate/number his⁺ revertants per plate

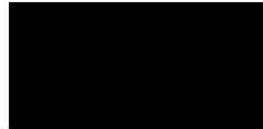
Promutagen	0	1	5	10	20	50
BP (5 µg)	114	223	391	506	745	1039
2-AA (2.5 µg)	139	378	1454	1973	2019	1592

MOLECULAR TOXICOLOGY, INC.
157 Industrial Park Dr.
Boone, NC 28607
(828) 264-9099
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Approved:



04/09/12



04/09/12

**MOLTOX POST MITOCHONDRIAL SUPERNATANT (S-9)
QUALITY CONTROL & PRODUCTION CERTIFICATE**

LOT NO.: 2921 SPECIES: Rat PREPARATION DATE: April 05, 2012
PART NO.: 11-101 STRAIN: Sprague Dawley EXPIRATION DATE: April 05, 2014
VOLUME: 5mL SEX: Male BUFFER: 0.154 M KCl
TISSUE: Liver INDUCING AGENT(s): Aroclor 1254
(Monsanto KL615), 500 mg/kg i.p.

REFERENCE: Maron, D & Ames, B, Mutat Res 113:173, 1983
STORAGE: At or below -70°C

For Research Purposes Only

BIOCHEMISTRY:

- PROTEIN

38.4 mg/ml

Assayed according to the method of Lowry et al., *JBC* 193:265, 1951 using bovine serum albumin as the standard.

- ALKOXYRESORUFIN-0-DEALKYLASE ACTIVITIES

Activity	P450	Fold - Induction
EROD	1A1, 1A2	115.5
PROD	2B1, 2B2	32.4
BROD	2B1, 2B2	54.9
MROD	1A1, 1A2	55.3

Assays for ethoxyresorufin-0-deethylase (EROD), pentoxy-, benzyl- and methoxyresorufin-0-dealkylases (PROD, BROD, & MROD) were conducted using a modification of the methods of Burke, et al., *Biochem Pharm* 34:3337, 1985. Fold-inductions were calculated as the ratio of the sample vs. uninduced specific activities (SA's). Control SA's (pmoles/min/mg protein) were 72.8, 23.7, 95.7, & 44.2 for EROD, PROD, BROD and MROD, respectively.

BIOASSAY:

- TEST FOR THE PRESENCE OF ADVENTITIOUS AGENTS

Samples of S-9 were assayed for the presence of contaminating microflora by plating 1.0 ml volumes on Nutrient Agar and Minimal Glucose (Vogel-Bonner E, supplemented with 0.05 mM L-histidine and D-biotin) media. Triplicate plates were read after 40 - 48 h incubation at 35 ± 2°C. The tested samples met acceptance criteria.

- PROMUTAGEN ACTIVATION

No. His+ Revertants
TA98 TA1535
168.8 1154

The ability of the sample to activate ethidium (EtBr) EtBr/CPA and cyclophosphamide (CPA) to intermediates mutagenic to TA98 and TA1535, respectively, was determined according to Lesca, et al., *Mutation Res* 129:299, 1984. Data were expressed as revertants per µg EtBr or per mg CPA.

Dilutions of the sample S9, ranging from 0.2 - 10% in S9 mix, were tested for their ability to activate benzo(a)pyrene (BP) and 2-aminoanthracene (2-AA) to intermediates mutagenic to TA100. Assays were conducted as described by Maron & Ames, (*Mutat Res* 113:173, 1983).

µl S9 per plate/number his⁺ revertants per plate

Promutagen	0	1	5	10	20	50
BP (5 µg)	93	160	231	287	370	523
2-AA (2.5 µg)	110	321	1212	1536	1694	1144

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Boone, NC 28607
(828) 264-9099
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