# POSTPRO3D DELIVERS END-USE PARTS THAT PASS HEALTH & SAFETY REGULATIONS

July, 2020

Any parts 3D printed for medical, cosmetic, food, packaging, or similar industries, must conform with local regulations before being used in final applications. AMT has performed a series of tests to ensure the safety of parts post-processed on our equipment are compliant.

| TEST | RESULTS | DETAILS | NORMATIVE REFERENCE |
|---|---|---|---|
| Food Contact Test | PASS | SLS printed PA-12 parts chemically vapor smoothed with PostPro3D **does not affect the consumer health nor influence the quality of food.** | According to regulation (EC) 10/2011 Annex V, chapter 3, table 3, OM 3, 2 hours at 70 degree C.<br><br>DS/EN1186-01:2002 DS/ EN1186-03:2002 DS/ EN1186-14:2002 |
| Skin Irritation Test | PASS | SLS printed PA-12 parts chemically vapor smoothed with PostPro3D **did not cause a skin irritating effect.** | ISO 10993-10 (2013); ISO 10993-1 (2018); OECD TG 439 |
| Cytotoxicity Test | PASS | MJF printed PA-12 parts chemically vapor smoothed with PostPro3D **did not cause a cytotoxic effect.** | ISO 10993-5 (2009); ISO 10993-1 (2010); ISO 10993-12 (2012) |
| Microbiological Test on MRSA Bacteria | PASS | MJF printed PA-12 parts chemically vapor smoothed with PostPro3D show a **reduction of bacterial growth quantified as 99.88% against MRSA.** | MOD ISO 22196: 2011 |
| Microbiological Test on E. coli Bacteria | PASS | MJF printed PA- 12 parts chemically vapor smoothed with PostPro3D **show a reduction of bacterial growth quantified as 99.78% against E. coli.** | MOD ISO 22196: 2011 |

# FOOD CONTACT TESTING

Ensuring that what we eat is safe does not stop at testing the food itself. Everything that comes in contact with food as it is produced, packaged, transported, stored, prepared, and consumed also needs to be safe. According to Regulation (EC) 1935/2004, under normal or predictable conditions of use, materials may not release substances into foods in quantities which may present a danger to human health cause unacceptable change in food composition, and cause a deterioration in food's organoleptic (odor and test) properties.

Food contact tests were carried out at a nationally recognized European laboratory with the following test methods and conditions:

- DS/EN1186-01:2002, Guide to selection of conditions and test methods for overall migration
- DS/EN1186-03:2002, Test methods for overall migration into aqueous food simulants by total immersion
- DS/EN1186-14:2002, Test methods for 'substitute tests' for overall migration from plastics intended to come into contact with fatty foodstuffs using test media isooctane and 95% ethanol.

The results show that no substances migrate from the PostPro3D vapor smoothed part to the food contact material, and therefore have passed the food contact tests.

TEST RESULTS:

| TEST | REP. A | REP. B | REP. C | AVERAGE | CONCLUSION |
|---|---|---|---|---|---|
| 10% v/v ethanol ($mg/dm^2$) | 2,1 | 2,5 | 2,4 | 2,3 | PASS |
| 3% v/v acetic acid ($mg/dm^2$) | 1,6 | 1,9 | 1,6 | 1,7 | PASS |
| 95% v/v ethanol ($mg/dm^2$) | 4,3 | 5,1 | 4,4 | 4,6 | PASS |
| Isooctane ($mg/dm^2$) | 2,5 | 2,5 | 2,5 | 2,5 | PASS |

*Ratio Surface to Volume: 10 $dm^2/l$*

# SKIN IRRITATION TESTING

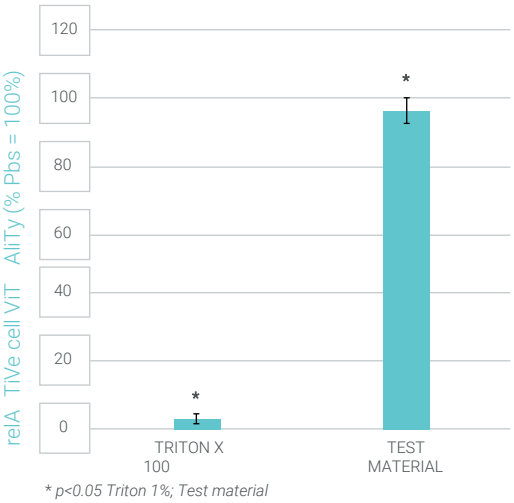
Skin irritation testing is an important biological evaluation and screening test that uses cells in vitro to evaluate the potential skin irritating effect of printed samples that were chemically vapor smoothed with PostPro3D.

Skin Irritation tests were carried out at a nationally recognized European laboratory with Normative References: ISO 10993-10 (2013); ISO 10993-1 (2018); OECD TG 439

The results show that in the presence of Triton X 100 on the skin culture insets, 1.8% of the cell vitality compared to the negative control was reached. The value is within the valid range of 15% cell vitality or less compared to the negative control. Materials are considered as skin irritating if it reduces the cell vitality of the skin samples to less than 50% compared to negative control samples.

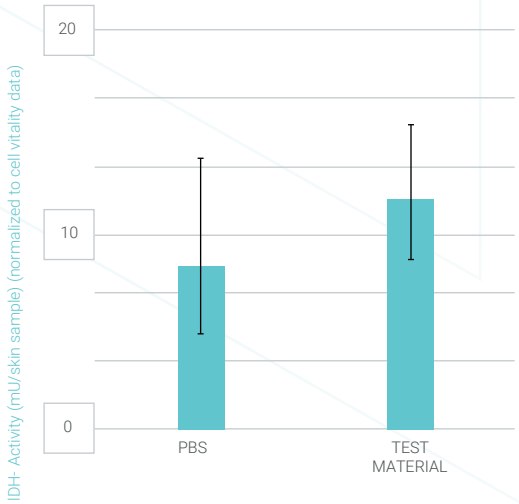
**This was not the case in this experiment. The test material that had been chemically vapor smoothed with PostPro3D did not show a skin irritating effect.**

Measurement of cell vitality (MTT-test) Skin irritation Test: cell vitality after42h incubation




| RESULT DATA (REL. CELL VITALITY) | n=2 PBS data not shown in graphic. | | |
|---|---|---|---|
| | Triton 100 | PBS | Test material |
| Mean | 1,76% | 100% | 95,98% |
| Standarddev. | 0,65% | 13,54% | 4,44% |

IDH-release
Skin irritation Test: LDH-activity after 42h incubation




| LDH-RELEASE (mU/skin sample) | n=2 Triton X 100 data not shown in graphic. | | |
|---|---|---|---|
| | Triton X 100 | PBS | Test material |
| Mean | 2228,48 | 7,92 | 10,68 |
| Standarddev. | 305,14 | 4,56 | 2,12 |

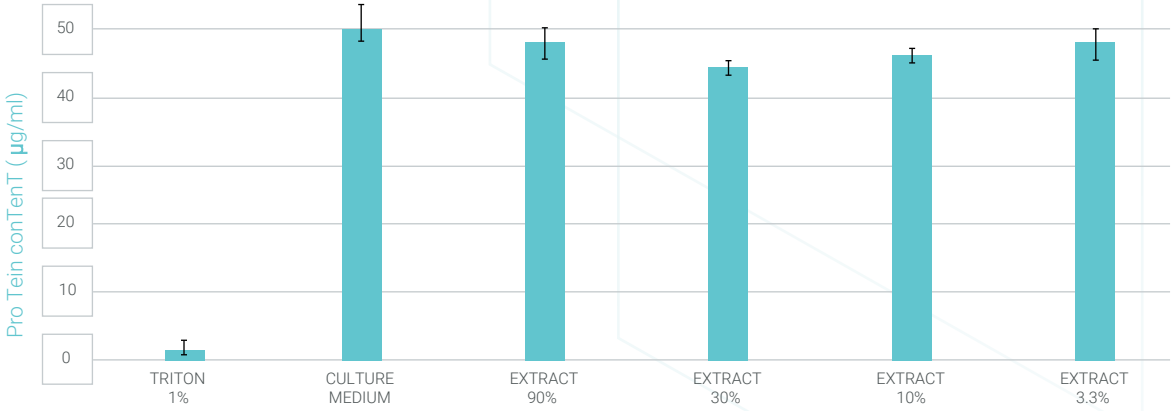
# CYTOTOXICITY TESTING

The cytotoxicity test is another important biological evaluations and screening tests that use tissue cells in vitro to observe the cell growth, reproduction, and morphological effects by medical devices. Cytotoxicity is an important indicator of toxicity evaluation of medical devices as it is simple, fast and has a high sensitivity.

Cytotoxicity tests were carried out at a nationally recognized European laboratory to Normative References: ISO 10993-5 (2009); ISO 10993-1 (2010); ISO 10993-12 (2012).

The results show that in the presence of Triton X 100 in the cell culture medium, 6.0% of the protein content compared to the negative control was reached. This value is within the valid range of 15% protein content or less compared to the negative control. Materials are considered cytotoxic, if the material extract leads to a protein content of the test cells of less than 70% compared to the negative control.

This was not the case in this test. The material extract therefore does not show a cytotoxic effect.




# MICROBIOLOGICAL TESTING

Microbiological tests are designed for: detection, enumeration of indicator organisms, or detection of environmental pathogens used, to obtain quantitative verification of the effectiveness of sanitation procedures. Due to the layered nature 'stair step effect' of 3D printing, the printed articles result in rough, powdery and porous surfaces. This causes the accumulation and growth of bacteria, fungi and increases the risk of the loose polymer particles attacking the respiratory system. AMT's vapor smoothing process with PostPro3D eliminates porosity, loose particles, and surface roughness by redistributing the surface material.

The effect of the smoothing process was evaluated in terms of bacterial activity and a microbiological analysis for the comparison between un-processed and processed Polyamide-12 3D printed parts carried out by an external laboratory using test based on MOD ISO 22196: 2011

Six raw 3D printed PA-12 parts and six post-processed PA-12 parts with PostPro3D were tested microbiologically against Gram-positive and Gram-negative bacteria (MRSA and E. coli respectively).

The analysis has shown that the processed parts have passed the antimicrobial test showing a reduction of bacterial growth quantified as 99.88% against MRSA and 99.78% against E. coli while the un-processed parts have failed the test showing a limited reduction of MRSA and a significant growth of E. coli over time.

**The results prove that PostPro3D effectively reduces the bacterial attachment and growth on the processed surfaces of PA-12 3D printed parts.**

| | | CONTACT TIME* | | REDUCTION AGAINST INITIAL | | |
|---|---|---|---|---|---|---|
| Sample | Test Bacteria | 0 Hrs | 24 Hrs | $Log_{10}$ | % | |
| Unprocessed Polyamide part | MRSA | $8.15 \times 10^4$ | $9.60 \times 10^3$ | 0.93 | 88.23% | FAIL |
| | E. coli | $9.08 \times 10^4$ | $7.71 \times 10^5$ | GROWTH | GROWTH | |
| Postpro3D processed Polyamide part | MRSA | $8.15 \times 10^4$ | ≤100 | ≥2.91 | ≥99.88% | PASS |
| | E. coli | $9.08 \times 10^4$ | $2.00 \times 10^2$ | 2.66 | 99.78% | |

**Numbers represent Colony Forming Units at representative contact times.*

## CONCLUSION

Biocompatibility testing is filled with potential pitfalls in areas such as cytotoxicity, bacteria growth, and irritation. To ensure that AMT's customers can use our technology for medical, food-contact, cosmetics, or whatever the application may be, we have followed strict testing protocols to ensure that parts that have undergone chemical vapor smoothing in PostPro3D are safe and compliant in accordance with the regulations noted above.

## CONTACT INFORMATION

For further information please contact AMT:

info@amtechnologies.com

EU: +44 114 3122 3344

US: +1 512 352 9393