To: Valued Customer

Re: Biocompatibility Testing Results – ProPell™ Standard, ProPell™ T, and ProPell™ Plus Low Friction Compounds

CLASS VI TEST – USP:

The biocompatibility of the ingredients used to formulate Foster's ProPell™ Standard, ProPell™ T, and ProPell™ Plus Low Friction Compounds was tested in representative polyamide (25D) and TPU (80A) compounds by a third-party testing service, LabCorp.

REFERENCES: Testing was based upon:

- USP-NF 2024. <88> Biological Reactivity Tests, In Vivo.
- ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and Calibration Laboratories.

GLP COMPLIANCE: The studies conformed to the current FDA 21 CFR, Part 58 – Good Laboratory Practice for Nonclinical Laboratory Studies.

SUMMARY: The USP 0.9% Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1 in 20 Ethanol in NaCl (EtOH), and Polyethylene Glycol 400 (PEG) extracts of the test articles, following Intracutaneous Injection in rabbits and Systemic Injection in mice, and the test articles, following Implantation in rabbits, did not produce a biological response. **Based on the criteria of the protocol and the USP guidelines for Class VI Plastics - 70 ℃, the test articles met the requirements of the tests.**

Cytotoxicity: (L929 MEM Elution Test – USP)

The cytotoxicity of the ingredients used to formulate Foster's ProPell™ Standard, ProPell™ T, and ProPell™ Plus Low Friction Compounds was tested in representative polyamide (25D) and TPU (80A) compounds by a third-party testing service, LabCorp.

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REFERENCES: Testing was based upon:

- USP-NF 2024. <87> Biological Reactivity Tests, In Vitro.
- ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and Calibration Laboratories.

GLP COMPLIANCE: The studies conformed to the current FDA 21 CFR, Part 58 – Good Laboratory Practice for Nonclinical Laboratory Studies.

SUMMARY: polyamide (25D) compound test article

"The potential biological reactivity of a mammalian cell culture (mouse fibroblast L929) in response to exposure to the extract of the test article, PEBAXX062624A1, was determined. The test article was extracted in Minimum Essential Medium (MEM) with 10 · Fetal Bovine Serum (referred to as complete MEM) for 24 ± 2 hours at 37 ± 1 ℃. Negative and positive controls were prepared similarly. The maintenance medium of L929 cells grown in 6-well plates was replaced with the 100% (neat) extracts in duplicate, and the cells were incubated for 48 ± 2 hours at 37 ± 1 ℃. The biological reactivity of the cells following the exposure to the extracts was visually observed with a microscope and graded on a scale of 0 to 4.

There was no biological reactivity (Grade 0) of the cells exposed to the test article extract after 24 hours and slight biological reactivity (Grade 1) of the cells exposed to the test article extract after 48 hours. The response obtained from the positive and negative control article extracts, as well as the untreated control, confirmed the suitability of the test system.

Based on the criteria of the protocol and the USP <87> guidelines, the test article meets the requirements of the test and is not considered to have a cytotoxic potential."

SUMMARY: TPU (80A) compound test article

"The potential biological reactivity of a mammalian cell culture (mouse fibroblast L929) in response to exposure to the extract of the test article, PUETXX062624A1, was determined. The test article was extracted in Minimum Essential Medium (MEM) with 10 · Fetal Bovine Serum (referred to as complete MEM) for 24 ± 2 hours at 37 ± 1 ℃. Negative and positive controls were prepared similarly. The maintenance medium of L929 cells grown in 6-well plates was replaced with the 100% (neat) extracts in duplicate, and the cells were incubated for 48 ± 2 hours at 37 ± 1 ℃. The biological reactivity of the cells following the exposure to the extracts was visually observed with a microscope and graded on a scale of 0 to 4.

There was no biological reactivity (Grade 0) of the cells exposed to the test article extract after 24 hours and no biological reactivity (Grade 0) of the cells exposed to the test article extract after 48 hours. The response obtained from the positive and negative control article extracts, as well as the untreated control, confirmed the suitability of the test system.

Based on the criteria of the protocol and the USP <87> guidelines, the test article meets the requirements of the test and is not considered to have a cytotoxic potential."

The test results are specific to the samples prepared. Any further extrapolation of the results would be the responsibility of the user of the compound(s).

If you have any questions or require any additional information, please do not hesitate to contact the undersigned.

Respectfully Submitted,

Foster Regulatory Support
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This document is produced electronically and is valid without a signature.