

# PEN Natural



## PEN Natural <Lot No.: 240419-04> USP <88> Class VI Study

**Client:** FLXR Engineering Co., Ltd.  
**Institution:** SGS Taiwan Industrial Service Ltd. Health Industry Service  
**Test Article No.:** PSG24900064  
**Date Received:** 2024.10.08  
**Final Report No.:** 113A001-D210709-FRE

### CONCLUSION

The test article "PEN" extracts of normal saline, olive oil, 1:20 ethanol and polyethylene glycol 400 (PEG 400) did not produce a significantly biological responses either in mice acute systemic toxicity test or in white rabbit intracutaneous irritation test. Besides, the test item "PEN" did not produce a significantly biological response in intramuscular implantation test in rabbits neither. Therefore, the test item "PEN" meets the requirements of the USP guidelines, for Class VI plastics.

Authorized by

*Wu Ping-Hsuan*

Wu Ping-Hsuan  
Study Director  
Biomedical Verification Lab.  
Plastics Industry Development  
Center  
Date: 2025.01.08

*Wei Chi-Chen*

Wei Chi-Chen  
Management  
Biomedical Verification Lab.  
Plastics Industry Development  
Center  
Date: 2025.01.08



## PEN Natural <Lot No.: R6A112102> Hemolysis Test

**Report No.:** RE25297HE01  
**Test article received date:** 2025.04.17  
**Experimental Starting Date:** 2025.04.25  
**Experimental Completion Date:** 2025.05.06  
**Study Completion Date:** See Study Director's signature date in the report

### CONCLUSION

The experiment was conducted in accordance with ASTM F756-17 (2017) guidelines. The hemolytic activity of the "PEN-Natural" was evaluated using both direct and indirect contact methods. The hemolytic index of the test article was less than 2 in both the indirect contact and direct contact hemolysis tests. Consequently, the test article was considered nonhemolytic.

*Yi-Jie Liao*

Yi-Jie Liao  
Quality Assurance Unit  
in Charge

*05/16/2025*

Date



## PEN Natural <Lot No.: 240419-04> In Vitro Cytotoxicity Test – Elution Test

**Report No.:** PUB24800022  
**Test article received date:** 2024.08.05  
**Experimental Starting Date:** 2024.08.15  
**Experimental Completion Date:** 2024.08.18  
**Study Completion Date:** See Study Director's signature date in the report  
**Name of Study Personnel:** Momo Shih

### CONCLUSION

Based on the grades, the "PEN" extract had none cell reactivity. The test article extracts did not induce cytotoxic effect in L929 cells, according to USP<87>.

Approval Signatory:

*Benson Lin*

Benson Lin  
SGS Taiwan Ltd.

Date

*2024.08.11*

*Shin Jyh Chen*

Shin Jyh Chen  
SGS Taiwan Ltd.

Date

*2024.08.11*



## PEN Natural PFAS Test

**Sample Submitted By :** FLXR ENGINEERING CO., LTD.  
**Sample Name :** PEN Natural  
**Sample Receiving Date :** 13-May-2025  
**Testing Period :** 13-May-2025 to 20-May-2025  
**Test Method :** Based on EN 17681 and BS EN 14582, total 552 PFAS evaluated (147 tested by LC-MS/MS, 405 listed for reference)  
**Test Result :** Not detected (n.d.) at ppb level

*Tory Chang*  
Tory Chang / Department Manager  
Signed for and on behalf of  
SGS TAIWAN LTD. Chemical Laboratory

**Test Method :** Total fluorine content was analyzed by ion chromatography (IC) in accordance with BS EN 14582:2016

**Test Result :** Not detected (n.d.) at ppb level

*Tory Chang*  
Tory Chang / Department Manager  
Signed for and on behalf of  
SGS TAIWAN LTD. Chemical Laboratory

**Test Method :** PFAS qualitative analysis was performed by SGS using method INSP-RD-0018, based on regulatory requirements from the EU, USA, and Canada. The test covered restricted PFAS species listed under REACH, EU POPs, TSCA, and Canada SOR 2012-285.

**Test Result :** Not detected (n.d.) at ppb level

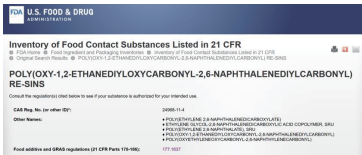
*Lennard Lin*

# PEN Natural & PEN HF

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1. FCN Nos. 13 (FCN 13) and 14 (FCN 14) permit the use of the food contact substances dimethyl-2,6-naphthalene dicarboxylate (NDC) or 2,6-naphthalene dicarboxylic acid (NDA aka PNDA) as "chemically bound components," i.e., as monomers, copolymerized with dimethyl terephthalate or terephthalic acid, and ethylene glycol, to form polyethylene terephthalate/naphthalate (PET/N aka CoPEN or PENCo) copolymers. FCN 13 covers finished copolymers that may contain from 0 to 50 weight percent of the polymer units derived from ethylene 2,6-naphthalate and FCN 14 covers from 50 to 100 weight percent of polymer units derived from ethylene 2,6-naphthalate. The finished copolymers prepared by the condensation of NDC or NDA with DMT or TA and ethylene glycol are permitted for use as the base sheet or polymer for manufacturing articles and films intended to contact all food types under Condition of Use A ("High temperature heat-sterilized (e.g., over 212 °F.)") through H ("Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use"); and
2. FCN 135 permits the use of dimethyl-2,6-naphthalene dicarboxylate (NDC) or 2,6-naphthalene dicarboxylic acid (NDA) as "chemically bound components," i.e., as monomers, in the manufacture of poly(ethylene terephthalate-isophthalate-2,6-naphthalate (PET/I/N) copolymers for use in manufacturing articles and films intended to contact Food Types I, II, IV-B, VI-A, VI-B, VII-B, and VIII (aqueous, acidic, and low alcohol foods) under Conditions of Use C ("Hot filled or pasteurized above 150 °F.") – H ("Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use"). In the case of the finished PET/I/N copolymers covered by FCN 135, these can incorporate not more than 2.5 mole percent (3.1 weight percent) of polymer units derived from ethylene 2,6-naphthalate. See FCN 135.





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