

Tài liệu được tổng hợp bởi đội ngũ kỹ thuật của **NPOWER** Bản quyền nội dung thuộc về **Toyox Co., Ltd.**
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5/15/2024

TOYOX Co.,LTD.

4371 Maesawa, Kurobe City, Toyama

FDA Declaration of Conformity

Covered products meet FDA safety requirements under Title 21 of the Code of Federal Regulations (CFR), Parts 170 through 199.

Target Products : TOYOSILICONE-S HOSE

Contents	:	An evaluation and detailed review was conducted to assess compliance with FDA regulations as an indirect food substance under Title 21 of the Code of Federal Regulations (CFR), Parts 170–199 and the U.S. Food and Drug Administration (FDA) Code. As a result of the evaluation and review, all components of this product meet FDA safety requirements.
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Series	part	number	:	TSIS-19	TSIS-25	TSIS-32
				TSIS-38	TSIS-50	

* We shall not be liable for any damages incurred in connection with this document, unless such damages are caused by our willful misconduct or gross negligence.

Date: May 1 ,2025

Toyox Co., Ltd.

Certificate of Non-Use of RoHS Directive Target Substances

This is to certify that the following products manufactured by TOYOX do not contain the RoHS Directive target substances as required in (EU) 2015/863, or do not, as of the issuance of this certificate, contain levels exceeding the threshold values of said substances.

[RoHS Directive Target Substances]

No.	Substance name	Threshold value
1	Cadmium and cadmium compounds	100 ppm or below
2	Lead and lead compounds	1000 ppm or below
3	Mercury and mercury compounds	1000 ppm or below
4	Hexavalent chromium compounds	1000 ppm or below
5	Polybrominated biphenyls (PBBs)	1000 ppm or below
6	Polybrominated diphenyl ethers (PBDEs)	1000 ppm or below
7	Bis(2-ethylhexyl) phthalate (DEHP) (117-81-7)	1000 ppm or below
8	Butyl benzyl phthalate (BBP) (85-68-7)	1000 ppm or below
9	Dibutyl phthalate (DBP) (84-74-2)	1000 ppm or below
10	Diisobutyl phthalate (DIBP) (84-69-5)	1000 ppm or below

Applicable products: TOYOSILICONE-S HOSE

The results above are based on the results of investigations within the scope normally possible for TOYOX at this time, such as “products where the substance is intentionally added or processed,” “products with disclosure of the level contained from the raw ingredient manufacturer, etc.” The products have not been analyzed. Product packages, etc., have also been excluded from the investigation.

5/15/2024

TOYOX Co.,LTD.

4371 Maesawa, Kurobe City, Toyama

USP87,88(class VI) Declaration of Conformity

The subject product complies with USP-NF2023<87>BIOLOGICAL REACTIVITY TESTS, IN VITRO ELUTION TEST and USP-NF2023<88>BIOLOGICAL REACTIVITY TESTS, IN VIVO for Plastic Classes VI The product conforms to the following

Target Products : TOYOSILICONE-S HOSE

[USP87 IN VITRO]

The cytotoxicity of the extract from the product was tested using L929 cells and the cytotoxicity was found to be "Grade 0", which meets the requirements of the guideline.

Test result : [USP88 IN VIVO (class VI)]

No biological reaction (abnormality) was observed as a result of acute systemic toxicity in mice, intradermal reaction test in rabbits, and implantation test, thus meeting the requirements of the guideline.

Series part number :	TSIS-19	TSIS-25	TSIS-32
	TSIS-38	TSIS-50	

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Certificate on Material

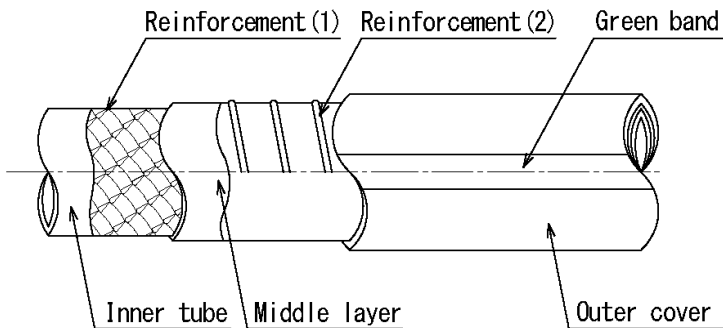
Date : June 1, 2021

【 Producer information 】

Company name : TOYOX CO., LTD.
Address : 4371 Maezawa Kurobe-city,
Toyama-pref. Japan 938-8585
Responsible department : R&D HQ.
Contact : Tel : 0765-52-3131
: Fax: 0765-52-4245

【 Product name 】 TOYOSILICONE-S HOSE

We herewith certify that the above described product is absolutely made of following materials.

1	Hose Structure	
		
2	Hose Material	Material
	Inner Material	Silicone rubber
	Reinforcement (1)	Polyethylene terephthalate
	Middle layer Material	Silicone rubber
	Reinforcement (2)	Stainless steel wire
	Outer Material	Silicone rubber

This product conforms to the standards of the Ministry of Health,
Labor and Welfare of Japan Notification No.380, 2020.
(Old the standards of the Ministry of Health, Labor and Welfare of Japan
Notification No.595, 2012.)

Phthalate plasticizer are not used.