

**Re: TED Stockings California Proposition 65 Labelling Assessment.**

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Internal Memorandum

From: Biocompatibility and Toxicology

Date: July 7, 2023

**Re: TED Stockings California Proposition 65 Labelling Assessment.**

The T.E.D.™ Anti-Embolism Stockings are meant to be used by adult patients that are non-ambulatory in the hospital, alternative care, or home setting. T.E.D.™ Anti-Embolism Stockings are used to reduce the risk of deep vein thrombosis (DVT), which can extend up to six weeks after hospitalization. Anti-embolism stockings are reported to function by reducing the overall cross-sectional area of the limb, increasing the velocity of venous flow, reducing venous wall distention, and improving valvular function. The suppliers of this product indicated that during the production process, minute residues of N, N-Dimethylacetamide (DMAC), a Proposition 65 listed compound, could be present on the device.

The purpose of this memo is to provide biocompatibility support regarding our previous recommendation that a Proposition 65 warning label is not necessary for this device. The Office of Environmental Health Hazard Assessment, California Environmental Protection Agency (California Proposition 65) (OEHHA) has set clear guidelines regarding evaluation of products containing any of the Proposition 65 listed compounds. Typically, an exposure assessment is conducted and compared to a pre-determined safe harbor level. This safe harbor level can be derived by toxicology experts in the absence of established limits by OEHHA.

A toxicological risk assessment was conducted, and it was determined that total exposures to DMAC in TED stockings were below projected thresholds for proposition 65 labeling. Therefore, these products will not require a warning label for the identified compound as per Office of Environmental Health Hazard Assessment, California Environmental Protection Agency.

**References**

1. California Office of Environmental Health Hazard Assessment overview, accessed at - <https://oehha.ca.gov/proposition-65>.
2. Derivation methodology for projection of safe harbor levels for MADL and NSRL limits, The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment

**Re: TED Stockings California Proposition 65 Labelling Assessment.**

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COMPLETED BY: *Osemwegie Odia* Electronically signed by:  
Osemwegie Odia  
Reason: Author  
Date: Jul 10, 2023 15:03 EDT DATE: Jul 10, 2023

Osemwegie Odia, PhD, DABT

Toxicologist, Biocompatibility/Toxicology

APPROVED BY: *Gloria Frost* Electronically signed by: Gloria  
Frost  
Reason: Approved  
Date: Jul 10, 2023 15:05 CDT DATE: Jul 10, 2023

Gloria Frost, MS, PhD, DABT

Director, Biocompatibility/Toxicology











# Memo- Prop 65 Labelling for TED Stockings

Final Audit Report

2023-07-10

Created:	2023-07-10
By:	Osemwegie Odia (osemwegie.odia@cardinalhealth.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAgl-V1QU34ttOzMFBhZbOz6Smd0DS18qF

## "Memo- Prop 65 Labelling for TED Stockings" History

-  Document created by osemwegie.odia@cardinalhealth.com  
2023-07-10 - 7:01:11 PM GMT
-  Document emailed to Gloria Frost (Gloria.Frost@cardinalhealth.com) for signature  
2023-07-10 - 7:02:48 PM GMT
-  Document emailed to osemwegie.odia@cardinalhealth.com for signature  
2023-07-10 - 7:02:48 PM GMT
-  Signer osemwegie.odia@cardinalhealth.com entered name at signing as Osemwegie Odia  
2023-07-10 - 7:03:26 PM GMT
-  Osemwegie Odia (osemwegie.odia@cardinalhealth.com) authenticated with Adobe Acrobat Sign.  
2023-07-10 - 7:03:28 PM GMT
-  Document e-signed by Osemwegie Odia (osemwegie.odia@cardinalhealth.com)  
Signing reason: Author  
Signature Date: 2023-07-10 - 7:03:28 PM GMT - Time Source: server
-  Email viewed by Gloria Frost (Gloria.Frost@cardinalhealth.com)  
2023-07-10 - 8:04:05 PM GMT
-  Gloria Frost (Gloria.Frost@cardinalhealth.com) authenticated with Adobe Acrobat Sign.  
2023-07-10 - 8:05:38 PM GMT
-  Document e-signed by Gloria Frost (Gloria.Frost@cardinalhealth.com)  
Signing reason: Approved  
Signature Date: 2023-07-10 - 8:05:38 PM GMT - Time Source: server
-  Agreement completed.  
2023-07-10 - 8:05:38 PM GMT