Green Solutions Group:
Tissue Preservative Non-Toxic Claims

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DEFINITION OF TOXICITY

The US Federal Trade Commission (FTC) is an independent federal agency dedicated to protecting consumers and developing policy to promote competition. The FTC has issued a Green Guide to provide guidance on the general principles applicable to environmental claims and how such claims can be qualified. 16 CFR 260.10 states the following:

> **Non-toxic claims**
> *(a) It is deceptive to misrepresent, directly or by implication, that a product, package, or service is non toxic. Non-toxic claims should be clearly and prominently qualified to the extent necessary to avoid deception.*
>
> *(b) A non-toxic claim likely conveys that a product, package, or service is non-toxic both for humans and for the environment generally. Therefore, marketers making non-toxic claims should have competent and reliable scientific evidence that the product, package, or service is non-toxic for humans and for the environment or should clearly and prominently qualify their claims to avoid deception.*
>
> *Example: A marketer advertises a cleaning product as "essentially non-toxic" and "practically non-toxic." The advertisement likely conveys that the product does not pose any risk to humans or the environment, including household pets. If the cleaning product poses no risk to humans but is toxic to the environment, the claims would be deceptive*.

In Canada, the Canadian Standards Association issued a document entitled "Environmental Claims: A Guide for Industry and Advertisers" in partnership with the Competition Bureau Canada. Per Section 4.4, a non-toxic claim is considered a type of vague and non-specific environmental claim. The document emphasizes the claim need to be clear, specific, and accurate.

Overall, companies should have strong scientific evidence that their product is non-toxic to both humans and the environment in order to substantiate a non-toxic claim.

Note that the US Labeling of Hazardous Art Materials Act is not discussed in this document. Art materials sold in the US must undergo this evaluation.

CRITERIA FOR ASSESSMENT

The FTC Green Guide and Competition Bureau Canada do not outline specific methodology that may be used to collect or measure scientific evidence. In this report, we will assess the Tissue Preservative under the classification criteria for Toxicity as defined 16 CFR 1500 of the Federal Hazardous Substances Act Regulations, under the Consumer Product Safety Commission (CPSC), and under the Canadian Consumer Chemicals and Containers Regulations (CCCR). These regulations are applicable to consumer products.

Acute Toxicity Criteria

Oral mg/kg	Dermal mg/kg	Inhalation (ppm or mg/L per 1 h)	
≤ 50 = Highly Toxic	≤ 200 = Highly Toxic	≤ 200 ppm = Highly Toxic	≤ 2 mg/L = Highly Toxic
>50≤5000 = Toxic	>200≤2000 = Toxic	>200 ≤20000 ppm = Toxic	>2 ≤200 mg/L= Toxic

Although the CPSC does not provide a mathematical formula to calculate acute toxicity, the CCCR does. The following formula is used to determine the LD50 (dermal, oral) and LC50 (inhalation) values of a mixture. LD50 and LC50 values for individual ingredients are taken from existing animal or human data found in literature.

Additivity Formula- LD50 or LC50 of Mixtures:

The LD_{50} or LC_{50} of a mixture may be determined from the LD_{50} or LC_{50} of its ingredients that are present in a concentration of 1% or more, using one of the following additivity formulas, as the case may be:

$$LD_{50} = \frac{1}{\frac{P_a}{LD_{50_a}} + \frac{P_b}{LD_{50_b}} + \ldots + \frac{P_n}{LD_{50_n}}}$$

- LD_{50} represents the LD_{50} of the mixture,
- LD_{50}a to LD_{50}n represent the LD_{50} of each ingredient that is present in a concentration of 1% or more, and
- P_a to P_n represent the proportion by weight of each ingredient that is present in a concentration of 1% or more.

Chronic Toxicity Criteria

A substance is considered to present a chronic toxicity hazard if it is a known or probable human carcinogen, neurotoxin, or developmental and reproductive toxicant.

Classification	Criteria
Carcinogen	EPA Group A or B, IARC Group 1 or 2, ANSI Category 1, 2, or 3, or listed on NTP
Neurotoxin	Not applicable
Developmental or Reproductive Toxin	EEC Category 1 or d, or FDA Category A1, D, or X

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FDA= Food and Drug Administration

SUMMARY OF TOXICITY

Using the toxicity criteria listed above, the Tissue Preservative discussed in this report **does not meet the criteria for oral, dermal, or inhalation toxicity.**

Below are additional details regarding known toxic components:

Known Toxic Components	Concentration	Classification	LD50 Value	Notes
DMDH HYDANTOIN (G1343)	2.96%	Orally toxic	542 mg/kg (source: ECHA)	Does not change the overall product toxicity
DMDH HYDANTOIN (G1343)	2.96%	Inhalation toxic	>10.3 mg/L/4h	Does not change the overall product toxicity

CONCLUSION

Based on our assessment, Green Solutions Group can make the claim that the Tissue Preservative are non-toxic for oral, dermal, and inhalation routes of exposure. We advise that the non-toxic claim is specific to these three routes of exposure, and references the appropriate regulation. Examples include:

- "Non-toxic by oral, dermal, and inhalation routes of exposure per the CCCR 2001 or 16CFR1500"
- "This product does not present a chronic toxicity hazard"

RESOURCES

16 CFR Part 260 - Guides For The Use Of Environmental Marketing Claims
https://www.law.cornell.edu/cfr/text/16/part-260

16 CFR Part 1500- Hazardous Substances and Articles: Administration and Enforcement Regulations https://www.law.cornell.edu/cfr/text/16/part-1500

Consumer Chemicals and Containers Regulations, 2001 (Canada). Classification of Toxic Products https://laws-lois.justice.gc.ca/eng/regulations/sor-2001-269/page-5.html#h-670859

Environmental claims: A guide for industry and advertisers
https://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/02701.html