

# BHT – Butylated Hydroxytoluene

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## Abstract

The Expert Panel for Cosmetic Ingredient Safety reviewed updated information that has become available since their original assessment from 2002, along with updated information regarding product types, and frequency and concentrations of use, and reaffirmed their original conclusion that BHT is safe as a cosmetic ingredient in the practices of use and concentration as described in this report.

## Keywords

Cosmetics, Safety, Butylated Hydroxytoluene

The Expert Panel for Cosmetic Ingredient Safety first published the Final Report on the Safety Assessment of BHT (butylated hydroxytoluene) in 2002.<sup>1</sup> The Expert Panel concluded that this ingredient is safe as used in cosmetic formulations. Data identified in the published literature<sup>2–16</sup> that have become available since the original review support the conclusion reached by the Expert Panel in 2002 publication. The Panel also reviewed updated information regarding product types and ingredient use frequencies as reported in the US Food and Drug Administration (FDA) Voluntary Cosmetic Registration Program (VCRP) database,<sup>17</sup> and the maximum use concentrations provided by the Personal Care Products Council (Council).<sup>18</sup> The Expert Panel determined to not reopen this safety assessment and reaffirmed the original conclusion that BHT is safe as a cosmetic ingredient in the present practices of use and concentration, as given in [Table 1](#).

The reported frequency of use for this ingredient has increased significantly since the initial review was considered. According to VCRP data, BHT was reported to be used in 1709 formulations in 1998.<sup>1</sup> In 2019, VCRP data indicate that BHT is used in 9485 formulations.<sup>17</sup> The current maximum concentration of use (0.5%) in leave-on products,<sup>18</sup> according to the results of the Council survey, is approximately the same as that reported in 1999 (0.5%).<sup>1</sup>

Although a substantial increase in frequency of use was reported, the lack of genotoxicity, systemic, and clinical effects continues to support the safety of this ingredient. According to the Expert Panel, BHT did not pose a toxicological risk as used in cosmetics; and therefore, the original conclusion was reaffirmed.

## Author's Note

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**Table I.** Current and Historical Frequency and Concentration of Use of BHT According to Duration and Exposure.

	# of Uses		Max Conc of Use (%)	
	2019 <sup>17</sup>	1998 <sup>1</sup>	2018 <sup>18</sup>	1999 <sup>1</sup>
<b>Totals*</b>	<b>9485</b>	<b>1709</b>	<b>0.0000007 – 0.5</b>	<b>0.0002 – 0.5</b>
<b>Duration of Use</b>				
Leave-On	7367	1460	0.0000007 – 0.5	0.002 – 0.5
Rinse-Off	2044	196	0.000001 – 0.5	0.01 – 0.5
Diluted for (Bath) Use	74	53	0.00024 – 0.15	0.05 – 0.1
<b>Exposure Type</b>				
Eye Area	976	610	0.00009 – 0.3	0.0002 – 0.5
Incidental Ingestion	981	261	0.000001 – 0.29	0.03 – 0.5
Incidental Inhalation-Spray	1708; 847 <sup>a</sup> ; 1581 <sup>b</sup>	146; 84 <sup>a</sup> ; 108 <sup>b</sup>	0.0000035-0.21; 0.0003-0.09 <sup>a</sup> ; 0.0000007-0.5 <sup>b</sup>	0.02-0.5; 0.008-0.5 <sup>a</sup> ; 0.02-0.5 <sup>b</sup>
Incidental Inhalation-Powder	226; 847 <sup>a</sup>	42; 84 <sup>a</sup>	0.0021-0.3; 0.0003-0.09 <sup>a</sup> ; 0.00005-0.5 <sup>c</sup>	0.05-0.5; 0.008-0.5 <sup>a</sup>
Dermal Contact	8071	1385	0.000001-0.5	0.008-0.5
Deodorant (underarm)	140 <sup>b</sup>	10 <sup>b</sup>	0.000001-0.4; 0.012-0.19 <sup>b</sup>	NR
Hair - Non-Coloring	270	40	0.0000007 - 0.5	0.02 - 0.5
Hair-Coloring	13	6	0.0015 - 0.005	0.05
Nail	37	8	0.0005 - 0.25	0.02 - 0.5
Mucous Membrane	2654	404	0.000001 - 0.31	0.03 - 0.5
Baby Products	6	5	0.0013 – 0.031	0.1

\* Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure types may not equal the sum of total uses.

<sup>a</sup> Not specified whether a powder or a spray, so this information is captured for both categories of incidental inhalation.

<sup>b</sup> It is possible these products may be sprays, but it is not specified whether the reported uses are sprays.

<sup>c</sup> It is possible these products may be powders, but it is not specified whether the reported uses are powders.

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