# CIR Supplement Manuscript

# **B**iotin

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## Abstract

The Expert Panel for Cosmetic Ingredient Safety reviewed updated information that has become available since their original assessment from 2001, along with updated information regarding product types, and frequency and concentrations of use, and reaffirmed their original conclusion that Biotin is safe as a cosmetic ingredient in the practices of use and concentration as described in this report.

## **Keywords**

Biotin, Cosmetics, Safety

The Expert Panel for Cosmetic Ingredient Safety published the Final Report on the Safety Assessment of Biotin in 2001.<sup>1</sup> Based on the available data, the Expert Panel concluded that Biotin is safe as used in cosmetics. Since then, new data were identified in the published literature;<sup>2-11</sup> these data were similar to data that were included in the original assessment. The Expert Panel reviewed updated information regarding product types and ingredient use frequencies provided by the US Food and Drug Administration (FDA)<sup>12</sup> and maximum use concentrations provided by the Personal Care Products Council.<sup>13</sup> The Expert Panel determined to not reopen this safety assessment and reaffirmed the original conclusion that Biotin is safe as used in cosmetic products as given in Table 1.

The reported frequency of use of Biotin in cosmetics has increased since safety was originally reviewed; 71 uses were reported 1998,<sup>1</sup> and 506 uses are reported in 2017.<sup>12</sup> The reported maximum leave-on concentration of use has decreased from .6% to .1%.<sup>1,13</sup> The number of uses in formulations with intentional application near the eye area increased from 2 to 54, and the maximum concentration of use reported for this type of exposure increased from .01% to .1%. However, this use concentration is still quite low and did not raise any new concerns.

As in the original assessment, the Expert Panel recognized that data on the irritation and sensitization potential of Biotin were absent. However, the Expert Panel was of the opinion that if Biotin had a strong potential for irritation or sensitization, case reports would be available in the published literature.

The Expert Panel also noted that there are reproductive studies of Biotin that show strong inhibition to spermatogenesis.<sup>11</sup>

However, these are oral studies at high levels which are irrelevant to uses in cosmetics. Therefore, it is the opinion of the Expert Panel that the results of those studies are not pertinent to the safety of Biotin as a cosmetic ingredient.

Finally, the Expert Panel stated that manufacturers should be aware that naturally occurring Biotin comprises only the D-stereoisomer. When produced synthetically, however, a racemic mixture of D- and L-stereoisomers is possible. There are potentially some differences in the activities of the L-isomer, present at 50% in DL-Biotin, in biological systems. However, because of the very low concentrations of use, the Expert Panel was not concerned about those differences regarding the safety of Biotin as used in cosmetics.

## Author's Note

Unpublished sources cited in this report are available from the Director, Cosmetic Ingredient Review, 1620 L Street, NW, Suite 1200, Washington, DC 20036, USA.

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	# of Uses		Max Conc of Use (%)	
	2017 <sup>12</sup>	<b>1998</b> <sup>1</sup>	2015-201613	1999 <sup>1 a</sup>
Totals <sup>b</sup>	506	71	.000002-0.1	.001-0.6
Leave-on	365	34	.000002-0.1	.0001-0.6
Rinse-off	140	36	.000001-0.1	.000101
Diluted for (bath) use	1	I	NR	NR
Eye area	54	2	.000002-0.1	.00101
Incidental ingestion	NR	NR	NR	NR
Incidental inhalation-spray	141 <sup>c</sup> ; 106 <sup>d</sup>	20 <sup>c</sup> ; 2 <sup>d</sup>	.0011; .001-0.1 <sup>c</sup>	.001005 <sup>c</sup> ; .002-0.6 <sup>d</sup>
Incidental inhalation-powder	106 <sup>d</sup>	2 <sup>c</sup>	.1; .000004-0.1 <sup>e</sup>	.002-0.6 <sup>d</sup>
Dermal contact	322	31	.000002-0.1	.0001-0.6
Deodorant (underarm)	NR	NR	NR	NR
Hair – non-coloring	166	40	.000002-0.1	.000101
Hair-coloring	5	NR	.0003	NR
Nail	6	NR	.0001-0.1	NR
Mucous membrane	I	3	.000006001	NR
Baby products	NR	NR	NR	NR

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

NR, no reported use.

<sup>a</sup>At the time of the original safety assessment, concentration of use data were not reported by the FDA; however, some concentration of use data were received from industry.

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

<sup>d</sup>Not specified whether a spray or a powder, but it is possible the use can be as a spray or a powder; therefore, the information is captured in both categories. <sup>e</sup>It is possible these products are powders, but it is not specified whether the reported uses are powders.

# **Author Contributions**

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