

## **PRUNUS AMYGDALUS DULCIS (SWEET ALMOND) SEED MEAL**

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report on the Safety Assessment of Sweet Almond Oil and Almond Meal in 1983.<sup>1</sup> On the basis of the available animal data and limited clinical experience presented in the report, the Panel concluded that Almond Meal (now named Prunus Amygdalus Dulcis (Sweet Almond) Seed Meal) is safe for topical application to humans in the present practices of use and concentration. Upon re-review in November 2002, the Panel reaffirmed the original conclusion, as published in 2005.<sup>2</sup> Prunus Amygdalus Dulcis (Sweet Almond) Oil was not considered in this re-review because it was included in the safety assessment of plant-derived fatty acids, published in 2017.<sup>3</sup>

Because it has been at least 15 years since the prior re-review was published, in accordance with Cosmetic Ingredient Review (CIR) Procedures, the Panel considered whether the safety assessment should be reopened. At its March 2023 meeting, the Panel considered updated (2022) 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>4</sup> and maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council.<sup>5</sup> Since the initial re-review was considered, the frequency of use for Prunus Amygdalus Dulcis (Sweet Almond) Seed Meal has decreased slightly from 15 to 14 uses.<sup>4</sup> In 2002, the maximum concentration of use for this ingredient was reported to be 27% in leave-on products and 2% in rinse-off products.<sup>2</sup> No concentrations of use were reported in the 2022 survey for this ingredient.<sup>5</sup> The cumulative frequency and concentration of use data are presented in Table 1.

In January 2023, an extensive search of the world's literature was performed for studies dated 1997 forward. No new toxicological data were found.

In summary, the Panel reviewed 2022 frequency and concentration of use data and noted the lack of any new, available, relevant safety data. Considering this information, as well as the information provided in the original safety assessment and the prior re-review document, the Panel reaffirmed the 1983 conclusion. The Panel discussed the possibility for this ingredient to be used in cosmetic products which may be incidentally inhaled. A detailed discussion and summary of the Panel's approach to evaluating incidental inhalation exposures to ingredients in cosmetic products is available at <https://www.cir-safety.org/cir-findings>.

**Table 1. Frequency and concentration of use (2022/2002) according to likely duration and exposure and by product category**

|   | # of Uses                       |                   | Max Conc of Use (%) |                      |
|---|---------------------------------|-------------------|---------------------|----------------------|
|   | 2022 <sup>4</sup>               | 2002 <sup>2</sup> | 2022 <sup>5</sup>   | 2002 <sup>2</sup>    |
| <b>Totals*</b>                                      | <b>14<sup>‡</sup></b>           | <b>15</b>         | <b>NR</b>           | <b>0.5-27</b>        |
| <b>summarized by likely duration and exposure**</b> |                                 |                   |                     |                      |
| <b>Duration of Use</b>                              |                                 |                   |                     |                      |
| Leave-On  | 12                              | 3                 | NR                  | 0.5-27               |
| Rinse-Off   | 2                               | 12                | NR                  | 0.5-2                |
| Diluted for (Bath) Use                              | NR                              | NR                | NR                  | NR                   |
| <b>Exposure Type</b>                                |                                 |                   |                     |                      |
| Eye Area  | 1                               | NR                | NR                  | NR                   |
| Incidental Ingestion                                | NR                              | NR                | NR                  | NR                   |
| Incidental Inhalation-Spray                         | 2 <sup>‡</sup> ; 1 <sup>b</sup> | 1 <sup>b</sup>    | NR                  | 0.5 <sup>b</sup>     |
| Incidental Inhalation-Powder                        | 2; 1 <sup>b</sup>               | 1 <sup>b</sup>    | NR                  | 27; 0.5 <sup>b</sup> |
| Dermal Contact                                      | 14                              | 14                | NR                  | 0.5-27               |
| Deodorant (underarm)                                | NR                              | NR                | NR                  | NR                   |
| Hair - Non-Coloring                                 | NR                              | NR                | NR                  | NR                   |
| Hair-Coloring                                       | NR                              | NR                | NR                  | NR                   |
| Nail  | NR                              | 1                 | NR                  | NR                   |
| Mucous Membrane                                     | 1                               | 3                 | NR                  | 0.5-2                |
| Baby Products                                       | NR                              | NR                | NR                  | NR                   |
| <b>as reported by product category</b>              |                                 |                   |                     |                      |
| <b>Eye Makeup Preparations</b>                      |                                 |                   |                     |                      |
| Other Eye Makeup Preparations                       | 1                               | NR                | NR                  | NR                   |
| <b>Fragrance Preparations</b>                       |                                 |                   |                     |                      |
| Powders (dusting/talcum, excl aftershave talc)      | NR                              | NR                | NR                  | 27                   |
| <b>Makeup Preparations</b>                          |                                 |                   |                     |                      |
| Face Powders  | 2                               | NR                | NR                  | NR                   |
| Makeup Bases  | 1                               | NR                | NR                  | NR                   |
| Makeup Fixatives                                    | 2                               | NR                | NR                  | NR                   |
| Other Makeup Preparations                           | 1                               | NR                | NR                  | NR                   |
| <b>Manicuring Preparations (Nail)</b>               |                                 |                   |                     |                      |
| Cuticle Softeners                                   | NR                              | 1                 | NR                  | NR                   |
| <b>Personal Cleanliness Products</b>                |                                 |                   |                     |                      |
| Bath Soaps and Detergents                           | NR                              | 2                 | NR                  | 0.5-2                |
| Other Personal Cleanliness Products                 | 1                               | 1                 | NR                  | NR                   |
| <b>Skin Care Preparations</b>                       |                                 |                   |                     |                      |
| Cleansing   | 1                               | 2                 | NR                  | NR                   |
| Body and Hand (exc. shave)                          | 1                               | 1                 | NR                  | 0.5                  |
| Moisturizing  | 2                               | NR                | NR                  | NR                   |
| Paste Masks (mud packs)                             | 1                               | 7                 | NR                  | 2                    |
| Other Skin Care Preparations                        | 1                               | 1                 | NR                  | NR                   |

NR – not reported

‡ Reported as Prunus Dulcis (Sweet Almond) Seed Meal in the 2022 VCRP.

\*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.

\*\*likely duration and exposure is derived based on product category (see Use Categorization <https://www.cir-safety.org/cir-findings>)

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

<sup>b</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

## REFERENCES

1. Elder R, (ed),. Final report on the safety assessment of Sweet Almond Oil and Almond Meal. *J Am Coll Toxicol*. 1983;2(5):85-99.
2. Andersen FA (ed). Annual Review of Cosmetic Ingredient Safety Assessments - 2002/2003. Sweet Almond Oil and Almond Meal. *Int J Toxicol*. 2005;24(Suppl 1):98-101.
3. Burnett CL, Fiume MM, Bergfeld WF, et al. Safety Assessment of Plant-Derived Fatty Acid Oils. *Int J Toxicol*. 2017;36(Suppl 3):51S-129S.
4. US Food and Drug Administration (FDA) Center for Food Safety & Applied Nutrition (CFSAN). 2022. Voluntary Cosmetic Registration Program - Frequency of Use of Cosmetic Ingredients. (Obtained under the Freedom of Information Act from CFSAN; requested as "Frequency of Use Data" January 4, 2022; received January 11, 2022). College Park, MD.
5. Personal Care Products Council. 2022. Concentration of use by FDA product category: Prunus Amygdalus Dulcis Seed Meal. Unpublished data submitted by Personal Care Products Council on October 28, 2022