ADMIN

Strategy Memo (SM):
PROPOLIS

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COSMETIC INGREDIENT REVIEW
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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Priya Ferguson, M.S.
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Date: September 11, 2026
Subject: Strategy Memo on Propolis-Derived Ingredients

CIR staff are currently preparing a Scientific Literature Review (SLR) on 4 propolis-derived ingredients (Table 1). A substantial body of literature is available on propolis and propolis extracts; however, staff are uncertain which of these data are applicable to the specific cosmetic ingredients under review and to what extent data may be read across among the various propolis materials. Staff therefore are seeking Panel guidance at this stage regarding how the available data should be categorized and applied in this safety assessment, and whether additional information regarding the composition and sourcing of the cosmetic ingredients is needed to inform these determinations.

Table 1. Propolis-derived ingredients included in the safety assessment

Ingredient	CAS No.	INCI Definition	Comments*	Technical Names*
Propolis Cera	85665-41-4	Propolis Cera is the substance Propolis.	Propolis Cera is the EU trivial name for Propolis Wax	propolis (EP) Propolis Wax (US)
Propolis Extract	85665-41-4	Propolis Extract is the Extract of Propolis Wax.	-	propolis (EP)
Propolis Wax	85665-41-4 9009-62-5	Propolis Wax is the material obtained from the extraction of propolis, a resinous substance found in beehives.	Propolis Cera and Propolis Wax represent the same material.	Propolis Cera (EU)
Hydrolyzed Propolis Extract	-	Hydrolyzed Propolis Extract is the hydrolysate of Propolis Extract, derived by acid, enzyme, or other method of hydrolysis.	-	-

* INCI definitions and technical names are according to the *Dictionary*; comments reflect clarification provided to CIR staff by PCPC; EP = European Pharmacopoeia

PCPC clarified to CIR staff that Propolis Cera is the EU trivial name for Propolis Wax and that the two represent the same material; accordingly, Propolis Cera and Propolis Wax will be considered as synonymous in this assessment. However, it is less clear how these ingredients relate to materials described as "propolis" in the published literature and to Propolis Extract. As shown in Table 1, Propolis Cera is defined as "the substance Propolis," Propolis Wax is defined as material "obtained from the extraction of propolis," and Propolis Extract is defined as the "extract of Propolis Wax." Propolis Cera, Propolis Wax, and Propolis Extract also share CAS No. 85665-41-4, and "propolis (EP)" (i.e., the name used in the *European Pharmacopeia*) is listed as a technical name for both Propolis Cera and Propolis Extract. Therefore, staff seek guidance regarding which forms of propolis reported in the literature are representative of these ingredients and the extent to which data may be read across among them.

Unlike ingredients derived from a defined botanical source, propolis is produced by bees using materials collected from local flora, and the plant source is an important determinant of its chemical composition.[1,2] Other factors that affect composition include geographical origin, season, and bee species. For example, poplar-type propolis found in Europe, North America, and non-tropical regions of Asia is primarily associated with plant sources from *Populus* spp. (e.g., *Populus nigra*, *Populus tremula*), whereas Brazilian green propolis is primarily associated with the plant species *Baccharis*

dracunculifolia.[1,3] Bee species may also influence propolis composition; differences in chemical profiles have been reported between propolis produced by *Apis mellifera* and that produced by various stingless bee species.[4] Thus, although many published studies characterize the propolis tested by geographic and/or botanical source and bee species, it is unclear whether these different propolis types are representative of the ingredients under review, or whether data may be read across among them.

The potential toxicological relevance of this variability is illustrated by the sensitization literature. Positive patch-test reactions to propolis increased from 2.8% in 2020 to 16.4% in 2023 following a change in the commercial patch-test material from Chinese to Brazilian propolis.[3] Subsequent concurrent testing of 239 patients resulted in positive reactions in 57 patients (23.8%) tested with Brazilian propolis, compared with 9 patients (3.8%) tested with Chinese propolis.[5] Chemical analyses of the propolis materials used for patch testing also demonstrated substantial compositional differences between the Brazilian and Chinese samples. These findings suggest that the source and composition of the propolis test material may be relevant when interpreting the available safety data.

Staff considered the approach used in the previous CIR safety assessment of honey-derived ingredients.[6] In that assessment, Honey itself, as well as Honey Extract and other derivatives, were included. Honey was defined according to specific bee species, and the available safety data were relatively limited. In contrast, substantial literature exists on the composition and allergenicity of various propolis types, but the relationship of these materials to Propolis Wax/Cera and Propolis Extract is less clear.

The primary difficulty in preparing the SLR is determining how the available data on the various propolis materials reported in the literature should be applied to the INCI ingredients under review. Even when a study adequately characterizes the test material (e.g., Brazilian green, Brazilian red, or poplar-type propolis), staff do not currently have corresponding information regarding the source and composition of the cosmetic ingredients to determine whether that material is representative. It is also unclear to what extent data from different characterized propolis types may be read across. A secondary issue arises for studies in which the test material is identified only as "propolis" or "propolis extract," without further characterization.

Additional information from industry regarding the starting materials, botanical/geographic source, composition/ specifications, and methods of manufacture of the ingredients under review may assist staff in determining which published propolis materials are representative and whether read-across is appropriate. Preliminary inquiries by PCPC indicate that detailed supplier information may be limited and that some supplier materials are complex mixtures containing propolis-derived ingredients. Given the extensive literature available on propolis, staff seek Panel guidance before incorporating these data into the SLR.

Specifically, staff request guidance on the following:

1. **Based on the information presented above regarding ingredient identity and variability of propolis, does the Panel consider there to be a sufficient basis for staff to determine which propolis materials reported in the literature are relevant to Propolis Wax/Cera and Propolis Extract, or is additional information regarding composition, botanical/geographic source, and/or manufacturing of the cosmetic ingredients needed?**
    a. **If additional information is needed, what information does the Panel consider necessary to establish the relevance of published data?**
    b. **If the necessary material identification information cannot be obtained from industry, should CIR issue an NTP rather than proceed with the preparation of the SLR?**
2. **To what extent can data be read across among the various characterized propolis materials reported in the literature?** For example, can data on propolis from different botanical/geographic sources be used collectively to support the ingredients under review, or should source and/or compositional similarity be considered when determining the relevance of individual studies?
3. **Once an approach to characterize propolis materials has been established, how should staff handle studies in which the test material is identified only as "propolis" or "propolis extract" without further characterization?** Should these studies be included as supporting information or excluded if their relevance cannot be established?

References

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