



Safety Statement

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Product Name: AC Royal Jelly Extract

Code: 20478

INCI Name: Butylene Glycol & 10-Hydroxydecanoic Acid & Sebacic Acid & 1,10-Decanediol

AC Royal Jelly Extract is manufactured by blending 10-hydroxydecanoic acid, sebacic acid, and 1,10-decanediol. That mixture is then combined with butylene glycol and filtered. The combination of these ingredients mimics natural royal jelly.

Butylene glycol is a synthetic compound commonly used as a solvent. In 1985, the Journal of the American College of Toxicology published a report entitled "Final Report on the Safety Assessment of Butylene Glycol, Hexylene Glycol, Ethoxydiglycol, and Dipropylene Glycol".¹

This report concluded that butylene glycol is safe for topical use in cosmetic products. This claim was substantiated by the results of several toxicity and irritation tests. Butylene glycol tested at 100% caused minimal to mild irritation of skin and eyes in test animals. Human skin patch tests on undiluted butylene glycol produced a very low order of primary skin irritation. An RIPT (Repeated Insult Patch Test) produced no evidence of skin sensitization.¹

While 10-hydroxydecanoic acid has not been individually analyzed for safety in topical applications, the Cosmetic Ingredient Review (CIR) conducted a safety analysis for alpha hydroxy acids in general, focusing mainly on glycolic and lactic acids. Since 10-hydroxydecanoic acid is an alpha hydroxy acid, it makes sense to infer its safety from this report. Alpha hydroxy acids were determined to be safe for use in cosmetic products when used at percentages less than or equal to 10.0%. Alpha hydroxy acids may cause sun sensitivity, so formulators should be mindful of this when incorporating into finished products.²

The CIR conducted a safety assessment of sebacic acid, along with other dicarboxylic acids, salts, and esters. As expected for acids, some irritation of the skin and eyes was reported. In animal studies, sebacic acid was not genotoxic or carcinogenic. The study concluded that all of the dicarboxylic acids, salts and esters that were studied are safe as currently used in cosmetic preparations.³

While data regarding topical application of 1,10-decanediol is fairly scarce, studies have shown that it can cause skin and eye irritation when used at a 100% concentration.⁴ Since the combination of 1,10-decanediol, sebacic acid, and 10-hydroxybenzoic acid in AC Royal Jelly Extract is only 5.0%, there is little concern for the irritating potential of 1,10-decanediol in this mixture. 1,10-decanediol is used in a variety of industries and products, many of which necessitate some type of contact with human skin (hair conditioning, laundry detergent, etc).⁵

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AC Royal Jelly Extract was tested using *in vitro* dermal and ocular irritation models. This product was found to be non-irritating in both models. The full report is attached for reference.

The above information supports the safety of AC Royal Jelly Extract in cosmetic applications at use levels of 1.0 – 10.0%. No further testing is required at this time.

1. "Final Reports on the Safety Assessment of Butylene Glycol, Hexylene Glycol, Ethoxydiglycol, and Dipropylene Glycol". Journal of the American College of Toxicity, Volume 4, Number 5. 1985.
2. "Final Report on the Safety Assessment of Glycolic Acid, Ammonium, Calcium, Potassium, and Sodium Glycolates, Methyl, Ethyl, Propyl, and Butyl Glycolates, and Lactic Acid, Ammonium, Calcium, Potassium, Sodium, and TEA-Lactates, Methyl, Ethyl, Isopropyl, and Butyl Lactates, and Lauryl, Myristyl, and Cetyl Lactates." Cosmetic Ingredient Review. <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr34.pdf>
3. "Final Report of the Cosmetic Ingredient Review Expert Panel on the Safety Assessment of Dicarboxylic Acids, Salts, and Esters". Cosmetic Ingredient Review. <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr528.pdf>
4. "Material Safety Data Sheet: 1,10-Decanediol". Acros Organics/Fisher Scientific. <https://www.fishersci.ca/viewmsds.do?catNo=AC181041000>
5. "1,10-decanediol". PubChem. <http://pubchem.ncbi.nlm.nih.gov/summary/summary.cgi?cid=37153>

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