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### Biotex Saffron Cream: Phytochemistry, Cutaneous Mechanisms, and a Preparation-Aware Evidence Appraisal of Kumkuma (*Crocus sativus* L.)

A Critical Narrative Review of the Scientific Basis for an Antioxidant-Rich Saffron Face Cream

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#### Abstract

**Background:** Biotex Saffron Cream is a topical face cream developed by Biotex Life Solutions Pvt. Ltd. around Kumkuma (*Crocus sativus* L.) (Sty. & Stg.; saffron style and stigma). Its intended cosmetic positioning encompasses visible radiance, antioxidant defence, protection against factors associated with premature visible ageing, hydration, a more even-looking skin tone, and calming of visible redness. Kumkuma contains characteristic saffron metabolites including crocins, crocetin, picrocrocin, and safranal. Objective: To critically synthesise preparation-matched evidence relevant to these six cosmetic benefit domains, and to define what remains to be demonstrated for the finished product. Evidence synthesis: Human topical studies of saffron-containing creams report instrumentally measured changes in melanin and erythema indices, improved skin moisture and transepidermal-water-loss parameters, and improvements in wrinkle geometry and skin elasticity. Mechanistic studies provide complementary evidence: stigma-derived compounds inhibit tyrosinase; a chemically characterised saffron extract inhibits tyrosinase and collagenase and promotes collagen and hyaluronic-acid synthesis in normal human dermal fibroblasts; crocin protects normal human keratinocytes and fibroblasts against oxidative and photoageing stress; crocetin attenuates melanogenic signalling in a murine melanoma line and reduces UVA-associated oxidative injury; and safranal inhibits collagenase, elastase, and hyaluronidase in cell-free biochemical systems. Limitations: No study of the finished Biotex Saffron Cream has been published. The human topical evidence comprises two independent saffron-containing formulations evaluated in 30 participants in total, one cohort being exclusively male, and neither formulation is compositionally identical to the product discussed here. Conclusion: Direct style/stigma phytochemistry, human topical saffron studies, normal human skin-cell experiments, and constituent-level mechanisms form a coherent and favourable ingredient-level evidence base for the cosmetic rationale of Biotex Saffron Cream. The conclusions are drawn at the ingredient level and are not efficacy claims for the finished formulation.

**Keywords:** *Crocus sativus*; saffron style and stigma; cosmeceutical; crocin; safranal; skin hydration; skin tone; topical antioxidant

#### Abbreviations

COX-2, cyclooxygenase-2; DPPH, 2,2-diphenyl-1-picrylhydrazyl; GAIS, Global Aesthetic Improvement Scale; GC-MS, gas chromatography–mass spectrometry; GPX-1, glutathione peroxidase 1; HA, hyaluronic

acid; HPLC-DAD, high-performance liquid chromatography with diode-array detection; IC<sub>50</sub>, half-maximal inhibitory concentration; INCI, International Nomenclature of Cosmetic Ingredients; iNOS, inducible nitric oxide synthase; LC-MS, liquid chromatography–mass spectrometry; MAPK, mitogen-activated protein kinase; MITE, microphthalmia-associated transcription factor; MMP, matrix metalloproteinase; NF-κB, nuclear factor kappa B; NO, nitric oxide; Nrf2, nuclear factor erythroid 2-related factor 2; O/W, oil-in-water; R2, gross elasticity; R5, net elasticity; ROS, reactive oxygen species; SANRA, Scale for the Assessment of Narrative Review Articles; SPF, sun protection factor; TEWL, transepidermal water loss; TRP-1, tyrosinase-related protein 1; TRP-2, tyrosinase-related protein 2; UV, ultraviolet; UVA, ultraviolet A; UVB, ultraviolet B; W/O, water-in-oil.

## 1. Introduction

Human skin is a dynamic barrier organ continuously exposed to ultraviolet radiation, visible and infrared light, atmospheric pollution, climatic variation, oxidants, and mechanical and microbial stress. The aggregate of these exposures—the skin ageing exposome—interacts with intrinsic ageing to influence pigmentation, barrier performance, surface texture, inflammation, dermal extracellular matrix integrity, and visible ageing<sup>[1-7]</sup>.

Cosmetic strategies that support several of these processes simultaneously have therefore attracted increasing attention. Botanical preparations are particularly relevant because a single plant may contain multiple chemical classes with complementary physicochemical and biological properties. In this context, *Crocus sativus* L. (Iridaceae), commonly known as saffron, is of interest because its stigmas contain apocarotenoid glycosides, volatile monoterpenes, carotenoid-derived aglycones, and phenolics with demonstrated antioxidant and skin-relevant activities<sup>[8-13]</sup>.

Biotex Saffron Cream, developed by Biotex Life Solutions Pvt. Ltd., is formulated around Kumkuma (*Crocus sativus* L.) (Sty. & Stg.; style and stigma) as its declared botanical ingredient. The intended cosmetic benefits are restoration of natural-looking radiance and glow, promotion of a more even-looking skin tone and smooth texture, improvement of hydration and nourishment in dull-looking skin, soothing of visible redness or sensitivity, and protection against environmental stress that may accelerate the appearance of ageing. Because the product ingredient is defined by botanical plant part rather than by a single extraction fraction, evidence from saffron stigma/style extracts and their characteristic volatile and nonvolatile constituents is relevant, provided each evidence type is interpreted according to its preparation and level of evidence.

A central problem in the saffron-cosmetic literature is the tendency to use the terms saffron, saffron extract, saffron essential oil, safranal, crocin, and crocetin as if they were interchangeable. They are not. Crocin is a highly polar, nonvolatile glycosylated apocarotenoid, whereas safranal is a low-molecular-weight volatile aldehyde. Hydrodistilled saffron oil is therefore expected to be enriched in volatile and lipophilic constituents and may contain little or no crocin, depending on the process<sup>[8,14-16]</sup>. This distinction remains critical when translating published studies to Biotex Saffron Cream. The declared ingredient is Kumkuma (*Crocus sativus* L.) (Sty. & Stg.), so the botanical source encompasses the style/stigma phytochemical system rather than a single volatile-oil fraction. The actual contribution of crocins, crocetin, picrocrocin, safranal, and other compounds will depend on how the style/stigma material is processed and standardised.

This critical narrative review evaluates the phytochemistry, cutaneous mechanisms, human topical evidence, and formulation science relevant to the six intended cosmetic benefit domains of Biotex Saffron Cream: radiance, antioxidant defence, protection against premature visible ageing, hydration, even-looking tone, and calming of visible redness. Evidence is interpreted according to the material actually studied—style/stigma, whole saffron extract, or isolated saffron constituent—so that supportive findings remain scientifically proportionate to the preparation tested. The review is explicitly an ingredient-level appraisal; it does not present, and does not claim, efficacy data generated on the finished cream.

## 2. Review Methodology and Evidence Appraisal

A structured narrative literature search was undertaken through August 2026. The review was not prospectively registered, and no formal risk-of-bias instrument was applied, since the included literature spans biochemical, cellular, animal and human designs for which a single appraisal tool is not appropriate.

Databases searched were PubMed/MEDLINE, Scopus, Web of Science and Google Scholar, supplemented by hand-searching of the reference lists of retrieved reviews and by direct interrogation of publisher platforms for journals not indexed in MEDLINE. Search concepts combined *Crocus sativus* or saffron with topical, cream, skin, pigmentation, tyrosinase, erythema, hydration, transepidermal water loss,

wrinkle, elasticity, fibroblast, collagen, hyaluronic acid, photoaging, UV, oxidative stress, safranal, crocin, crocetin, liposome, lipid nanoparticle, essential oil, and GC-MS. No language restriction was applied at the search stage; only English-language full texts were ultimately included. Records were screened by title and abstract and then at full text; 36 sources were retained for the final synthesis.

Each reference used for a central claim was cross-checked for bibliographic identity and claim relevance. Where available, we verified the title, author list, journal, year, volume/issue, pagination or article number, DOI, and PMID/PMCID against PubMed and/or the publisher record. We excluded citations with incorrect attribution or uncertain existence. Mechanistic claims from the earlier saffron framework were also re-audited; mechanisms such as direct MITF/TRP-1/TRP-2 suppression by the Biotex style/stigma ingredient in human skin, safranal-specific conversion of stratum-corneum lipid packing, and cutaneous enzymatic conversion of crocin to crocetin were not treated as established because direct supporting human skin studies were not identified. These mechanisms are consequently absent from the figures, tables and claim-translation framework presented here.

For translational interpretation, evidence was grouped by proximity to the intended cosmetic use. Tier 1 comprised human topical saffron studies. Tier 2 comprised direct style/stigma phytochemistry and cutaneous cellular or ex vivo evidence generated in normal human skin cells. Tier 3 comprised isolated saffron constituents in non-cutaneous or non-human systems, formulation and delivery studies, and broader mechanistic literature. Greater interpretive weight was assigned to Tier 1 and Tier 2 evidence, while Tier 3 studies were used only to explain biological plausibility. This tier assignment is applied consistently in Tables 2, 3 and 5. Instrumental endpoints reported in the included human studies—Mexameter melanin and erythema indices, corneometry, transepidermal water loss, and cutometry—correspond to the biophysical methods conventionally accepted for cosmetic claim support<sup>[17]</sup>.

**Table 1. Evidence-relevant saffron material classes and their relationship to the declared Kumkuma (*Crocus sativus* L.) (Sty. & Stg.) Ingredient.**

| Material/fraction                         | Representative chemistry                                                                   | Source/processing                                                                            | Interpretive relevance                                                                                                                                                                                                |
|-------------------------------------------|--------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Volatile fraction of saffron style/stigma | Safranal; ionone/isophorone-related compounds; other volatile and lipid-soluble molecules  | Hydrodistillation/volatile fraction                                                          | One chemically relevant fraction of the declared style/stigma botanical; particularly informative for safranal and related volatiles. GC-MS profiles vary substantially by origin and processing <sup>[14-15]</sup> . |
| Crocin-rich style/stigma extract          | Crocin-1/crocin-3 and related glycosylated apocarotenoids; picrocrocin; variable phenolics | Aqueous/hydroalcoholic extract                                                               | Directly relevant to the declared style/stigma plant part at ingredient level; exact transferability depends on how the Biotex raw material is processed and standardised <sup>[8,18-21]</sup> .                      |
| Crocetin                                  | Aglycone dicarboxylic apocarotenoid                                                        | Present at low and variable levels; can arise from crocin metabolism or extraction chemistry | More lipophilic than crocin; mechanistic support only, and product presence requires analytical confirmation <sup>[10,21]</sup> .                                                                                     |
| Safranal                                  | Volatile monoterpene aldehyde                                                              | Important saffron aroma and volatile quality marker                                          | Relevant as a characteristic volatile constituent of saffron style/stigma chemistry; antioxidant and matrix-                                                                                                          |

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enzyme inhibition  
demonstrated in cell-free  
systems<sup>[14,22]</sup>.

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### 3. Botanical Identity, Style/Stigma Phytochemistry, and Raw-Material Standardisation

The style is not an incidental contaminant of saffron chemistry. Lamari et al. specifically characterised cultivated *C. sativus* styles and found the species to have high style volatile content together with crocin and picrocrocin profiles, providing direct phytochemical evidence for the style component of the declared Biotex ingredient<sup>[23]</sup>. Accordingly, the literature should be read as a spectrum: style/stigma material represents the botanical source; saffron extracts represent preparation-level evidence; and crocin, crocetin, or safranal studies represent constituent-level evidence. Independent developmental metabolite studies of *C. sativus* stigmas likewise demonstrate accumulation of crocetin derivatives and picrocrocin and a characteristic evolving volatile profile during stigma maturation<sup>[24]</sup>. Modern HPLC analyses of authenticated stigmas continue to quantify crocin, picrocrocin, and safranal as principal quality markers<sup>[25]</sup>.

#### 3.1 Botanical and phytochemical context

*Crocus sativus* is a sterile triploid geophyte propagated vegetatively through corms. Commercial saffron is derived principally from the dried red stigmas, often with a short portion of the style depending on harvesting and trimming practice. For Biotex Saffron Cream, the declared botanical material is specifically Kumkuma (*Crocus sativus* L.) (Sty. & Stg.), thereby identifying both style and stigma as the source plant parts. These tissues contain the chemical markers responsible for saffron colour, bitterness, and aroma. Crocins are water-soluble glycosylated apocarotenoids; picrocrocin contributes characteristic bitterness; crocetin is the apocarotenoid aglycone; and safranal is an important aroma-active volatile generated in part during post-harvest processing<sup>[8-9]</sup>.

The chemistry is highly sensitive to harvest, drying, storage, extraction, light, oxygen, and temperature. These factors are particularly important in a topical product because both volatile loss and carotenoid degradation can alter the exposure delivered to skin. Analytical characterisation links the broader saffron literature to the defined Kumkuma style/stigma material used in topical formulation<sup>[9,16,26]</sup>.

#### 3.2 Volatile and nonvolatile fractions of saffron style and stigma

GC-MS and phytochemical studies demonstrate that the volatile fraction of *C. sativus* style/stigma is chemically distinct from the nonvolatile crocin/picrocrocin-rich fraction. Essential-oil studies therefore describe one fraction of the botanical material rather than the complete Kumkuma ingredient. Kanakis and colleagues characterised saffron volatiles and quantified safranal among the principal aroma compounds<sup>[14]</sup>. More recently, Drioiche et al. reported a Moroccan hydrodistilled essential oil in which the major components included phorone (12.90%), a dioxolane methanol derivative (11.65%), isopropyl palmitate (9.68%), dihydro- $\beta$ -ionone (8.62%), safranal (6.39%), trans- $\beta$ -ionone (4.81%), 4-keto-isophorone (4.72%), and 1-eicosanol (4.55%)<sup>[15]</sup>. It is notable that safranal was a minority component even in a hydrodistilled oil, which further cautions against equating saffron volatile chemistry with safranal alone.

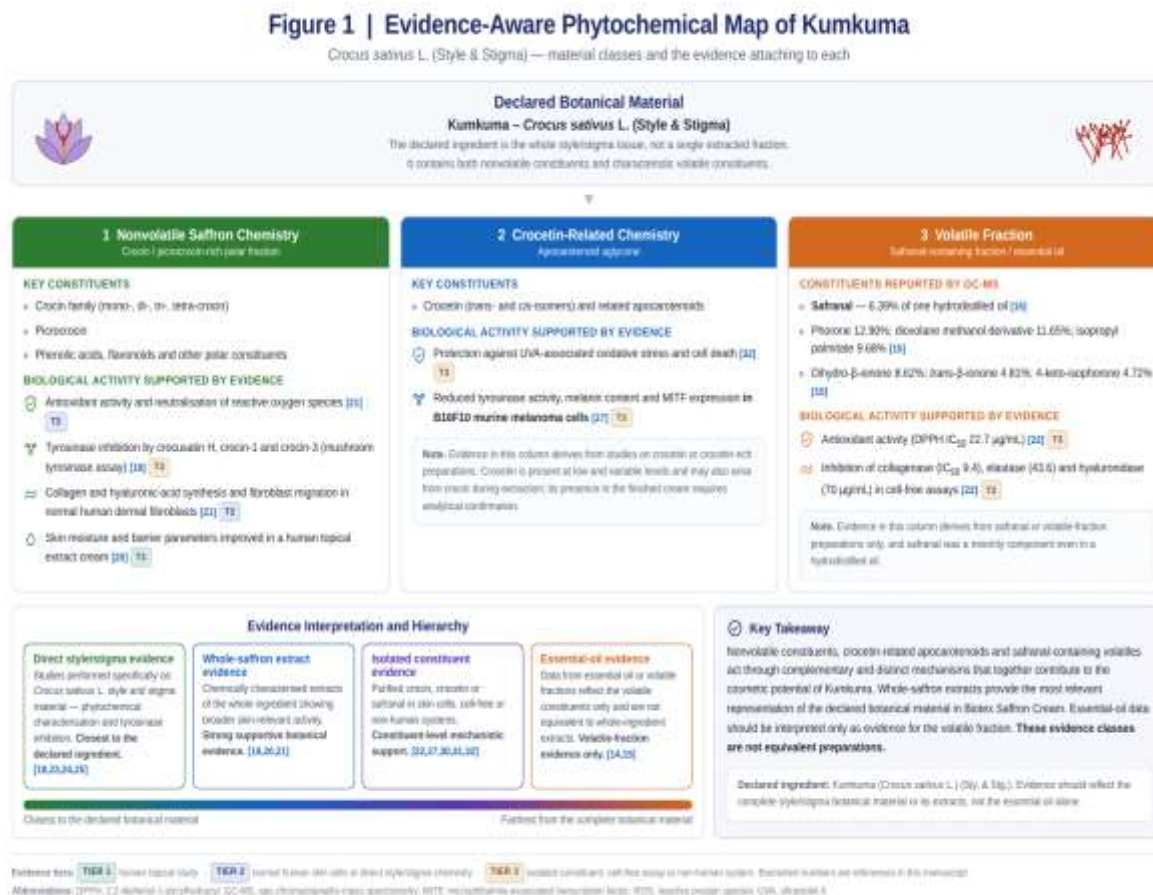
This analytical evidence is relevant to Biotex Saffron Cream as one component of the broader style/stigma phytochemical spectrum, but the product should not be characterised as an essential-oil formulation unless manufacturing records demonstrate isolation of that fraction. Because the declared ingredient is Kumkuma (*Crocus sativus* L.) (Sty. & Stg.), evidence from aqueous or hydroalcoholic stigma/style extracts, isolated crocins and crocetin, and safranal-rich volatile fractions can all contribute to biological plausibility. Exact transferability depends on the processing method used for the Biotex ingredient and on analytical confirmation of marker compounds in the raw material and finished cream.

#### 3.3 Quality control and standardisation

A robust specification for Kumkuma (*Crocus sativus* L.) (Sty. & Stg.) should combine botanical authentication with chemical fingerprinting suited to the preparation. HPLC-DAD or LC-MS methods are appropriate for nonvolatile crocins, crocetin, and picrocrocin, while GC or GC-MS can characterise volatile components such as safranal where relevant. The analytical strategy should therefore profile the style/stigma ingredient rather than assume that a single essential-oil marker represents the whole botanical material<sup>[15-16,26]</sup>.

For a face cream built around a botanical active, routine controls such as botanical authentication, microbiological quality, contaminant limits, adulteration screening, and stability of the saffron markers

help preserve the chemical profile on which the ingredient-level evidence depends. Saffron is among the most frequently adulterated botanical commodities, so identity testing is a substantive quality requirement rather than a formality.



**Fig 1:** Evidence-aware phytochemical map of Kumkuma (*Crocus sativus* L.) (Sty. & Stg.), showing the nonvolatile, crocetin-related and volatile fractions with the demonstrated activity and reference attached to each, and the evidence classes ordered by proximity to the declared ingredient. Tier 1, human topical study; Tier 2, normal human skin cells or direct style/stigma chemistry; Tier 3, isolated constituent, cell-free assay or non-human system.

## 4. Cutaneous Biological Rationale

### 4.1 Radiance, pigmentation, and more even-looking skin tone

Visible radiance is a composite cosmetic endpoint influenced by surface smoothness, hydration, pigmentation uniformity, erythema, and optical reflection. It is important to note at the outset that radiance and brightness were not themselves instrumental endpoints in any of the human studies reviewed here; they are inferred from the measured pigmentation, erythema, hydration and texture parameters. Pigmentation is therefore only one component of glow, but it is a measurable one. Tyrosinase is central to melanogenesis, catalysing early reactions that lead from tyrosine and L-DOPA toward melanin formation<sup>[13]</sup>.

A stigma-specific phytochemical study provides direct support for a pigmentation-related mechanism. From an aqueous extract of *C. sativus* stigmas, Li and Wu isolated 25 compounds and found that crocusin H together with crocin-1 and crocin-3 significantly inhibited mushroom tyrosinase<sup>[18]</sup>. This is a non-human enzyme system, and mushroom tyrosinase inhibition is a screening assay rather than a demonstration of activity in human skin. Complementary cellular work with crocetin showed lower tyrosinase activity and melanin accumulation, accompanied by reduced tyrosinase and MITF protein expression and lower intracellular reactive oxygen species<sup>[27]</sup>; this study was performed in B16F10 murine melanoma cells, so it establishes a plausible melanogenic mechanism for the constituent but does not establish MITF regulation in normal human melanocytes or in the finished formulation. Together, these

findings connect characteristic saffron constituents with pathways relevant to a more even-looking complexion at Tier 3 level.

The strongest direct human evidence for tone and visible redness comes from an 8-week vehicle-comparison study in 10 healthy volunteers using a 3% *C. sativus* extract water-in-oil cream. Percentage changes in Mexameter measurements were  $-24.04 \pm 3.23$  for skin melanin content and  $-13.57 \pm 2.28$  for erythema, and the extract-containing formulation differed significantly from the base cream<sup>[19]</sup>. These instrumental findings provide human topical support for a brighter, more even-looking complexion and a reduction in the appearance of redness. Two constraints should be stated alongside them: all ten volunteers were male and aged 25-40 years, and the comparator was the corresponding base cream rather than an established depigmenting agent.

A chemically characterised saffron extract also inhibited tyrosinase in the study by Xiong et al., while showing additional antioxidant and matrix-related activities<sup>[21]</sup>. Taken together, these findings justify describing saffron-derived material as supporting the appearance of a more even tone. They do not justify presenting the product as a treatment for melasma or other pigmentary disorders, and they do not establish direct MITF/TRP-1/TRP-2 regulation in human skin by the declared style/stigma ingredient or finished formulation.

#### 4.2 Hydration, barrier function, and nourishment

The stratum corneum is the dominant permeability barrier of skin and limits uncontrolled water loss while protecting against external chemical and physical stress. Its function depends on differentiated corneocytes, cornified-envelope proteins, and an extracellular lipid matrix rich in ceramides, cholesterol, and free fatty acids<sup>[1-2]</sup>. Cosmetic hydration can therefore arise from humectancy, emollience, occlusion, improved barrier organisation, or combinations of these processes.

In a companion 8-week human study, a 3% *C. sativus* extract water-in-oil cream produced significant improvement in measured skin moisture together with significant changes in transepidermal water loss when compared with the control base<sup>[20]</sup>. This is the most directly relevant human evidence for the hydration and moisture-retention positioning of a saffron-containing cream, and it is particularly pertinent to a cream-based product because it demonstrates that a saffron-containing emulsion can produce measurable barrier-associated cosmetic effects during repeated topical use. This finding is complemented at the mechanistic level by the observation that a chemically characterised saffron extract increased hyaluronic-acid production in normal human dermal fibroblasts<sup>[21]</sup>.

The hydration evidence should nevertheless be reported with its counterweights. The two Akhtar studies<sup>[19-20]</sup> originate from the same research group, use the same 3% extract concentration and the same 8-week design, and cannot be treated as independent replications. Furthermore, two other studies reviewed here found no hydration benefit: the 12-week saffron/avocado-oil cream trial reported no significant change in skin hydration<sup>[28]</sup>, and safranalinanoliposome studies showed no moisturisation advantage of 1% or 4% safranalin liposomes over empty liposomes<sup>[29]</sup>. The reasonable synthesis is that hydration benefit in a saffron cream is attributable to the combination of the vehicle and a suitably prepared style/stigma extract, and is not a property of isolated saffron volatiles.

#### 4.3 Smooth texture and extracellular-matrix preservation

Dermal texture and mechanical resilience depend strongly on collagen organisation, elastic fibres, proteoglycans, and glycosaminoglycans. Chronic ultraviolet exposure generates oxidative stress and alters fibroblast signalling, leading to collagen fragmentation and progressive deterioration of dermal extracellular matrix architecture<sup>[3,6-7]</sup>.

Safranalin provides a complementary matrix-preservation mechanism. In cell-free biochemical assays, Madan and Nanda observed dose-responsive antioxidant activity together with inhibition of collagenase, elastase, and hyaluronidase, with IC<sub>50</sub> values of 9.4, 43.6, and 70 µg/mL respectively; the same study reported a DPPH IC<sub>50</sub> of 22.7 µg/mL and an in-vitro sun protection factor of 6.6<sup>[22]</sup>. Because safranalin is a characteristic volatile of saffron style/stigma chemistry, these findings support a mechanistic link between Kumkuma-derived volatiles and preservation of proteins and glycosaminoglycans associated with youthful-looking skin. As isolated-enzyme data, they sit at Tier 3 and the reported in-vitro sun protection factor must not be presented as a sunscreen claim.

A chemically characterised whole-saffron extract provides broader skin-relevant evidence. Xiong and colleagues reported inhibition of tyrosinase and collagenase, stimulation of collagen and hyaluronic acid synthesis in normal human dermal fibroblasts, enhanced fibroblast migration, and antioxidant and anti-inflammatory activity in complementary cell assays<sup>[21]</sup>. This multidomain profile in normal human

skin cells is Tier 2 evidence and is highly relevant to the product's radiance, hydration, smoothness, antioxidant, and healthy-ageing positioning.

Human evidence also supports visible-ageing and elasticity endpoints. In a 12-week study involving 20 healthy volunteers, a topical cream containing saffron extract and avocado oil was associated with significant reductions in nasolabial-fold area and volume and significant increases in gross elasticity (R2) and net elasticity (R5). At least a one-grade improvement on the Global Aesthetic Improvement Scale was recorded in 30% of participants at week 6 and 45% at week 12, and no allergic reactions were reported<sup>[28]</sup>. Because the formulation also contained avocado oil, the study is best interpreted as supportive human evidence for a saffron-containing anti-ageing cream rather than as an isolated saffron effect.

#### 4.4 Oxidative environmental stress and photoageing

Oxidative stress is a central convergence point between ultraviolet exposure, pollution, inflammatory signalling, lipid oxidation, and matrix remodelling<sup>[4-7]</sup>. Saffron-derived compounds have a comparatively strong evidence base in this area.

Crocin has been evaluated in normal human epidermal keratinocytes and dermal fibroblasts, where it showed antioxidant and anti-inflammatory activity; in complementary lipid-oxidation assays reported in the same work, crocin limited UVA-driven peroxidation of squalene<sup>[30]</sup>. These findings are relevant to an antioxidant-rich face cream because they connect a characteristic saffron apocarotenoid with protection of both skin cells and an oxidation-prone surface lipid, while keeping the cellular and cell-free observations distinct.

Crocin also protected human dermal fibroblasts exposed to UVB: it improved proliferative recovery, reduced senescence-associated  $\beta$ -galactosidase-positive cells and intracellular reactive oxygen species, increased GPX-1 expression, and supported type I collagen expression<sup>[31]</sup>. A separate study found that crocetin reduced UVA-associated oxidative injury and cell death in skin in vitro and in vivo<sup>[32]</sup>. Together, these data strengthen the antioxidant and premature-visible-ageing rationale across both UVA- and UVB-related stress models. Of the endogenous antioxidant enzymes, only GPX-1 has been directly demonstrated to be upregulated by a saffron constituent in human skin cells; superoxide dismutase, catalase and Nrf2-pathway effects are not established in this context and are not claimed here.

A saffron compound essence applied to a UV-photoageing mouse model reduced wrinkle formation and altered skin thickness, collagen I/III, microcirculation, and ERK1/2-associated signalling<sup>[33]</sup>. Importantly, the study reported up-regulation—not suppression—of MMP-2 in the high-dose group. The paper should therefore not be cited as evidence of saffron-mediated MMP inhibition, and no study reviewed here demonstrates inhibition of MMP-1, MMP-2 or MMP-3 by saffron preparations in human skin. This distinction corrects a common overstatement in secondary summaries and is applied consistently throughout the present review.

Collectively, the evidence supports positioning Kumkuma-derived bioactives as cosmetic antioxidants that help defend skin against oxidative environmental stress associated with premature visible ageing. This rationale is supported across normal human keratinocytes, human dermal fibroblasts, biochemical enzyme systems, and topical-delivery models<sup>[22,30-32]</sup>. The claim is appropriately framed as antioxidant and photo-oxidative skin support rather than as a sunscreen or SPF claim.

#### 4.5 Soothing, visible redness, and inflammatory balance

Visible redness can reflect vascular reactivity, barrier stress, oxidative burden, and inflammatory signalling. In the 8-week human saffron-extract cream study, Mexameter erythema values improved significantly relative to the base formulation<sup>[19]</sup>. This provides direct human topical support for the cosmetic positioning of calming visible redness.

Mechanistic findings reinforce the human redness signal. A chemically characterised saffron extract reduced reactive oxygen species and nitric oxide generation in stimulated cell assays<sup>[21]</sup>, while crocin showed anti-inflammatory activity in normal human cutaneous cell models<sup>[30]</sup>. The available data characterise a general reduction in oxidative and inflammatory mediator output; specific transcription-factor or eicosanoid-pathway mechanisms such as NF- $\kappa$ B or MAPK inhibition, COX-2 or iNOS suppression, or mast-cell stabilisation have not been demonstrated for saffron preparations in human skin and are not claimed here.

These convergent human and mechanistic findings support cosmetic wording such as 'helps soothe skin' and 'helps reduce the appearance of redness associated with everyday environmental stress', while maintaining a clear distinction from therapeutic disease claims. They do not support any claim relating to rosacea, atopic dermatitis or other inflammatory dermatoses.

**Table 2. Human topical evidence relevant to saffron-containing cosmetic formulations, with preparation-specific limitations (Tier 1).**

| Study                                  | Preparation                                                   | Design                                            | Endpoints                                | Main finding                                                                            | Key limitation                                                                                               |
|----------------------------------------|---------------------------------------------------------------|---------------------------------------------------|------------------------------------------|-----------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| Akhtar et al., 2014 <sup>[19]</sup>    | 3% <i>C. sativus</i> stigma-derived extract W/O cream vs base | 10 healthy male volunteers, aged 25-40 y; 8 weeks | Mexameter melanin and erythema indices   | Percentage change in melanin -24.04 ± 3.23; erythema -13.57 ± 2.28; significant vs base | Small, single-sex cohort; base-cream comparator only; same group as <sup>[20]</sup>                          |
| Akhtar et al., 2014 <sup>[20]</sup>    | 3% <i>C. sativus</i> stigma-derived extract W/O cream vs base | Human volunteers; 8 weeks                         | Skin moisture; transepidermal water loss | Significant improvement in skin moisture with significant TEWL change vs control        | Small study; shares design, group and concentration with <sup>[19]</sup> , so not an independent replication |
| Naeimifar et al., 2020 <sup>[28]</sup> | Saffron extract + avocado oil                                 | 20 healthy volunteers; daily for 12               | GAIS; nasolabial-fold area and           | Reduced nasolabial-fold area and volume;                                                | Multi-ingredient cream, so effects not attributable                                                          |

|                        |       |                                           |                                                                                                                            |                                                                    |
|------------------------|-------|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| O/W anti-wrinkle cream | weeks | volume; biophysical parameters; cutometry | R2 and R5 elasticity improved; $\geq 1$ -grade GAIS improvement in 30% at week 6 and 45% at week 12; no allergic reactions | to saffron alone; reported no significant change in skin hydration |
|------------------------|-------|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|

*GAIS, Global Aesthetic Improvement Scale (reported as GIAS in the source publication); O/W, oil-in-water; TEWL, transepidermal water loss; W/O, water-in-oil.*

**Table 3. Verified mechanistic and cutaneous preclinical evidence used for claim plausibility, with plant-part, preparation and tier assignment indicated.**

| Study                               | Test material                            | Model                                                                                    | Tier   | Principal finding                                                                                                       | Translational interpretation                                                                                                 |
|-------------------------------------|------------------------------------------|------------------------------------------------------------------------------------------|--------|-------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| Li & Wu, 2002 <sup>[18]</sup>       | Stigma-derived compounds                 | Mushroom tyrosinase assay                                                                | Tier 3 | Crocusatin H, crocin-1 and crocin-3 inhibited tyrosinase                                                                | Pigmentation mechanism in a non-human enzyme screening system                                                                |
| Xiong et al., 2023 <sup>[21]</sup>  | Chemically characterised saffron extract | Tyrosinase/collagenase assays; normal human dermal fibroblasts; inflammatory cell assays | Tier 2 | Tyrosinase and collagenase inhibition; collagen and hyaluronic-acid synthesis; fibroblast migration; reduced ROS and NO | Multidomain whole-saffron evidence in normal human skin cells supporting tone, hydration, smoothness and antioxidant defence |
| Fagot et al., 2018 <sup>[30]</sup>  | Crocin                                   | Normal human keratinocytes and fibroblasts; UVA squalene peroxidation assay              | Tier 2 | Antioxidant and anti-inflammatory effects in cells; protection of squalene from UVA peroxidation                        | Normal human skin-cell support for antioxidant-rich and photo-oxidative-stress positioning                                   |
| Deng et al., 2018 <sup>[31]</sup>   | Crocin                                   | UVB-exposed human dermal fibroblasts                                                     | Tier 2 | Reduced ROS and senescence markers; increased GPX-1; supported type I collagen                                          | Human fibroblast support for antioxidant defence and preservation of youthful-looking matrix biology                         |
| Madan & Nanda, 2018 <sup>[22]</sup> | Safranal                                 | Cell-free enzyme and radical-scavenging assays                                           | Tier 3 | Anti-collagenase, anti-elastase and anti-hyaluronidase activity; antioxidant activity                                   | Volatile-constituent support for matrix-enzyme inhibition; in-vitro SPF value is not a sunscreen claim                       |

|                                             |                          |                                                    |        |                                                                                       |                                                                                                |
|---------------------------------------------|--------------------------|----------------------------------------------------|--------|---------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| Li et al., 2022 <sup>[33]</sup>             | Saffron compound essence | UV-photoageing mouse skin                          | Tier 3 | Wrinkle, collagen and ERK1/2 effects; MMP-2 up-regulated in the high-dose group       | Animal model of a multicomponent formulation; does not support an MMP-inhibition claim         |
| Ohba et al., 2016 <sup>[32]</sup>           | Crocetin                 | UVA-exposed skin cells in vitro and in vivo        | Tier 3 | Reduced UVA-associated oxidative stress and cell death                                | Constituent-level support for photo-oxidative protection                                       |
| Hashemi-Shahri et al., 2018 <sup>[27]</sup> | Crocetin                 | B16F10 murine melanoma cells                       | Tier 3 | Reduced tyrosinase activity, melanin content, MITF expression and ROS                 | Melanogenic mechanism in a murine melanoma line; no evidence for MITF regulation in human skin |
| Alemzadeh & Oryan, 2018 <sup>[34]</sup>     | Saffron extract          | Rat burn wounds and human dermal fibroblast assays | Tier 3 | Repair, fibroblast proliferation and migration, cytokine and growth-factor modulation | Repair biology only; not cosmetic efficacy                                                     |

## 5. Topical Delivery and Formulation Science

Biological activity measured in solution does not guarantee efficacy after topical application. A compound must remain stable in the vehicle, be released from that vehicle, partition into or onto the relevant skin compartment, and remain at an effective local concentration. These considerations are particularly important for saffron because the relevant constituents span a wide polarity range, from hydrophilic crocin to relatively lipophilic volatile safranal.

Safranal has been incorporated into nanoliposomes and evaluated for skin penetration and retention and by human corneometry. Golmohammadzadeh et al. found low penetration of a 1% liposomal safranal formulation and no significant difference in skin moisture content between 1% and 4% safranal liposomes and empty liposomes<sup>[29]</sup>. This indicates that a lipid carrier can alter localisation without necessarily creating a hydration benefit attributable to safranal itself, and it is an important negative result for any claim built on saffron volatiles alone.

Safranal-loaded solid lipid nanoparticles have also been developed. Khameneh et al. reported mean particle sizes of approximately 106 nm by probe sonication and 233 nm by high-pressure homogenisation, encapsulation efficiency of around 70%, and increasing in-vitro SPF values with increasing safranal content<sup>[35]</sup>. These results show formulation feasibility but must not be used to imply clinical sunscreen protection.

Crocin poses a different problem because of its hydrophilicity, molecular size, and susceptibility to degradation. Esposito et al. developed monoolein-based nanostructured lipid dispersions and showed in Franz-cell experiments that the systems could control crocin diffusion through skin, reduce degradation, and prolong antioxidant activity<sup>[36]</sup>. The study is a strong demonstration that topical delivery systems can materially change the cutaneous behaviour of saffron-derived molecules.

For Biotex Saffron Cream, the formulation-development priority should be to characterise the actual marker compounds in Kumkuma (*Crocus sativus* L.) (Sty. & Stg.) and then select release or skin-retention assays that match those markers. Because style/stigma material can contain both nonvolatile apocarotenoids and volatile aroma constituents depending on processing, a combined HPLC/LC-MS and GC-MS fingerprint is scientifically preferable where feasible. Crocin, crocetin and picrocrocin can be followed by LC-based methods, whereas safranal is better evaluated by GC-based methods. These data would clarify which literature-derived mechanisms are most directly transferable to the finished cream.

**Table 4. Topical-delivery and formulation studies for saffron-derived constituents. These studies support delivery feasibility rather than finished-product efficacy.**

| Delivery system                  | Saffron-derived material | Evaluation                                               | Interpretation                                                                                                                 |
|----------------------------------|--------------------------|----------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|
| Nanoliposomes                    | Safranal                 | Mouse-skin diffusion and retention; human corneometry    | Topical localisation demonstrated; no moisturisation advantage over empty liposomes at the doses tested <sup>[29]</sup>        |
| Solid lipid nanoparticles        | Safranal                 | Particle characterisation; in-vitro SPF; corneometry     | Approximately 70% encapsulation; feasible topical carrier; in-vitro UV data are not equivalent to clinical SPF <sup>[35]</sup> |
| Nanostructured lipid dispersions | Crocin                   | Franz-cell skin diffusion, stability, antioxidant assays | Controlled diffusion, reduced degradation and prolonged antioxidant activity <sup>[36]</sup>                                   |
| Conventional W/O or O/W creams   | Saffron extracts         | Human topical studies                                    | Measurable tone, hydration and wrinkle/elasticity endpoints depend on both active and vehicle <sup>[19-20,28]</sup>            |

## 6. Product-Relevant Evidence Appraisal for Biotex Saffron Cream

The available evidence is favourable but heterogeneous, and no published study has evaluated the Biotex formulation itself. The evidence base includes direct stigma studies, a style-specific phytochemical study, whole saffron-extract studies, human topical saffron formulations, and isolated-constituent investigations; each level is interpreted according to its preparation. Because the declared Biotex ingredient is Kumkuma (*Crocus sativus* L.) (Sty. & Stg.), these studies are more directly relevant at the botanical-source level than they would be for a narrowly defined essential-oil ingredient. The proper translational question is whether the evidence forms a coherent, scientifically credible rationale for the intended cosmetic benefits, not whether every published saffron effect can automatically be claimed for the product.

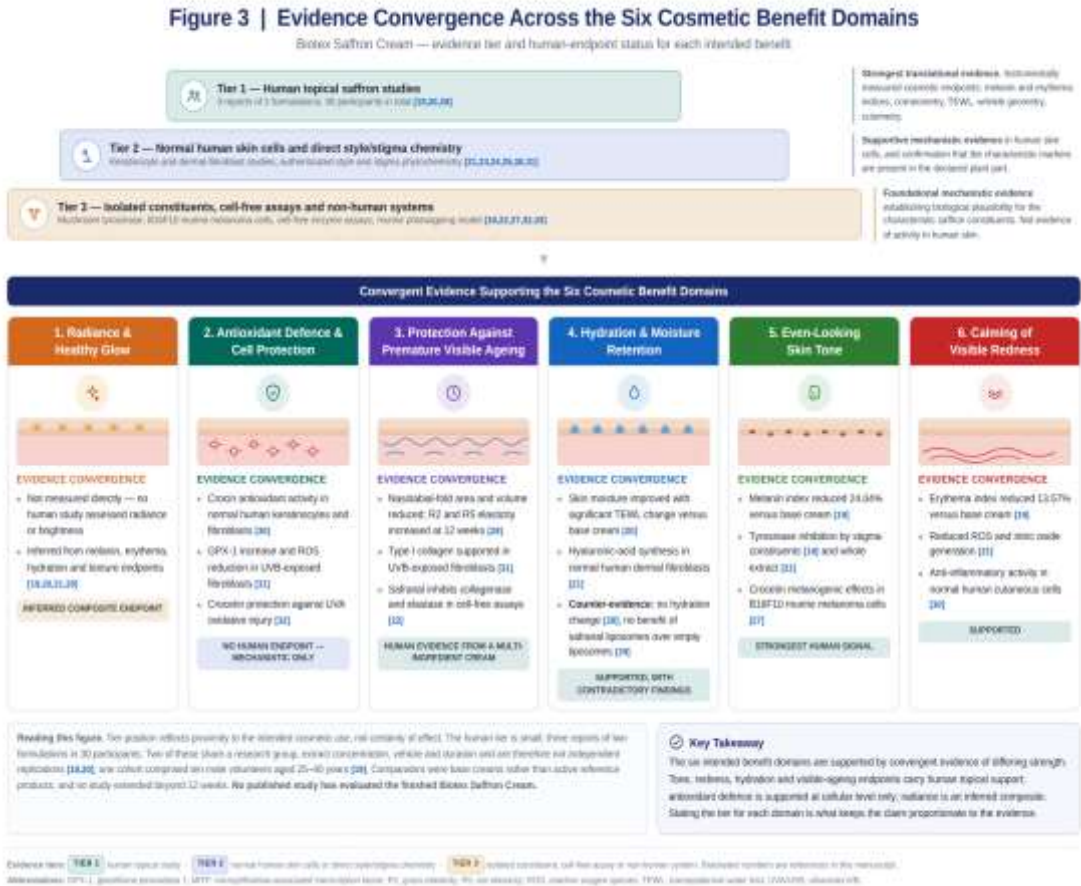


**Product Image.** Biotex Saffron Cream, the finished formulation to which this ingredient-level appraisal refers. Illustrative only; not evidence of efficacy.

For radiance and even-looking tone, the evidence is supported by a human saffron-extract cream study showing significant changes in instrumental melanin and erythema measurements, together with stigma-derived tyrosinase-inhibitory compounds and complementary whole-saffron and crocetin mechanisms<sup>[18-19,21,27]</sup>. The combined evidence supports the appearance of a brighter and more uniform complexion.

For hydration, the most directly relevant human topical evidence shows significant improvement in skin moisture together with changes in transepidermal water loss parameters after repeated use of a 3% *C. sativus* extract cream<sup>[20]</sup>. This supports positioning Biotex Saffron Cream as helping improve hydration and moisture retention, with the cream vehicle and Kumkuma-derived activity acting as complementary contributors.

For visible redness, human erythema measurements provide direct topical support, while whole-saffron extract and crocin studies add antioxidant and inflammatory-balance mechanisms<sup>[19,21,30]</sup>. This combination supports the cosmetic positioning 'helps calm visible redness and soothe stressed-looking skin.' For protection against premature visible ageing, the evidence is strongest at the mechanistic level because normal human skin cells show crocin- and crocetin-associated protection against photo-oxidative stress, while safranal inhibits collagenase, elastase, and hyaluronidase in cell-free systems<sup>[22,30-32]</sup>.



**Fig 3:** Evidence convergence across the six cosmetic benefit domains of Biotex Saffron Cream, giving the evidence tier, supporting references and human-endpoint status for each. Radiance is an inferred composite endpoint; the hydration domain records contradictory findings. No published study has evaluated the finished product.

**Table 5. Claim-to-evidence translation for Biotex Saffron Cream using a preparation-aware evidence hierarchy.**

| Proposed benefit                   | Evidence basis                                                                               | Highest tier available | Strength                                                       | Publication-defensible wording                                                 |
|------------------------------------|----------------------------------------------------------------------------------------------|------------------------|----------------------------------------------------------------|--------------------------------------------------------------------------------|
| Promotes visible radiance and glow | Human melanin and erythema study plus hydration and texture mechanisms <sup>[19-21,28]</sup> | Tier 1 + Tier 2        | Good convergent support; radiance itself not directly measured | Helps promote visibly radiant, healthy-looking skin and a natural-looking glow |
| Promotes an even skin tone         | Human melanin reduction plus stigma tyrosinase inhibition <sup>[18-19,21]</sup>              | Tier 1 + Tier 3        | Good                                                           | Helps promote a more even-looking skin tone                                    |

|                                                                     |                                                                                                                                  |                 |                                                                                  |                                                                                                                         |
|---------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|-----------------|----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| Promotes smooth texture                                             | Human wrinkle and elasticity study plus collagen/HA and matrix-enzyme evidence <sup>[21-22,28]</sup>                             | Tier 1 + Tier 2 | Good                                                                             | Helps support smoother, more supple, youthful-looking skin                                                              |
| Hydrates and helps retain moisture                                  | Human moisture and TEWL study plus hyaluronic acid synthesis evidence <sup>[20-21]</sup>                                         | Tier 1 + Tier 2 | Moderate-to-good; two other studies found no hydration effect <sup>[28-29]</sup> | Helps improve hydration and moisture retention                                                                          |
| Calms visible redness                                               | Human erythema reduction plus oxidative and inflammatory evidence <sup>[19,21,30]</sup>                                          | Tier 1 + Tier 2 | Moderate-to-good                                                                 | Helps calm visible redness and soothe stressed-looking skin                                                             |
| Antioxidant defence and protection against premature visible ageing | Normal human skin-cell oxidative protection, crocetin UVA protection and safranin matrix-enzyme inhibition <sup>[22,30-32]</sup> | Tier 2 + Tier 3 | Strong mechanistic support; no human endpoint in this domain                     | Provides antioxidant skin support and helps defend against oxidative stressors associated with premature visible ageing |

*No claim in this table is supported by a study of the finished Biotex Saffron Cream. Wording in the final column is proposed as ingredient-level, appearance-based cosmetic language and is not a therapeutic claim.*

### 6.1 Interpreting ingredient-level evidence at product level

The evidence appraised above is ingredient-level evidence. Its transferability to any finished cream is governed by three variables that are properties of the formulation rather than of the botanical literature.

The first is the material actually present. Because style/stigma material can yield both nonvolatile apocarotenoids and volatile aroma constituents depending on processing<sup>[8-9,14-16]</sup>, the marker profile of a given raw material determines which of the four evidence classes set out in Figure 1 most nearly applies to it. A crocin-rich hydroalcoholic extract and a hydrodistilled volatile fraction are supported by different bodies of evidence, and neither inherits the other's.

The second is concentration and vehicle. The human topical studies reviewed here used a 3% extract in a water-in-oil cream and a saffron-and-avocado-oil oil-in-water cream, and both reported effects attributable to the vehicle as well as the active<sup>[19-20,28]</sup>. Ingredient-level evidence therefore constrains what is plausible for a formulation rather than establishing what is demonstrated for it.

The third is stability. Crocins and saffron volatiles are sensitive to light, oxygen, temperature and storage<sup>[9,16,26]</sup>, so the exposure delivered to skin across a product's shelf life is a function of formulation and packaging, not of the raw material alone.

For these reasons, the present review is framed throughout as an appraisal of Kumkuma (*Crocus sativus* L.) (Sty. & Stg.) as a cosmetic active, and the claim wording proposed in Table 5 is expressed as ingredient-supported, appearance-based language.

## 7. Safety and Dermatological Tolerability

Human topical tolerability data for saffron-containing creams are reassuring as far as they extend. In the 12-week study of a saffron-extract and avocado-oil cream, no allergic reactions were reported among the

20 participants<sup>[28]</sup>. No safety signal was identified in the other human topical studies reviewed<sup>[19-20]</sup>. However, the total human exposure represented by the topical literature reviewed here is approximately 30 participants across two formulations, neither of which is the Biotex product, and none of these studies was designed or powered as a safety study.

Saffron is a well-characterised food botanical with a long history of dermal and culinary use, and reported cutaneous hypersensitivity is uncommon. Nonetheless, botanical extracts are a recognised source of contact sensitisation, and volatile constituents in particular warrant attention. Where processing of the style/stigma material yields a volatile-enriched fraction, any resulting fragrance-allergen constituents that are subject to declaration thresholds under applicable cosmetic regulations should be quantified and labelled accordingly. As with other botanical face creams, consistent raw-material identity, formulation stability, microbiological quality, oxidation control and excipient compatibility remain relevant to maintaining product quality and tolerability.

For a leave-on facial product, dermatological substantiation on the finished formulation is the appropriate standard. Human repeat-insult patch testing or equivalent tolerability assessment under dermatological supervision, together with cumulative irritation and, where relevant, ocular-area compatibility assessment, is the conventional standard for a leave-on facial cosmetic. The product is a cosmetic and should be developed, labelled and marketed within the applicable cosmetic regulatory framework in each market of sale; no claim reviewed here supports a therapeutic indication, and the in-vitro sun protection factor values reported for isolated safranin preparations<sup>[22,35]</sup> do not support any sun-protection claim for the finished cream.

Broader repair-model studies are considered only as contextual evidence for fibroblast activity, oxidative balance and tissue-repair biology; the principal cosmetic conclusions in this review are anchored instead to human topical saffron studies and skin-relevant cellular evidence<sup>[34]</sup>.

## 8. Evidence Integration and Translational Relevance

The botanical identity is well defined: Kumkuma (*Crocus sativus* L.) (Sty. & Stg.) corresponds to the style/stigma material from which the characteristic saffron apocarotenoids and volatiles arise. Direct style and stigma studies confirm crocins, picrocrocin, safranin, and related metabolites in these tissues<sup>[23-25]</sup>. This botanical alignment substantially strengthens the relevance of the saffron literature to the declared Biotex ingredient.

Across the literature, preparation and concentration vary, but the direction of evidence is notably consistent: saffron style/stigma extracts and their characteristic constituents demonstrate antioxidant, pigmentation-modulating, matrix-supportive, hydration-associated and soothing activities in complementary experimental systems<sup>[18-22,27-28,30-32]</sup>. This consistency across preparation classes supports a robust ingredient-level biological rationale, while the heterogeneity of preparations is itself a reason for caution in transferring any single result to a specific finished product.

The human topical literature is encouraging and directly relevant at the saffron-ingredient level. The strongest studies demonstrate measurable effects on pigmentation and erythema, hydration and barrier parameters, and visible-ageing and elasticity endpoints in saffron-containing creams<sup>[19-20,28]</sup>. These findings provide a clinically anchored rationale for the intended cosmetic positioning of Biotex Saffron Cream, subject to the cohort and design limitations set out in Section 9.

Antioxidant photoprotection should be distinguished from sunscreen efficacy. The reviewed evidence supports protection against photo-oxidative stress through control of reactive oxygen species, inflammatory modulation, squalene protection, and matrix-preserving mechanisms<sup>[22,30-32]</sup>; accordingly, the product rationale is strongest when framed around antioxidant defence rather than SPF.

Third, endpoint substitution is a genuine risk in this literature. Radiance, glow and brightness were not measured as instrumental endpoints in any included human study; they are inferred from melanin, erythema, hydration and texture measurements. The antioxidant and premature-visible-ageing domain rests on cellular and biochemical evidence with no corresponding human endpoint.



Fourth, much of the mechanistic evidence derives from isolated constituents or non-human systems. Mushroom tyrosinase<sup>[18]</sup>, B16F10 murine melanoma cells<sup>[27]</sup>, cell-free enzyme assays<sup>[22]</sup> and a murine photoageing model<sup>[33]</sup> establish plausibility, not cutaneous activity in humans. Several mechanisms frequently attributed to saffron in secondary sources are not supported by the primary literature reviewed here and are deliberately excluded: MITF, TRP-1 and TRP-2 regulation in human skin; inhibition of MMP-1, MMP-2 or MMP-3; Nrf2, superoxide dismutase or catalase induction; NF-κB, MAPK, COX-2 or iNOS pathway inhibition; mast-cell stabilisation; anti-glycation activity; and effects on cutaneous microcirculation in humans.

Fifth, this is a narrative rather than a systematic review. Although the search was structured and the bibliographic identity of every cited source was verified, study selection was not performed in duplicate, no formal risk-of-bias tool was applied, and the possibility of selection bias in favour of positive findings cannot be excluded. Publication bias in the botanical cosmetic literature is likely to favour positive results.

Sixth, all authors are employed by the manufacturer of the product under discussion. This competing interest is declared in full below. It has been mitigated by restricting every conclusion to the preparation actually studied, by reporting negative and contradictory findings<sup>[28-29,33]</sup> alongside supportive ones, and by verifying each cited reference against the primary record; it cannot be eliminated, and readers should weigh the conclusions accordingly.

## 10. Discussion

Saffron has a comparatively broad cosmeceutical evidence base spanning human topical use, normal human skin-cell studies, direct enzyme assays, formulation science, and well-developed analytical chemistry. The convergence of these evidence types provides a stronger basis for cosmetic positioning than reliance on traditional use alone.

At the same time, the evidence highlights why botanical reviews must be chemically disciplined. The strongest human pigmentation and moisturising studies used saffron style/stigma extracts, which are directly relevant at the botanical-source level but are not equivalent to the finished Biotex formulation. Crocin and crocetin evidence can appropriately be considered stigma-derived constituent evidence, while safranal represents the volatile fraction of saffron chemistry. Both evidence streams can contribute to the rationale for Kumkuma (*Crocus sativus* L.) (Sty. & Stg.), provided analytical testing establishes which markers are present and at what concentrations in the Biotex raw material and finished cream<sup>[14-15,22,30-31]</sup>.

The six intended benefit domains of Biotex Saffron Cream are supported by complementary evidence of differing strength. Radiance and even-looking tone are anchored by human instrumental melanin and erythema data and tyrosinase-related mechanisms<sup>[18-19,21,27]</sup>. Hydration is supported by an 8-week human moisture and TEWL study and by saffron-extract stimulation of hyaluronic-acid synthesis in normal dermal fibroblasts<sup>[20-21]</sup>, while acknowledging two studies that found no hydration effect<sup>[28-29]</sup>. Healthy-ageing appearance and smoothness are supported by the 12-week human wrinkle and elasticity study together with collagen, collagenase, elastase and hyaluronidase evidence<sup>[21-22,28]</sup>. Antioxidant defence is supported by normal human keratinocyte and fibroblast studies of crocin and crocetin under UVA- and UVB-associated stress<sup>[30-32]</sup>. Visible-redness calming is supported by the human erythema signal and complementary antioxidant and inflammatory-balance findings<sup>[19,21,30]</sup>.

A recurring problem in the secondary saffron literature is the accumulation of mechanistic claims that the primary sources do not support. The MMP-2 result of Li et al. is a useful illustration: the high-dose group showed up-regulation, yet the study is frequently cited as evidence of saffron-mediated MMP inhibition<sup>[33]</sup>. A preparation-aware, source-verified approach of the kind applied here is therefore not merely a formal exercise; it materially changes which claims survive scrutiny.

The appropriate scholarly interpretation is that the current literature provides a coherent, multi-level evidence base for Kumkuma as a cosmetic active. Direct style/stigma chemistry, human topical saffron studies, normal human skin-cell experiments, and constituent-level mechanistic studies converge on pigmentation balance, hydration, extracellular-matrix support, soothing, and antioxidant defence. This convergence is compatible with, and supportive of, the intended positioning of Biotex Saffron Cream, and it defines a clear and achievable programme of product-specific work.

## 11. Conclusion

The available literature supports Kumkuma (*Crocus sativus* L.) style and stigma as a scientifically credible botanical foundation for an antioxidant-rich face cream. Human saffron-containing cream studies demonstrate skin-relevant effects on melanin and erythema indices, moisture and TEWL parameters,

wrinkle geometry, and elasticity<sup>[19-20,28]</sup>. Complementary skin-cell and biochemical research links saffron extracts and characteristic constituents to tyrosinase and collagenase inhibition, collagen and hyaluronic-acid synthesis, antioxidant defence, and inhibition of collagenase, elastase, and hyaluronidase<sup>[18,21-22,27,30-32]</sup>.

Taken together, these findings provide an internally consistent, ingredient-level scientific rationale for Biotex Saffron Cream and its intended cosmetic positioning: promoting visible radiance, delivering antioxidant-rich skin support, helping protect against processes associated with premature visible ageing, improving hydration and moisture retention, supporting a more even-looking tone, and calming the appearance of redness. The evidentiary strength arises from convergence across direct style/stigma chemistry, human topical saffron studies, normal human skin-cell experiments, and complementary constituent-level mechanisms<sup>[18-25,27-28,30-32]</sup>.

What this review establishes is an ingredient-level rationale. The evidence assembled here characterises Kumkuma (*Crocus sativus* L.) style and stigma as a cosmetic active with convergent support across four evidence classes; it is not, and does not purport to be, efficacy data for the finished formulation. The cosmetic wording proposed in Table 5 is framed accordingly and represents the limit of what the current evidence base will defensibly support.

## Declarations

### Author contributions

All authors contributed to the conception of the review, literature appraisal, evidence grading, dermatological interpretation, reference verification, manuscript drafting and critical revision. All authors reviewed and approved the final manuscript and agree to be accountable for the accuracy and integrity of the work.

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## Competing interests

All authors are employed by Biotex Life Solutions Pvt. Ltd., the developer and prospective commercial beneficiary of Biotex Saffron Cream. This constitutes a significant competing interest. No independent or external author contributed to the evidence appraisal. To mitigate this, evidence in this review is attributed to the exact saffron preparation studied, negative and contradictory findings are reported alongside supportive ones, the bibliographic identity and content of every cited source were verified against the primary record, and no efficacy claim is made for the finished product. Readers should nonetheless interpret the conclusions in light of this affiliation.

## Ethics approval

Not applicable. This article is a review of published literature and did not involve recruitment of human participants or new animal experimentation.

## Data availability

No new datasets were generated. All scientific evidence discussed in this review is derived from the cited published literature.

## Use of AI-assisted tools

AI-assisted tools were used to support literature organisation, reference cross-checking, language editing, manuscript formatting and figure development. Bibliographic details, scientific interpretations, evidence grading, and the final text were reviewed and approved by the authors. AI-assisted output was not treated as a primary scientific source, and the authors accept full responsibility for the content of the manuscript.

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