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Bix'Activ® for decreased sebum production

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Oily skin affects about 35 percent of people worldwide. However, solutions for this condition are often ineffective for many consumers because skin has a different composition of oil and lipids depending on ethnicity. This shows the urgent need for personal care products that are suitable for the requirements of all skin types – and a clinical study on people with African skin has now confirmed that BASF's plant-based active ingredient Bix'Activ® [1] is a truly multiethnic solution for oily skin.

Oily skin, known as *seborrhea*, occurs when the sebaceous glands produce excessive amounts of an oil-like substance called sebum that waterproofs and lubricates the skin to protect it from becoming dry. This can be triggered by hormonal changes, as well as by lifestyle factors like stress or a rich diet, or even by environmental factors like weather and air pollution. Oily skin often looks shiny and pores can become enlarged, which makes them more susceptible to getting clogged up. This can lead to inflammation and imperfections such as blemishes or acne. As a result, many people affected by *seborrhea* state that they suffer from a negative self-image and feel like their skin is dirty [2].

Up to 80 percent of people in their teens and early twenties are affected by oily skin [3], and it remains a concern for around 35 percent of people into their thirties and beyond – regardless of their location, gender or ethnicity. However, even though it is known that different ethnic groups have different structures of the epidermis and dermis, many of the topical skin care solutions available today are not effective on

all skin types. This is a particular problem for African people, whose skin tends to produce more sebum – and there is a severe lack of customized solutions that respond to the unique needs of this target group.

Demand for these products in Africa is increasing rapidly, driven by other factors such as the growing middle class and increasing levels of disposable income among consumers in this region. In fact, Africa is expected to be home to some of the world's fastest-growing economies in the coming years, with growth rates far above the global average. It is the world's second most populous continent and is expected to command more than 20 percent of the global population by 2025. The market for beauty and personal care products in Africa grew by 14 percent in 2017, with consumers placing a particularly strong focus on brands that offer customized products [4]. Altogether, this means a huge number of people with African skin want an effective solution for oily skin – and are willing and able to pay for it.

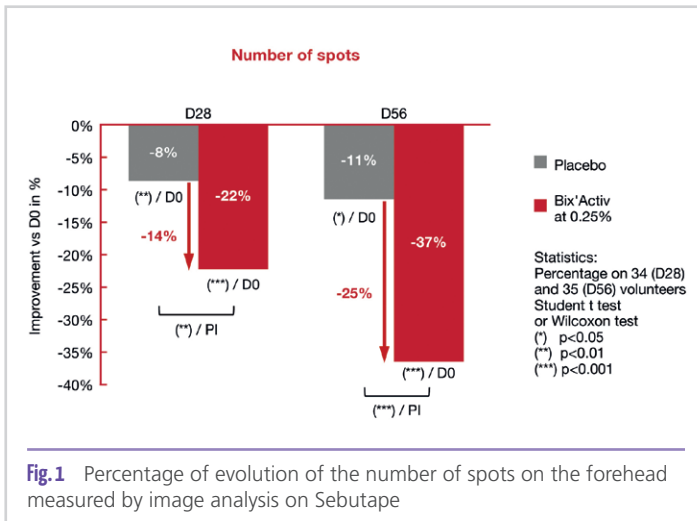
A multi-ethnic solution for oily skin

BASF is committed to providing innovative solutions that respond to the unique needs of people around the world, across all genders and ethnicities. That's why its research teams have created the active ingredient Bix'Activ®. It targets the main pathways that trigger oily skin by reducing sebum overproduction in sebaceous glands, decreasing the size of pores and acting against *Cutibacterium acnes* (*C. acnes*), a bacterium that colonizes the sebaceous glands and can lead to skin imperfections.

Bix'Activ is obtained through an environmentally compatible process that uses water as a solvent. It is extracted from seeds of the *Bixa orellana* plant, commonly known as the red lip tree, an evergreen shrub with white and pink flowers that produces inedible fruit and clusters of seed pods. Each pod contains many seeds that are covered with a thin layer of aril. At maturity, the pods dry out and harden before splitting open to expose the seeds. BASF extracts Bix'Activ from the grinded seeds of the *Bixa orellana*, and then standardizes and concentrates it to create a preservative-free powder with maltodextrin (30-50 percent *Bixa orellana* seed extract; 50-70 percent maltodextrin).

Initial *in vivo* study on Asian skin types

In 2018, a double-blind, randomized, split-face, placebo-controlled clinical study was performed on 35 Asian females. These participants were aged between 20 and 45, all showing a lipidic index of $\geq 120 \mu\text{g}/\text{cm}^2$ on the face (measured with a Sebumeter) and presenting cheek sebaceous pores graded between 2 and 4 (*R. Bazin / F. Flament, Skin Aging Atlas*). Twice a day for 56 days, they applied a formulation containing 0.25 percent active ingredient on one half of the face and a placebo on the other half of the face. These *in vivo* tests



examined the plant extract's ability to reduce sebum production, pore size and skin imperfections. Measurements were taken at Day Zero, Day 28 and Day 56. Sebum production was measured with a sebum-sensitive adhesive film called Sebupape and then image analysis was performed using binary images of sebum droplet distribution on this tape. The level of sebum and sebum density on each measuring day were calculated and then compared to the placebo formulation. After 28 days of treatment with Bix'Activ at 0.25%, the number of spots significantly decreased by 22% vs baseline and 14% vs placebo. After 56 days of treatment, it significantly decreased by 37% vs baseline (p<0.001) and 25% vs placebo (p<0.001) (Fig. 1).

The active ingredient was able to have this effect without dehydrating the skin, which is extremely important because sebum plays a key role in keeping the skin flexible and preventing water loss from the body. This study also evaluated the size of the pores on the participants' cheeks. After 28 and 56 days, a qualified evaluator provided a visual clinical score for the sebaceous pores before and after the product was applied. This was scored using the scale described in the Skin Aging Atlas (Bazin) that rates pores on six grades, from zero (not visible) to six (very visible). After 28 days, the active ingredient (0.25 percent concentration)

had visibly reduced the size of the sebaceous pores by 3% vs baseline, and it further decreased pore size for a total reduction of 9% vs baseline and 3% vs placebo by Day 56. On top of this, the participants also reported a reduction in pore size during self-assessment. They perceived their pores to have become smaller and less visible. The participants also stated that they felt their skin appeared healthier. And the *in vivo* tests showed that skin imperfections such as blemishes and pimples were significantly reduced by the active ingredient (0.25 percent concentration).

New *in vivo* tests on African skin types

As part of BASF's strong focus on responding to the unique needs of people worldwide, a second clinical study that directly examined the efficacy of Bix'Activ on oily skin for African skin types has now been completed. This double-blind, randomized, split-face, placebo-controlled study was performed on 29 black men and women (phototypes V and VI). The participants were aged from 19 to 40 years old. They all had oily skin (Lipidic index $\geq 100 \mu\text{g}/\text{cm}^2$, measured with a Sebumeter), as well as shiny skin. Twice a day for 28 days, the participants applied Bix'Activ (0.25 percent concentration) to one half of their faces and a placebo formula to the other half. Measurements were taken on Day Zero and Day 28.

The Bix'Activ (0.25 percent concentration) formula was shown to decrease the quantity of sebum excreted on the skin surface by 44 percent compared to the baseline and by 12 percent compared to the placebo after 28 days (Fig. 2).

The study also showed a mattifying effect that reduced shininess by 11 percent compared to the first day of the study. This was measured using a glossymeter on the forehead to measure the fraction of light being reflected directly from the skin, as well as the scattered fraction of reflected light (Fig. 3). In addition, the study confirmed that Bix'Activ (0.25 percent concentration) preserves the hydration of the skin on the

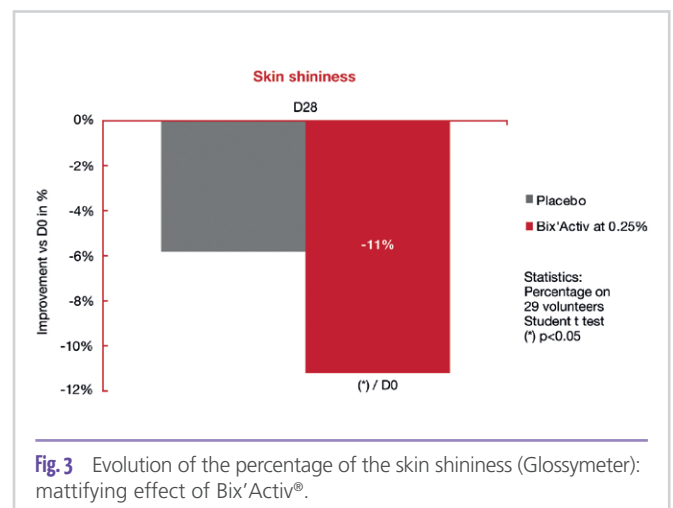
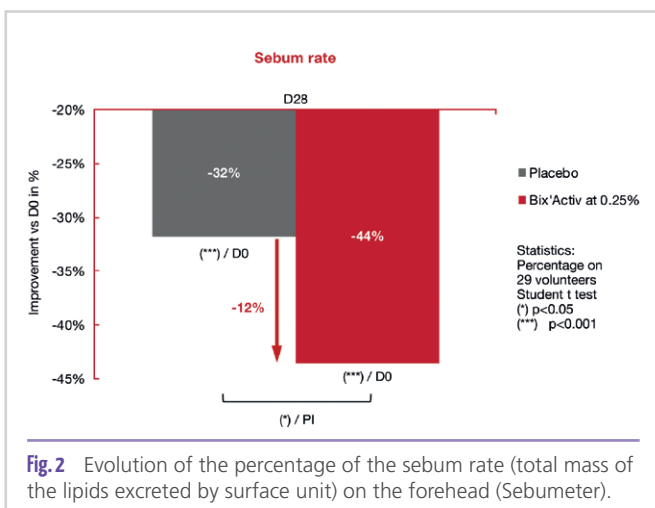




Fig. 4 Illustrative pictures of skin shininess, before (D0) and after treatment with Bix'Activ® at 0.25% for 28 days.

cheeks. Using a Corneometer, the study showed no significant difference in hydration levels between Day Zero and Day 28. This demonstrates that the active ingredient can be used to treat oily skin on African skin types without causing skin dryness.

In the self-assessment questionnaire, a significant majority of the participants also stated that Bix'Activ had improved the overall appearance of their skin. 93 percent perceived their skin to be less oily after 28 days, with 97 percent stating that they felt their skin was hydrated and not dry. And 90 percent of participants felt that their pores had tightened, while the same percentage said they felt that the active had reduced imperfections such as pimples or blemishes. Taken together with the results of the study, these self-assessments show that Bix'Activ (0.25 percent concentration) has a capacity to improve the appearance of oily skin, creating a mattified and healthy appearance on African skin types (Fig. 4).

Conclusion

Bix'Activ offers a multi-ethnic solution to the problem of oily skin, which affects 35 percent of people worldwide. The active ingredient from BASF, which is extracted from *Bixa orellana* seeds, is 100-percent from natural origin. Moreover, it is COSMOS and ECOCERT-approved, and is also suitable for use in NATRUE-certified formulations. *In vivo* tests on Asian and African skin types have demonstrated that Bix'Activ slows down sebum production, decreases the size of pores and reduces blemishes, while also reducing shininess and keeping the skin moisturized. It is proven to reduce the number and size of active sebaceous glands from Day 28 onwards, which has an overall effect that beautifies the skin.

In particular, Bix'Activ has now demonstrated its efficacy for African skin types. This addresses a significant gap in the personal care market, as many currently available topical skin care solutions for African skin are too harsh and further in-

duce sebum production. The new data shows that this active ingredient is suitable for all ethnicities, with clinical tests and self-assessments both clearly indicating a positive impact on oily skin among study participants with African skin types.

Bix'Activ is one example of BASF's overall strategy of developing customer-oriented solutions that address the unique needs of people worldwide. With the market for beauty and personal care products in sub-Saharan Africa widely predicted to achieve highly attractive growth in the coming years, Bix'Activ has the potential to meet rising demand for customized solutions that are specifically targeted at consumers in this region. BASF will continue its research and development activities to make sure it meets the specific needs of consumers around the globe.

Formulations

Mattifying Cream (SC-FR-18-BC-50802-07) (see appendix)

Pore Refining Toner (SC-FR-18-BC-50848-01) (see appendix)

References

- [1] The trademarks symbolized with a ® or ™ are either property of or licensed to BASF group and registered and/or applied for registration in relevant countries. Other product names and trademarks mentioned may belong to third parties.
- [2] Sakuma, Thais Harumi and Howard Ira Maibach. Oily Skin: An Overview. *Skin Pharmacol Physiol.* 25(5):227-35, 2012.
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Mattifying Cream | SC-FR-18-BC-50802-07

Phase	Ingredients	INCI	% by weight	Function
A	Emulgade® Sucro Plus	Sucrose Polystearate, Cetyl Palmitate	3.00	Emulsifier (O/W)
	Cutina® PES	Pentaerythrityl Distearate	1.00	Consistency agent
	Myritol® 318	Caprylic/Capric Triglyceride	3.00	Emollient
	Cetiol® C 5C	Coco-Caprylate/Caprate	3.00	Emollient
	Cetiol® CC	Dicaprylyl Carbonate	3.00	Emollient
	Cosmedia® SP	Sodium Polyacrylate	0.70	Rheology modifier
B	Water, demin.	Aqua	80.90	
	Glycerin	Glycerin	2.00	Humectant
	Eumulgin® SG	Sodium Stearoyl Glutamate	0.50	Emulsifier (O/W)
	Preservative*		qs	Preservative
C	Bix'Activ™ BC10050	Bixa Orellana Seed Extract, Maltodextrin	0.25	Active ingredient
	Water, demin.	Aqua	2.00	
D	Perfume*	Parfum	q.s.	Fragrance
E	Citric Acid (10% solution)	Citric Acid	0.65	pH Adjustment

Specifications:

pH value (23°C): 6.20

Viscosity (Brookfield; RVT; spindle TC, Helipath; 20 rpm; 23°C): 15 000 mPa s

Performance:

Additional performance has not been evaluated

Manufacturing process:

Heat phases A and B at 75°C.

Add phase A into B under mixing.

Allow to cool to room temperature under mixing. Add phase C and D at 30°C under mixing.

Adjust pH with phase E.

Additional information:

Preservative*: Elestab 388 at 2.50%

Perfume*: Just Delicious RS32785 Technicoflor 0.20%

Stability test:

Stable 3 months at 4°C, RT, 40°C, 45°C

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Pore Refining Toner | SC-FR-18-BC-50848-01

Phase	Ingredients	INCI	% by weight	Function
A	Water, demin.	Aqua	87.65	
	Glycerin	Glycerin	4.00	Humectant
	EDTA® BD	Disodium EDTA	0.05	Complexing agent
	Euxyl K 712 (Schülke)	Aqua, Sodium Benzoate, Potassium Sorbate	1.00	Preservative
	Eumulgin® SML 20	Polysorbate 20	1.00	Emulsifier (O/W)
	Pluracare® L 64 G	Poloxamer 184	2.00	Surfactant
	Zinc Gluconate (Corbion)	Zinc Gluconate	0.05	Active ingredient
B	Water, demin.	Aqua	3.00	
	Bix'Activ™ BC10050	Bixa Orellana Seed Extract, Maltodextrin	0.25	Active ingredient
	Citric Acid (10% solution)	Citric Acid	0.40	pH Adjustment
C	Cetiol® HE	PEG-7 Glyceryl Cocoate	0.50	Emollient
	Perfume*	Parfum	0.10	Fragrance

Specifications:

pH value (23°C): 5.10

Performance:

Additional performance has not been evaluated

Manufacturing process:

1- Mix phase A, phase B and phase C at RT.
 2- Add phase B and phase C under phase A while stirring.
 Perfume* Lotus Rose RS41228 (Technicoflor)

Stability test

Stable 3 months at 4°C, RT, 40°C, 45°C

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