Scientific Evidence on Picasol SPF 25 & SPF 50 Sunscreens (10% Icaridin) - Picasol Aftersun (20% Icaridin)

Contents

What is ultraviolet radiation?

Ultraviolet (UV) radiation has a spectrum between 290 and 400 nm, and can be subdivided into UVA (320-400 nm) and UVB (290-320 nm), as shown in figure 1.

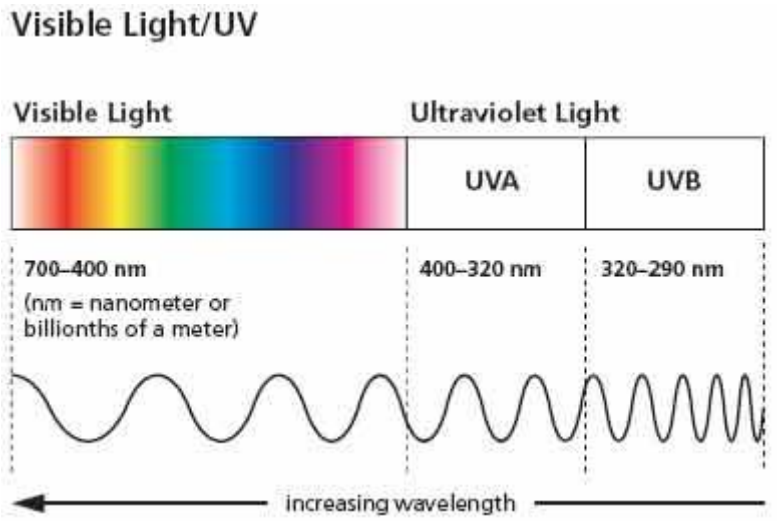

Figure 1: Visible light - Ultraviolet light spectrum (adapted from: http://www.skincancer.org/prevention/uva-and-uvb)

UVA rays account for up to 95% of the UV radiation to which humans are exposed. It penetrates the skin more deeply when compared to UVB and plays a key role in skin aging and wrinkling. Also, an increasing number of studies indicate that UVA rays may enhance the development of skin cancers, probably mediated by increased oxidative cell stress.

UVB, the main cause of skin reddening (erythema) and sunburn, tends to damage the skin's more superficial epidermal layers. It plays a key role in the development of skin cancer and a contributory role in tanning and photo aging. Its intensity varies by season, location, and time of day. UVB rays do not significantly penetrate glass (1).

What is the Sun protection factor or SPF?

The sun protection factor (SPF) is the measure of a sunscreen's ability to prevent UVB from damaging the skin. For example, if it takes 10 min for unprotected skin to start turning red, using a SPF25 sunscreen will theoretically prevent reddening (also called erythema) 25 times longer, thus about 4h.! However, erythema is a reaction to UVB irradiation alone and is no good indication for the total skin damage, or the potential skin cancer risk from sun exposure.

Another approach to interpret the SPF value is to look in terms of percentages: SPF15 filters out approximately 93% of all incoming UVB rays, SPF30 97% and SPF50 98%, respectively. Although the difference in % between the SPF values appears to be negligible, it does make a significant difference for people who are light-sensitive or have a history of skin cancer (1).

It is important to underline that the SPF test can ONLY measure UVB protection, not UVA protection, because of the relation to skin reddening. Obviously, a product with high SPF will be more likely to protect against UVA than a product with low SPF.

SPF of Picasol and waterproofing

The sun protection factor (SPF) of both Picasol SPF25 and Picasol SPF50 products, containing 10% Icaridin, has been extensively tested according to the international standard for sun protection ISO24444:2010. Briefly, test subjects have been exposed to UV radiation (complete spectrum: 290-400 nm) before and after water immersion.

The prerequisite to claim that a product is “waterproof” implies that the post-immersion SPF value must be at least 50% of the pre-immersion SPF value. This is clearly demonstrated by the results of two experiments, performed by two independent laboratories. In one test, Picasol SPF25 achieved a mean pre-immersion SPF value of 30.72 (SPF30 in practice) and a mean post-immersion value of 27.14 (88% “recovery”). Picasol SPF50 achieved a mean pre-immersion SPF value of 51.20 and a mean post-immersion value of 44.22 (86% “recovery”) (2).

The product with the lowest SPF (Picasol SPF 25) was also evaluated by another laboratory. The mean SPF for the product was 27.9 (95% confidence interval (CI): 24.7 to 31.1). After 40 min of water immersion, the mean SPF value was 17.1 (61% “recovery”). The lower bound of the 90% CI for water resistance retention was 51.1% (3).

The results of both experiments clearly indicate that, under the described experimental conditions, both Picasol SPF25 and SPF50 products are water-resistant and that the measured SPF values correspond to the value, claimed on the product label.

UVA specific protection of Picasol

UVA protection for Picasol SPF25 (lowest protection factor) was tested according to ISO 24443:2012 guideline, which requires the UVA protection factor to be at least one third of the total UV factor.

Briefly, a polymethyl methacrylate (PMMA) plate is treated with test product and following drying (min. 30 min), the plate is placed in the light-path of the UV spectrophotometer. Absorbance of UV radiation through the sample is determined for each wavelength, from 290 nm to 400 nm, with steps

of 1 nm. As mentioned above, the spectrum of the applied UV light contains both UVA and UVB radiation. Raw data of each experiment are then converted to the corresponding UVA protection factor value using standardized formulas. In this experiment, the UVA protection factor values for Picasol SPF 25 varied between 10.7 and 14.7 and were higher than 1/3 of the total UV factor (8.333). Therefore, the product meets the required standard (4).

Repellent efficiency of Icaridin and of Picasol

Icaridin-supplemented products (including Picasol SPF25, SPF50, and Aftersun) are able to repel different types of insects, including ticks, mosquitos, and vespids. A summary of both literature and experimental data is provided below.

Repellent effect of icaridin against ticks

Icaridin (also known as Saltidin, KBR3023) is an effective active ingredient for protection from ticks. The median of the protection time of a 10% Icaridin solution was 5h in nymphs of *Ixodes scapularis* ticks, and 8h in those of *Ixodes ricinus* ticks (5).

Ixodes persulcatus, the common Eastern European, Russian *Ixodes* species, is also significantly sensitive to Icaridin. Repellency lasted 5 hours and was relatively independent from the type of formulation (6).

For *Ixodes ricinus* repellency, commercial products containing Icaridin demonstrated a better response when compared to IR3535 (7). Specifically, with regard to tick bite prevention, Icaridin compares very favorably to other repellents and alternatives such as N, N-diethyl-meta-toluamide (DEET), requiring high concentrations to repel ticks (8).

In the Netherlands, a country of 16 million in a densely populated rural/suburban landscape, yearly one million people are bitten by ticks (9). More information on Lyme disease can be found on the website of the Centers for Disease Control and Prevention (CDC) (10).

Repellent effect of Picasol against mosquitos

The repellent effect of Picasol SPF25 and SPF50 products, containing 10% Icaridin, against different types of mosquitos was tested by an independent CRO according to the EU Biocidal Products Regulation (BPR) and Technical Notes for Guidance (TNsG) guidelines (Ref. 11, 12). To allow commercialization, all biocidal products must be tested according to these guidelines in order to obtain approval by the responsible authorities.

The repellent protection times are summarized in tables 1a and 1b.

Table 1a: Protection time (average 12 subjects) following application of Picasol SPF25 Sun & Insect protection.

Species	**SPF 25 - Protection Time (n=10)**
Aedes albopticus (Asian tiger mosquito)	4.9h
Culex cinquefasciatus (Southern house mosquito)	5.6h
Stomoxys calcitrans (Stable fly)	4.2h

Table 2b: Protection time (average 12 subjects) following application of Picasol SPF50 Sun & Insect protection.

Species	**SPF50 - Protection Time (n=10)**
Aedes albopticus (Asian tiger mosquito)	4.0h
Culex cinquefasciatus (Southern house mosquito)	5.2h
Stomoxys calcitrans (Stable fly)	5.3h

Depending on the tested species, protection time varies between 3.7h and 5.6h, hereby confirming that both SPF25 and SPF50 products are able to efficiently protect during the complete period of application. Indeed, it is generally accepted that sunscreen products must be applied every 1-2h or following swimming. Data also indicate that there is no significant difference in protection times between the SPF 25 and SPF50 product, respectively.

The repellent effect of Picasol Aftersun, containing 20% Icaridin, against different types of mosquitos has been tested by an independent CRO (Ref. 13-16). Results are summarized in table 2.

Table 3: Protection time

Species	**Protection Time (average 12 subjects)**
Aedes albopticus (Asian tiger mosquito)	4.3h
Aedes Aegypti (Yellow fever mosquito)	2.1h
Anopheles gambiae (Malaria mosquito)	> 8h
Culex cinquefasciatus (Southern house mosquito)	> 8h
Stomoxys calcitrans (Stable fly)	>7.7h

Experimental data demonstrate that Picasol Aftersun is able to protect against the malaria mosquito and the southern house mosquito for at least 8 hours (comparable to an overnight period). A similar outcome was observed for protection against the stable fly. The Aftersun product offers protection between 2.1h and 4.3h for both *Aedes* species.

Repellent effect of Picasol against vespids

In 2015, the repellent effect of Picasol Aftersun has been evaluated in field conditions in the botanic garden of Brussels (Auderghem, Belgium). Briefly, an experimental setup was designed in which 6 artificial skin pieces (10 x 10 cm) were video-recorded for 1 h, to count each min the numbers of flying and feeding vespids. Prior to monitoring, 5 pieces were successively smeared with 2 mg of cream per cm2, in 30 min intervals, from t = -120 min to 0. The sixth sheet remained untreated to serve as a control. One ml of an attractant (fruit jam) was deposited on each of the 6 surfaces at t = 0.

The control surface was free of any flying or feeding vespids during an average period of 25 min, whereas the other 5 surfaces (treated at t = -120, -90, -60, -30, and 0 min) remained vespid-free for 39, 40, 45, 49, and 51 min, respectively.

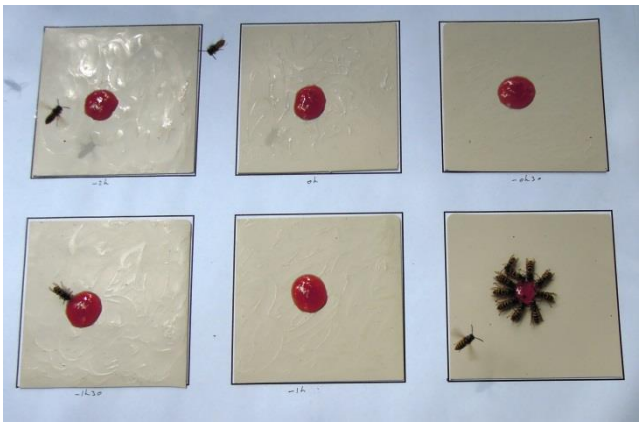

Figure 1. Picture of the running field test that involved *Vespula vulgaris*. Jam was used as an attractant. In the example shown here, the only surface not treated with the skin lotion was the below, right one. For further explanation, see text.

In conclusion, the skin lotion remained significantly active for at least 2 h. A detailed description of the test set-up and the result can be found in the publication of Bouvé, 2016 (17).

Safety of Picasol

Patch tests have been performed by an independent CRO to assess skin irritation, both in subjects with normal and sensitive skin. All Picasol products have been assessed (SPF25, SPF50, and Aftersun) according to a standardized protocol. None of the products induced skin irritation. In other words, all Picasol products are safe for application on both normal and sensitive skin (18-21). Nevertheless, none of these products can be applied on skin with serious burn wounds (second- or third-degree) or on damaged skin, as mentioned on the instructions for use.

The advantages of combining insect repellents with sunscreen ingredients?

The Picasol products have been formulated to fulfill the following requirements:

1. Allowing optimal sun protection against UVA and UVB radiation for the whole family (from 2 yrs.).
2. Picasol sun & insect protection SPF25 and SPF50 products are water-proof.
3. Protection against several types of biting insects (ticks, mosquitos, vespids…)
4. Stable and safe formulation with guaranteed SPF
5. Neutral odor

These characteristics allow Picasol products to offer optimal sun and insect protection for the whole family.

It is often said that the active repellent ingredients may interact with the sun protection filters. This is a fact. For this reason, it is important not to accept any untested combination of ingredients. Picasol is one of the few products on the market with full substantiation of efficacy against insects and sun, as well as safety

Additional information

This report does not intend to summarize all literature available on icaridin. More information can be found here:

- “10% and 20% Picaridin (= Icaridin, Saltidin) provided effective tick bite protection for 12-hour periods.” (5-6)
- “Picaridin is effective against mosquitoes, flies, chiggers (larval Trombiculid mites), and ticks and is available as lotions, sprays, and wipes in strengths of 7% to 20%.” (22)
- http://saltidin.com: general information site on Saltidin (23).
- ‘Picaridin’s comparable efficacy to DEET and favourable side-effect profile make it an appealing option and an acceptable alternative for protection against malaria and other vector-borne diseases in endemic areas.” (24).

- http://lanxess.cn/uploads/tx_lxsmatrix/all_family_spray20.pdf: effect of 20% Saltidin product against different insects (25).

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