



ALL Family Insect Repellent Spray 20 % Saltidin® (known as Picaridin in the US)

Issued in June 2009

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1. Preliminary Remarks

The use of repellents by application to skin and clothing is an important means of human protection against blood-sucking insects and ticks as well as arthropod-borne disease transmission.

Saltidin® belongs to a new generation of synthetic repellents developed as an alternative to DEET.

Developed by Bayer using molecular modelling techniques, Saltidin® showed the best performance among more than 800 substances against a variety of arthropods and the best characteristics as far as safety and compatibility with skin and plastic materials are concerned.

Presently, this molecule is owned by Saltigo GmbH (LANXESS Group) and is marketed by LANXESS Corporation (previously a Division of Bayer Corporation) in the USA and Canada

Saltidin® is a safe and reliable insect repellent and stands for effective protection against various diseases transmitted by:

- ✓ Mosquitoes
- ✓ Ticks
- ✓ Flies
- ✓ Horseflies
- ✓ Sandflies
- ✓ Biting midges
- ✓ Fleas

Due to its broad spectrum of efficacy, its favourable toxicological and cosmetic properties, Saltidin® can be safely used by consumers.

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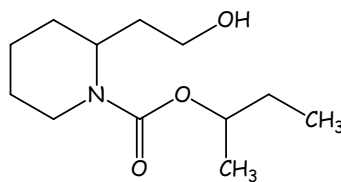
2. Physical and Chemical Properties

Chemical Name: 1-PIPERIDINECARBOXYLIC ACID, 2-(2-HYDROXY-ETHYL), 1-METHYLPROPYLESTER

Commercial Name: Saltidin®

Other Names: Icaridin, KBR 3023, Bayrepel™, Picaridin, (US EPA Registration)

Structure:



Empirical Formula: $C_{12}H_{23}NO_3$

ELINCS Number: 423-210-8

CAS Number: 119515-38-7

Molecular weight: 229.3 g/mol

Melting point: $< -170\text{ °C}$

Boiling point: 272 °C at 1013 hPa

Viscosity: 30.7 sec. flow time accord. To DIN 53211, Dynamic: 129 mPa.s at 20 °C

Vapour pressure: 3.4×10^{-4} hPa at 20 °C

5.9×10^{-4} hPa at 25 °C

7.1×10^{-3} hPa at 50 °C

Flash point: 142 °C

Density: 1.036 g/m^3 at 20 °C

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| | | |
|---------------------|--------------------------------------|--------------------|
| Solubility: | In water: | 8.6 g/L at 20 °C |
| | In propane-2-ol: | > 250 g/L at 20 °C |
| | In acetone: | > 250 g/L at 20 °C |
| | In n-heptane: | > 250 g/L at 20 °C |
| | In xylene: | |
| Appearance: | Clear liquid, colourless to brownish | |
| Odour: | Slightly odorous | |
| Storage conditions: | Store at room temperature | |

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3. Formulation

ALL Family Insect Repellent Spray 20 %

3.1 Formulation:

| No | Ingredient | CAS Nr. | Content % |
|----|-------------------------|----------------|-----------|
| 1 | Saltidin® | 119515-38-7 | 20,6 |
| 2 | Polyethylene Glycol 400 | 25322-68-3 | 20,0 |
| 3 | Ethanol abs. DAB | 64-17-5 | 29,0 |
| 4 | Floral D 12889 G | Not applicable | 1,0 |
| 5 | G-Water | 7732-18-5 | 29,4 |

3.2 Preparation:

Mix all ingredients at room temperature.

3.3 Stability:

Short term stability for 6 weeks.

This spray is stable after storage for 6 weeks at 20 °C, 40 °C, 45 °C and at 50 °C.

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4. Toxicological Data

The toxicological properties of the proposed formulation have been assessed on the basis of available data, in accordance with the above intended usages on behalf of Saltigo GmbH (Germany). The studies are described in the report: "ICARIDIN. Tier II Summary Reports for Acute Studies All-Family Insect Repellent Spray (EP)", October 27, 2007.

| Extrapolated Acute Toxicity and Precautionary Signal Words for All-Family Insect Repellent Spray (20 % Spray-Formulation) | | | |
|--|----------------------|------------------------------------|--------------------------|
| Study type | Species | Results | EU Classification |
| Acute Oral | Rat LD ₅₀ | Male and Females = > 5050 mg/kg | Not classified |
| Acute Dermal | Rat LD ₅₀ | Male and Females = > 5020 mg/kg | Not classified |
| Acute Inhalation | Rat LC ₅₀ | > 30.2 mg/L (4- hours) | Not classified |
| Eye Irritation | Rabbit | No Eye Irritation | Not classified |
| Skin Irritation | Rabbit | No Skin Irritation | Not classified |
| Dermal Sensitization | Guinea Pig | Non Sensitizing | Not classified |

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5. Efficacy Studies

The efficacy of the proposed formulation has been assessed on the basis of available data, in accordance with the above intended usages on behalf of Saltigo GmbH (Germany). Reported here below are efficacy data against mosquitoes, ticks, flies, sandflies, biting midge and fleas obtained with formulations containing 10 % of Saltidin®. The studies are summarized in the report: "ICARIDIN. Summary Report of Efficacy Data", Report N° 07-LX-12, October 20, 2007.

5.1 Effectiveness Against Mosquitoes

Saltidin® has been shown to be a safe and effective repellent against various species of mosquitoes (e. g., *Aedes aegypti*, *Aedes albopictus*, *Culex quinquefasciatus*, and *Anopheles dirus*). Two types of protocols were used for testing the efficacy of Saltidin® on Mosquitoes: cage tests on human volunteers and field tests on human volunteers.

Cage tests on human volunteers were conducted during the development of the product to estimate the efficacy of the product and to compare different formulations of the product under standardized conditions.

The tests by Yap et al. (1997) were conducted in screened cages (1 x 1 x 1 m) with circular openings (15 cm in diameter) fitted with cloth sleeves. Eight volunteers (6 male and 2 females) were involved in the experiment. The application rate was 150 uL/90 cm². The applied product was left to dry before covering it with a rubber sleeve with an opening window of 25 cm² as a surface for landing/biting activities of mosquitoes. Both hands of volunteers were covered with thick rubber gloves up to the wrists to prevent unwanted bites.

In the study by Luepkes (2005), the test protocol was similar to the Yap protocol: the cages measured 90 x 30 x 40 cm and the application rate was 150 ug/90 cm².

The results showed that the 20 % formulation provided 4 - 8 hours protection and that the efficacy was similar or even superior to that of DEET (Table 1).

In the study by Zhao (2008) and Chen et al. (2008), the test protocol was similar to that of Yap. Results provided over than 7 and 10 hours protection against *Aedes albopictus* (Tiger Mosquito).

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Table 1: Efficacy (Protection time = PT) of 20 % Saltidin® and DEET formulation against mosquitoes in cage tests.

| Test Species | Test Location (Time of test) | Saltidin® | | DEET | | Study ID/Reference |
|-------------------------|---|-----------|--------|----------------|--------|-----------------------------------|
| | | (%) | PT (h) | (%) | PT (h) | |
| <i>Aedes aegypti</i> | University Sains, Malaysia | 20.0 | 4 - 6 | 20.0 | 4.0 | Yap et al., 1997 ^[1] |
| <i>Aedes aegypti</i> | BioGenius, Monheim, Germany | 20.0 | 6.8 | Not determined | | Luepkes, 2005 ^[2] |
| <i>Anopheles dirus</i> | University Sains, Malaysia | 20.0 | 8.0 | 20.0 | 6.0 | Yap et al., 1997 ^[1] |
| <i>Aedes albopictus</i> | Military Medical Research Institute, China | 20.0 | > 7.0 | Not determined | | Zhao, 2008 ^{[3]*} |
| <i>Aedes albopictus</i> | Nanjing Military District, Military Medical Research Institute, China | 20.0 | > 10 | Not determined | | Chen et al., 2008 ^{[4]*} |

* tests carried out on All Family Spray 20 %

Field tests were designed to determine the efficacy of products under real life conditions. It is common knowledge that cage tests are more conservative and that often the protection time for the cage tests is lower than in field tests. Therefore, field studies are important in order to establish the efficacy of the product. For this reason, this report will focus on field studies and on the more relevant data obtained from the cage tests using animals and human volunteers.

In the study by Yap et al. (1998), the trials against *Aedes albopictus* were conducted outdoors in a plantation on Penang Island during the day in order to coincide with the day-time biting activities. The trials against *Culex quinquefasciatus* were conducted in the

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living rooms of residential houses during the night to coincide with peak biting activities. The dosages tested for the repellents formulation were 1ml on the leg and 0.5 ml on the hand.

In the studies by Frances et al. (2004), 4 male volunteers participated in the test. Each wore a long sleeved shirt buttoned at the wrist, long trousers and running shoes without socks. A mesh jacket was worn over the head and arms, and the legs of the trousers were rolled up to the knee to expose only the lower leg and ankles to biting mosquitoes. The repellents were spread evenly by the volunteers over each leg from the base of the knee to the ankle. The amount of repellent applied was determined by weighing the container before and after application. The mean of application rate was 0.91 - 1.67 mg/cm² for studies conducted in 2002 and 1.33 - 1.74 mg/cm² for studies in 2004.

In the study by Carroll-Loye, carried out in Central Valley, California, 5 male and 5 female participated in the test. The application rates used in the field efficacy study were 0.97 µl/cm² on arms and 0.83 µl/cm² on legs and they exposed treated limbs to mosquitoes.

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Table 2: Efficacy (Protection time = PT) of 20 % Saltidin® and DEET formulation against mosquitoes in field tests.

| Test Species | Test Location (Time of test) | Saltidin® | | DEET | | Study ID/Reference |
|-------------------------------|--|-----------|--------|----------------|--------|-------------------------------------|
| | | (%) | PT (h) | (%) | PT (h) | |
| <i>Aedes albopictus</i> | Residential-Mainland Peninsular, Malaysia (Day) | 20.0 | 8.0 | 20.0 | 6.0 | Yap et al., 1998 ^[5] |
| <i>Culex quinquefasciatus</i> | Residential-Mainland Peninsular, Malaysia (Night) | 20.0 | 8.0 | 20.0 | 8.0 | Yap et al., 1998 ^[5] |
| <i>Mosquito spp</i> | Rain forest, Northern Queensland, Australia (Day, Night) | 19.2 | 9.0 | 20.0 | 7.0 | Frances et al., 2002 ^[6] |
| <i>Mosquito spp</i> | Northern Territory, Australia | 19.2 | 8.0 | 20.0 | 8.0 | Frances et al., 2004 ^[7] |
| <i>Mosquito spp</i> | Central Valley, California | 20 | 11.6 | Not determined | | Caroll-Loye, 2008 ^{[8]*} |

* tests carried out on All Family Spray 20 %

From the results of all the laboratory and field tests carried out by various researchers and in various parts of the world, it may be concluded that the formulation containing 20 % Saltidin® provides 8 - 11.6 hours of protection (Table 2). It can also be concluded that the performance of Saltidin® often proves to be superior to DEET in comparative studies.

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5.2 Effectiveness Against Ticks

Saltidin® has been shown to be a safe and effective repellent against various species of ticks (e. g., *Ixodes ricinus* and *Ixodes scapularis*).

In studies conducted in Austria by Sixl (1993), the results of cage tests and field tests on human volunteers showed that 20 % Saltidin® formulation provided at least four hours of protection (test duration) against *Ixodes ricinus*. A similar protection time was achieved using DEET.

In the field test, 20 people (9 men and 11 women) were involved in the experiment. The selected people were particularly attractive to ticks. 10 - 14 ml of test formulations were applied to arms, legs and exposed areas of the body. The test duration was four hours (Table 3).

Table 3: Efficacy (Protection time = PT) of 20 % Saltidin® and DEET formulation against ticks in field tests.

| Test Species | Test Location | Saltidin® | | DEET | | Study ID/ Reference |
|-----------------------|-----------------------------------|-----------|--------|------|--------|---------------------------|
| | | (%) | PT (h) | (%) | PT (h) | |
| <i>Ixodes ricinus</i> | Kaiser Wald near Graz, Austria | 20.0 | 4.0** | 20.0 | 4.0** | Sixl, 1993 ^[9] |

** Duration of the test

In the cage tests on human volunteers conducted in Austria by Sixl (1993), volunteers were treated with 20 % Saltidin® or 20 % DEET with protection extenders PEG400 and were exposed to ticks (*Ixodes ricinus* in an active phase: 25 females, 25 nymphs and 10 males) placed in highly air-permeable gauze containers. The containers were fitted onto the forearm and upper arms. Assessments were carried out once every hour for four hours.

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In the cage tests with human volunteers carried out by Todd (1997), 4ug/cm² of formulation containing Saltidin® or DEET were applied onto volunteers forearms (in a 5.65 cm diameter circle). A 20 % Saltidin® formulation provided protection time of 2.5 hours against the deer tick *Ixodes scapularis* (compared to 0.5 hours four DEET) (Table 4).

Table 4: Efficacy (Protection time = PT) of 20 % Saltidin® and DEET formulation against ticks in cage tests.

| Test Species | Test Location | Saltidin® | | DEET | | Study ID/Reference |
|--------------------------|--|-----------|--------|------|--------|----------------------------|
| | | (%) | PT (h) | (%) | PT (h) | |
| <i>Ixodes ricinus</i> | Near the laboratory Kaiser Wald in Graz, Austria | 20.0 | 4.0** | 20.0 | 4.0 | Sixl, 1993 ^[9] |
| <i>Ixodes scapularis</i> | ICR (Insect Control and Research, Inc.), Baltimore USA | 20.0 | 2.5 | 20.0 | < 0.5 | Todd, 1997 ^[10] |

** Duration of the test

5.3 Effectiveness Against Flies

In the efficacy tests carried out against flies, LANXESS used a low quantity of Saltidin® (7.5 - 12.0). The repellence against this kind of insect is high even with this amount and even higher with a 20 % Saltidin® content.

Efficacy of formulations containing 7.5 % Saltidin® was determined against tabanids under field conditions. The study was conducted in Austria by Prof. Muelhofer (1993) at the LHS - Labor fuer Hygiene and Sicherheit (Laboratory for Hygiene and Safety). The

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following abundance of various species was present: *Tabanus bovinus*, 35 %; *Haematopota pluvialis*, 30 %; *Stomoxys calcitrans*, 20 %; and *Chrysops relictus*, 15 %.

Ten volunteers (5/product) wearing protective sleeves with a 10 x 10 cm² opening were used in the test. 200 µl of the tested product were applied to each volunteer. The exposure time was 30 minutes and the test was repeated every hour. The test was stopped when one bite occurred over a 30 minute test period. The overall protection time (average of all insect densities) for 7.5 % Saltidin® was five hours and for DEET was six hours (Table 5). At normal insect densities, protection time for 7.5 % Saltidin® was 6 hours and for 10 % DEET was 7 hours. At high insect densities, the corresponding values were 4 and 6 hours. Under extreme insect pressure, the efficacy declined to 4 hours for Saltidin® and to 5 hours for DEET.

Table 5: Efficacy (Protection time = PT) of 7.5 % Saltidin® and 10 % DEET formulations against flies in field tests.

| Test Species | Test Location | Saltidin® | | DEET | | Study ID/ Reference |
|--|---------------|-----------|--------|------|--------|---------------------------------|
| | | (%) | PT (h) | (%) | PT (h) | |
| <i>Tabanus bovinus</i> , 35 %; <i>Haematopota pluvialis</i> , 30 %; <i>Stomoxys calcitrans</i> , 20 %; <i>Chrysops relictus</i> , 15 %. | Austria | 7.5 | 5.0 | 10.0 | 6.0 | Muelhofer, 1993 ^[11] |

In a cage test by Nentwig (1997), a formulation containing 12 % Saltidin® was tested against *Stomoxys calcitrans*. The insects were placed in cages (90 x 30 x 40 cm, with gauze side walls) equipped with two cloth sluices. 90 cm² of each forearm of a volunteer was treated with 150 µl of the test product. A sleeve with an opening of 25 cm² was fastened around the arm: the opening was positioned over the treated area. Both arms were introduced into the cage through the cloth sluice and the number of bites per arm in a three minutes test period was registered.

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The protection time for the Saltidin® formulation was 7 hours compared to 4 hours for DEET (Table 6).

Table 6: Efficacy (Protection time = PT) of 12.0 % Saltidin® and 17.0 % DEET formulations against flies in cage tests.

| Test Species | Test Location | Saltidin® | | DEET | | Study ID/ Reference |
|------------------------------|-----------------------------------|-----------|-----------|------|-----------|----------------------------------|
| | | (%) | PT (h) | (%) | PT (h) | |
| <i>Stomoxys calcitrans</i> , | Bayer Lab, Monheim, Germany | 12.0 | 7.0 | 17.0 | 4.0 | Nentwig, 1997 ^[12] |

5.4 Effectiveness Against Sandflies

The efficacy of the formulations was tested on the laboratory bred strain of *Phlebotomus (Phlebotomus) duboscqi* in human volunteers (Perrotey *et al.*, 2002, laboratory report and Pesson and Perrotey, 2005, published short communication). A 50 % DEET formulation was also tested for comparative purposes.

In the test, a group of 30 unfed female insects were released into gauze cages (20 x 20 x 20 cm). The test was carried out with six human volunteers (three males and three females). The repellents were applied to the back of the hand and wrist. During the test, a latex glove was worn with a square opening (4 x 4 cm) permitting skin exposure of only a part of hand and wrist. The treated surfaces were exposed in the cage for 5 minutes at hourly intervals until one bite was recorded, terminating the test.

The results of laboratory test with human volunteers showed that Saltidin® formulation had a high degree of repellence against *P. duboscqi* (10 hours). The formulation containing 50 % DEET provided 8.4 hours protection. It can be concluded that Saltidin® is highly effective against Sandflies (Table 7).

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Table 7: Efficacy (Protection time = PT) of 20.0 % Saltidin® and 50.0 % DEET formulations against sandflies in cage tests.

| Test Species | Test Location | Saltidin® | | DEET | | Study ID/Reference |
|---|---|-----------|--------|------|--------|--|
| | | (%) | PT (h) | (%) | PT (h) | |
| <i>Phlebotomus (Phlebotomus) duboscqi</i> | Parasitology laboratory, Strasbourg, France | 20.0 | 10 | 50.0 | 8.4 | Perrotey et al., 2002 ^[13] Pesson and Perrotey, 2005 ^[14] |

5.5 Effectiveness Against Biting Midges

In a field study with human volunteers, Saltidin® was tested against the Scottish biting midge *Culicoides impunctatus*, and was shown to be a highly effective repellent, preventing landing and biting for more than 8 hours post-application with no significant differences between individuals. It can be concluded that Saltidin® is a highly effective repellent against the Scottish biting midge (*Culicoides impunctatus*).

The test was carried out by Mordue (1999) and Carpenter (2005) at dusk in a marshy field. The application rate was 30 ug of active ingredient/100 cm² of skin, the recommended application dose. The average forearm surface area of the 5 volunteers (three males and two females) was 600 cm².

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Table 8: Efficacy (Protection time = PT) of 20.0 % Saltidin® formulation against biting midges in field tests.

| Test Species | Test Location | Saltidin® | | DEET | | Study ID/Reference |
|-------------------------------|------------------------------|-----------|--------|--------------|--------|---|
| | | (%) | PT (h) | (%) | PT (h) | |
| <i>Culicoides impunctatus</i> | Argyllshire, Scotland (dusk) | 20.0 | > 8.0 | Not detected | | Mordue, 1999 ^[15] Carpenter, 2005 ^[16] |

5.6 Effectiveness Against Fleas

Saltidin® is recommended as a safe and effective repellent of *Ctenocephalides felis* (cat fleas) for human use.

In the study by Nentwig (1998), 150 uL of 20 % Saltidin® or 20 % DEET products were applied on 90 cm² of each arm of two volunteers. Small transparent boxes containing 5 adult fleas each were fastened to the arm treated with the repellent by a bracelet. The number of bites per arm in a three minutes test period was registered, every hour for 9 hours. The repellent effect was considered to fail if two bites occurred in three minutes. It can be concluded that Saltidin® is an effective repellent against fleas.

Table 9: Efficacy (Protection time = PT) of 20.0 % Saltidin® and DEET formulation against fleas in cage tests.

| Test Species | Test Location | Saltidin® | | DEET | | Study ID/Reference |
|------------------------------|---------------------------|-----------|--------|------|--------|-------------------------------|
| | | (%) | PT (h) | (%) | PT (h) | |
| <i>Ctenocephalides felis</i> | Bayer Laboratory, Germany | 20.0 | 9.0 | 20.0 | 9.0 | Nentwig, 1998 ^[17] |

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