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SUMMARY OF PRODUCT CHARACTERISTICS

- 1) **NAME OF PRODUCT:** Bob Martin Flea Killing Mousse Plus for Cats & Kittens
- 2) **QUALITATIVE AND QUANTITATIVE COMPOSITION:**

Formulation:

<u>Active Ingredients</u>	<u>% w/w</u>
Pyrethrins (free)	0.05
Piperonyl Butoxide (free)	0.5
Sectrol Concentrate supplying:	
Pyrethrins (encapsulated)	0.1
Piperonyl Butoxide (encapsulated)	0.8

- 3) **PHARMACEUTICAL FORM:** Cutaneous foam
- 4) **PHARMACOLOGICAL PROPERTIES:** The pyrethrins are potent, non-systemic, contact insecticides causing a rapid paralysis or "knockdown", death occurring at a later stage. Their mechanism of action is considered to involve inhibition of the inactivation of sodium channels and the activation of potassium conductance at the neurone axon level. This results in prolonged action potentials, repetitive neuronal firing after a single stimulus and spontaneous trains of action potentials.

The insecticidal activity of the pyrethrins is markedly enhanced by the inclusion of cytochrome P₄₅₀ inhibitors which decrease their rate of metabolism by the insects; piperonyl butoxide is a methylenedioxyphenol synergist for pyrethrins and related insecticides and is included in the formulation.

Pyrethrins and piperonyl butoxide are incorporated both as a free active component for rapid "knockdown" effect and as a microencapsulated component providing sustained release of active ingredients to maintain insecticidal activity for up to 14 days.

- 5) **CLINICAL PARTICULARS:**
- 5.1 Target Species: Cats
- 5.2 Therapeutic Indications: The product is indicated for the control of fleas (*Ctenocephalides* spp.) on cats.
- 5.3 Contra-indications: Do not use on nursing queens or kittens less than twelve weeks old. Do not use on animals with known sensitivity to pyrethrins.

- 5.4 Undesirable Effects: Pyrethrins and piperonyl butoxide, both individually and in combination, possess low toxicity in mammalian species.

Application of the foam may induce a grooming response in treated animals. This may cause adverse reactions, e.g. increased salivation, lethargy and breathing difficulties, which may be severe in cases of acute toxicity or hypersensitivity.

If reactions continue, it is recommended that a veterinary surgeon is consulted.

- 5.5 Special Precautions for Use:

Contents under pressure. Do not puncture or incinerate container. Do not use near heat or open flames.

- 5.6 Use During Pregnancy and Lactation: Do not use on nursing queens or kittens less than twelve weeks old. Remove fleas from young kittens and nursing queens by careful use of a flea comb.

- 5.7 Interaction with other Medicaments and other forms of Interaction: None reported or envisaged.

- 5.8 Posology & Method of Administration:

The can should be shaken well before use. **Use 2 one-second depressions of the can actuator for each 1 kilogram (2.2lb) of bodyweight.** A one second depression of the can actuator delivers a golf ball-sized dose of foam. Use the following table to calculate how much foam would be needed to treat the cat:

Size of Cat	Number of 1-second bursts of foam required
Small, i.e. approx. 2kg (4.4lb)	4
Medium, i.e. approx. 4kg (8.8lb)	8
Large, i.e. approx. 6kg (13.6lb)	12

DIRECTIONS

1. Shake canister well before use to ensure mixing. 2. Expel the foam onto a gloved hand, one burst at a time. Household rubber gloves should be worn when applying the product or handling recently treated animals. These gloves should not be used for any other purpose. Avoid contact with eyes. 3. Massage foam into hair until it disappears. 4. Repeat until the required dose has been applied. This will moisten the hair coat, but avoid drenching the fur. 5. Make sure foam covers toes, footpads and anywhere fleas could hide. 6. Allow pet to dry naturally. Protection against fleas will last for up to 10 days when applied at this rate. Wetting the animal prior to treatment will enhance protection for up to 14 days. Treatment may be repeated after 7 days in cases of heavy infestation. After treatment, if the animal is completely brushed, or becomes very wet, then careful reapplication may be necessary.

5.9 Overdose

If any adverse reactions occur, the affected animal should be bathed immediately in warm soapy water to remove the foam product from the haircoat. This water should be disposed of onto a patch of bare soil.

5.10 Special Warning for each Target Species:

i) Do not use on nursing queens or kittens less than twelve weeks old.

ii) For external use only.

iii) The product should be used as part of a flea control programme. The pet's bedding, basket and regular resting areas, such as carpets and soft furnishings should be treated with an environmental insecticide and vacuumed regularly.

iv) If signs of disease persist or appear consult your veterinary surgeon or veterinary practitioner.

5.11 Withdrawal Period: The product is for topical application on the domestic cat. The product is not indicated for treatment of food-producing animals and hence no withdrawal period is required.

5.12 Special Precautions to be taken by the Person Administering the Product:

i) Avoid contact with eyes. Wash hands with soap and water immediately after use. If contact with eyes occurs, flush immediately with plenty of water; seek medical attention if irritation persists.

6) **PHARMACEUTICAL PARTICULARS:**

6.1 Incompatibilities: (Major) None envisaged. The product is filled into a sealed aerosol container and administered directly from the container onto the treated animal.

6.2 Shelf Life: Two years.

6.3 Storage:

- i) Pressurised container. Protect from sunlight and do not expose to temperatures above 50°C. Do not pierce or burn, even after use.
- ii) Do not spray on a naked flame or any incandescent material.
- iii) Store in a dry place.
- iv) Store away from food, drink and animal feedstuffs.
- v) Do not freeze.

6.4 Nature and Contents of Containers: A one-piece aluminium aerosol can of nominal rated capacity 210ml fitted with a valve and an actuator composed of white polypropylene with a clear K-resin overcap.

Each container is filled with a minimum of 150g of foam product (138g fill-material and 12g propellant).

6.5 Special Precautions for the Disposal of Unused Product or Waste Materials:

Harmful to fish. Cover or remove all fish bowls and aquaria before use. Do not contaminate ponds, waterways or ditches with the product. Empty and part used containers should be disposed of in the household refuse.

7) FINAL INFORMATION:**Name and Address of Marketing Authorisation Holder:**

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- i) UK Marketing Authorisation Number: Vm 00715/4067
- ii) Date of Revision of Summary of Product Characteristics: 19/07/01
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- iii) Date Renewal issued: TBC