



Product Information Sheet on Dried Marihuana (Cannabis)

General Information

This material has been cultivated and harvested by Prairie Plant Systems Incorporated under a contract with Health Canada.

- The marihuana has been harvested from the selected line MS-17/338 and is comprised of mature flowering heads of female plants.
- The dried marihuana provided has a THC level of $12.5 \pm 2\%$ and a moisture content of approximately 14%.
- Please read carefully the leaflet «Information for the patient», provided with your shipment.

Storage

- Upon receipt, the marihuana should be kept refrigerated in its original packaging. Ensure the pouches are closed properly after each use.
- It is recommended to always mix the contents of the pouch before use to ensure the product is homogenous.

Plant Description

- The production line MS-17/338 consists of female *Cannabis sativa* L. 'Indica' and is described as moderate in height (90-120 cm) with a moderate degree of branching (10-15 side branches) from the main stalk. The main stalk terminates in a dense, conical, resin laden flowering head of an average length of 25-45 cm.

Cannabinoids and Chemical Profile

- Although marihuana contains over 60 cannabinoids and several hundred other chemical substances, delta-9-tetrahydrocannabinol (THC) is the most prominent psychoactive cannabinoid component and its concentration determines the "potency" of marihuana.
- The MS-17/338 production line has THC concentrations typically higher than 10%. The plant component containing the highest concentration of THC is mature flowering heads.
- Many factors may influence the cannabinoid concentration and chemical profile. Genetic stock of the plant is a predominant factor as well as processing steps and storage conditions.

Cultivating and Processing

- The marihuana plants are cultivated in a pasteurized soil-free medium and irrigated with potable water, which is monitored monthly for microbial and metal contents including heavy metals, and with limited use of pest control products. All fertilizers used consist of water-soluble hydroponic vegetable fertilizers commercially available for horticulture.
- The manufacturing process involves milling of the plant material to produce a homogeneous marihuana product. Homogeneity is required for research purposes and for therapeutic purposes so that the overseeing physician knows the level of THC the patient is receiving.
- To ensure product consistency and quality, all aspects of the cultivation, harvesting, drying, milling, packaging, storage and testing are done under strict and controlled conditions utilizing standard operating procedures.

Packaging and Irradiation

- The marihuana is packaged into resealable, plastic foiled-lined pouches and labelled. The label indicates the THC content for that specific lot of product, the expiry date and storage instructions.
- After processing, the product is stored and maintained under strictly controlled environmental conditions until shipment. The metalized sealed plastic pouches ensure that the moisture content is maintained and that the product is not degraded by light.
- The product has been irradiated by gamma irradiation to reduce to undetectable levels, potentially harmful bacteria and microbial load which may cause spoilage of product. The lowest dose required is utilized for the irradiation process (i.e. 10 kilogray - standard level for herbs and spices), ensuring that the chemical characteristics of the marihuana product are not altered. Irradiation also ensures that users who may have compromised immune systems are not exposed to toxic spores which occur naturally in plants. For more information concerning the irradiation of food, consult the Health Canada Web site http://www.hc-sc.gc.ca/fn-an/secure/irradiation/faq_food_irradiation_aliment01_e.html

Quality Control

The finished product is tested for THC level, microbial, mycotoxin and metal contents, including heavy metals and meets applicable Canadian requirements for Natural Health Products. The following list outlines the acceptance criteria for the finished product distributed to authorized persons:

Physical Identity : Dried and milled *Cannabis sativa* spp. dark green to light green and tan coloured Flowering Heads plant particulates with characteristic aroma having citrus and pine overtones

Pesticides: Absent

Foreign Materials: Stalks, insects and other vermin are absent

Moisture content : Approx 14% w/w

Chemical Identity: Cannabinoids profile (delta-9 THC, delta-9-THC-acid, CBD, CBG, CBN, CBC)

Potency: Total THC content (delta 9-THC and delta-9-THC acid): $12.5 \pm 2\%$

Potency of related substances: CBD < 0.5%

Metals and heavy metals: Arsenic <0.14 µg/kg b.w./day*; Cadmium <0.09 µg/kg b.w./day*; Lead <0.29 µg/kg b.w./day*; Mercury <0.29 µg/kg b.w./day*; Reports for Aluminium, Antimony, Barium, Beryllium, Bismuth, Calcium, Chromium, Cobalt, Copper, Iron, Magnesium, Manganese, Molybdenum, Nickel, Phosphorus, Selenium, Silicon, Silver, Strontium, Thallium, Tin, Titanium, Vanadium and Zinc.

Microbiological purity

- Total Aerobic and Anaerobic counts: < 100 CFU/g
- Enumeration of Coliforms < 3 MPN/g
- *E. Coli*: Absent
- Enumeration of Yeasts and Moulds: < 100 CFU/g

Aflatoxins B1, B2, G1, G2 and ochratoxin A: <20 µg/kg (ppb) of substance

* Based on average body weight of 70 kg

For more information on the product you received today, or if you have any questions on marihuana for medical purposes, please contact **Health Canada toll-free at 1-866-337-7705** or consult our Web site at http://www.hc-sc.gc.ca/dhp-mps/marihuana/index_e.html

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