Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



Release certificate

| Product: Country: | | bis flos, variety Bedroc old on the pharmaceut | - | | | |
|---|--|---|---|-------|--|--|
| Strength: Dosage form: | | /drocannabinol: ca. 229 | cannabidiol: < 1.0% | | | |
| Package size: | flowers 5 grams in container, 400 grams in bags | | | | | |
| Batch: | 24H19EY24I11 | | | | | |
| Order numbers: | | ners: 386755 to 3867 | 63 | | | |
| 0 | bags: | 386765 | | | | |
| Grower/drier: | P.O. Bo | can Nederland B.V. ox 2009 | harvest date/period: 19 Aug 2024 | | | |
| | | 40 CA Veendam | | | | |
| Gamma | | y Health Ede B.V. | date: dose: | | | |
| irradiation: | | reinstraat 2 '9 NN Etten-Leur | 11 Sep 2024 ≥ 10,0 kGy | | | |
| Packager: | Fagron | Nederland B.V. | date: | | | |
| | | baan 101 | 22 Nov 2024 – 03 Dec 2024 | | | |
| | NL-290 | 08 KE Capelle a/d IJssel | | | | |
| Laboratory: | Labora | torium Ofichem B.V. | 1. General analysis | | | |
| | Heemb | badweg 5 | Analysis number: 50375 | | | |
| | NL-956 | 61 CZ Ter Apel | Report date: 18 Sep 2024 | | | |
| | | | 2. Microbiology of end product in conta | ainer | | |
| | | | Analysis number: 51484 | | | |
| | | | Report date: 03 Dec 2024 | | | |
| Testing method: | OMC N | Ionograph Cannabis F | ower / Version 8.0 / November 01, 2021 | | | |
| | | Method | Specification Result | | | |
| Characters | | Monograph | Odour characteristic for conform | | | |
| | | | Cannabis flower. Leaves | | | |
| | | | shoot out no more than | | | |
| | | | 20% of the length of the | | | |
| | | | flower and stalks are | | | |
| | | | mostly cut off directly | | | |
| | | | under the bottom site of | | | |
| | | | the flowers | | | |
| Identification | . , | 1.0 | | | | |
| <i>Macroscopic botanical characters</i> | | Visual | Brown, green clustered | | | |
| | | | flowers of about 1.5 to conform | | | |
| | | Manager | 3.0 cm length | | | |
| Microscopic botanical | | Monograph | Gland hairs are mainly conform | | | |
| characters | o ara-L. | Dh. Fun (aussist - 1) | observed | | | |
| Thin-layer chromatography | | | Comparable with conform | | | |
| | | 2.2.27, Monograph | reference | | | |

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Office of Medicinal Cannabis

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2411105124111

| 24H19EY24I11 | | | |
|---|--|---------------------------------------|----------------------------|
| Foreign material | Visual | Free from insects and other vermin | conform |
| Microbial contamination Total aerobic microbial count (TAMC) | Ph. Eur. (current ed.) 2.6.12, 2.6.13 | ≤10² cfu/gram | < 10² cfu/gram |
| Total combined yeasts/moulds count (TYMC) | | ≤10¹ cfu/gram | < 10 ¹ cfu/gram |
| S. aureus, P. aeruginosa, bile-tolerant gram- negative bacteria | | Absent (1 gram) | conform |
| Aflatoxins | Monograph | | |
| Aflatoxin B ₁ | | ≤ 2 µg/kg | < 2.0 µg/kg |
| Sum of aflatoxins B1, B2, G1 and G2 | | ≤ 4 µg/kg | < 4.0 µg/kg |
| Pesticides | Ph. Eur. (current ed.) 2.8.13 | ≤ Limits Ph. Eur. 2.8.13* | conform |
| Heavy metals | Ph. Eur. (current ed.) | | |
| Lead | 2.4.27, 2.2.58 | max. 20.0 ppm | <5 ppm |
| Cadmium | | max. 0.5 ppm | < 0.125 ppm |
| Mercury | | max. 0.5 ppm | < 0.125 ppm |
| Loss on drying | Ph. Eur. (current ed.) 2.2.32 | ≤ 10.0 % | 8.1 % |
| Assay (HPLC) | Ph. Eur. (current ed.) | | |
| Tetrahydrocannabinol (THC, total equivalent) | 2.2.29, Monograph | 22 % [17.6 – 26.4] | 19.2 % |
| Cannabidiol (CBD, total equivalent) | | <1.0 % | 0.3 % |
| Related substances (HPLC) | Ph. Eur. (current ed.) | | |
| Cannabinol (CBN, total equivalent) | 2.2.29, Monograph | ≤ 1.0 % | < 0.1 % |
| Content of container | BMC-SWV 455 | 5 gram | ± 5.15 gram |
| Expiry date | | | 31 Jul 2025 |

*The following pesticides are not analysed: dithiocarbamates (expressed as CS2), methoxychlor, paraoxonmethyl and tetradifon. The limit of detection is increased for fenpropathrin to 0.1 mg/kg and azinphos-ethyl to 1 mg/kg.

I hereby certify that the above information is authentic and accurate. This batch of product has been cultivated and manufactured, including packaging and quality control at the above mentioned sites in full compliance with the GAP requirements as published in the Dutch State Gazette (Staatscourant) as the annex to the Regulation of the Minister of Health, Welfare and Sport of 9 January 2003, GMT/BMC 2340685, and with the specifications as stated in this document. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GAP and GMP.

The Hague, the Netherlands, 17 december 2024

100 6 Anpersch

S. Vos- de Schipper / K. Amponsah QA, Office of Medicinal Cannabis