

Office of Medicinal Cannabis



## Release certificate

Product:

Cannabis flos, variety Bedrocan (hemp flowers)

Country: Strength: to be sold on the pharmaceutical market

cannabidiol: < 1.0%

Dosage form:

flowers

Dookogo oizar

.....

Package size:

5 grams in container, 400 grams in bags

Batch:

22K07EY23B22

Order numbers:

containers: 384216 to 384225

tetrahydrocannabinol: ca. 22%

bags:

384227

Grower/drier:

Bedrocan Nederland B.V.

P.O. Box 2009

harvest date/period: 07 November 2022

NL- 9640 CA Veendam

Gamma

Packager:

Synergy Health Ede B.V.

date:

dose:

irradiation:

Soevereinstraat 2

22 February 2023

≥ 10,0 kGy

NL-4879 NN Etten-Leur

Fagron B.V.

date:

Venkelbaan 101

22 March 2023 – 31 March 2023

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5

NL-9561 CZ Ter Apel

1. General analysis

Analysis number: 40753

Report date: 20 December 2022

2. Microbiology of end product in container

Analysis number: 43164 Report date: 11 April 2023

Testing method:

OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021

Method
Characters Monograph

Specification
Odour characteristic for

Result 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

characters

Macroscopic botanical

Visual

Brown, green clustered

flowers of about 1.5 to

conform

3.0 cm length

Microscopic botanical

Monograph

Gland hairs are mainly

conform

observed

characters

Thin-layer chromatography Ph. Eur. (current ed.)

Comparable with

conform

2.2.27, Monograph

reference

P.O. Box 16114 NL-2500 BC THE HAGUE The Netherlands

The Netherlands
Telephone +31 70 340 5113
Telefax +31 70 340 7426

Address: Hoftoren Rijnstraat 50 NL-2515 XP THE HAGUE

The Netherlands

All correspondence addressed to the postal address quoting date and reference of this letter. Internet address: www.minvws.nl www.cannabisbureau.nl e-mail: info@cannabisbureau.nl

## Ministry of Health, Welfare and Sport

## Office of Medicinal Cannabis

Page 2

Our reference

22K07EY23B22					
Foreign material	Visual	Free from insects and other vermin		conform	
Microbial contamination	Ph. Eur. (current ed.)				
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gram		< 10 <sup>2</sup>	cfu/gram
Total combined yeasts/moulds count		≤10¹ cfu/gram		< 10¹	cfu/gram
(TYMC)					
S. aureus, P. aeruginosa,					
bile-tolerant gram-		Absent (1 gram)		conform	
negative bacteria					
Aflatoxins	Monograph				
Aflatoxin B <sub>1</sub>		≤ 2 µg/kg		< 2.0	µg/kg
Sum of aflatoxins B <sub>1</sub> , B <sub>2</sub> ,		≤ 4 µg/kg		< 4.0	μg/kg
$G_1$ and $G_2$					
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	%	9.3	%
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	22 % [17.6	6 – 26.4]	20.9	%
Cannabidiol (CBD, total equivalent)		<1.0	%	0.1	%
Related substances (HPLC)	Ph. Eur. (current ed.)				
Cannabinol (CBN, total equivalent)	2.2.29, Monograph	≤ 1.0	%	< 0.1	%
Content of container	BMC-SWV 360	5	gram	± 5.15	gram
Expiry date				29 Feb.	2024

<sup>\*</sup>The following pesticides are not analysed: dithiocarbamates (expressed as CS2), methoxychlor, paraoxon-methyl 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, 19 April 2023

r. M.J. van de Velde

Head, Office of Medicinal Cannabis

Dr. M.J. van de Velde