Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



Release certificate

Product:		bis flos, variety Bedroca	· ·					
Country:		to be sold on the pharmaceutical market						
Strength:		drocannabinol: ca. 22%	cannabidiol: < 1.0%					
Dosage form:	flowers							
Package size:	5 grams in container, 400 grams in bags							
Batch:	23I12EY23K16							
Order numbers:	containers: 386090 to 386094							
	bags:	not applicable						
Grower/drier:		an Nederland B.V. ox 2009	harvest date/period: 12 September 2023					
	NL- 964	40 CA Veendam						
Gamma	Synerg	y Health Ede B.V.	date:	dose:				
irradiation:	Soever	einstraat 2	15 November 2023	≥ 10,0 kGy				
	NL-487	9 NN Etten-Leur						
Packager:	Fagron	Nederland B.V.	date:					
	Venkel	baan 101	07 – 13 May 2024					
	NL-290	8 KE Capelle a/d IJssel						
Laboratory:	Labora	torium Ofichem B.V.	1. General analysis					
	Heemb	adweg 5	Analysis number: 46045					
	NL-956	1 CZ Ter Apel	Report date: 30 October 2	2023				
		2. Microbiology of end product in con						
			Analysis number: 49148					
			Report date: 22 May 2024	l .				
Testing method:	OMC N	1onograph Cannabis Fl	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								
<i>Macroscopic botanical characters</i>		Visual	Brown, green clustered					
			flowers of about 1.5 to	conform				
			3.0 cm length					
Microscopic botanical		Monograph	Gland hairs are mainly	conform				
characters			observed					
Thin-layer chromat	tography		Comparable with	conform				
		2.2.27, Monograph	reference					

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All correspondence addressed to the postal address quoting date and NL-2515 XP THE HAGUE reference of this letter.

Internet address: www.minvws.nl www.cannabisbureau.nl e-mail: info@cannabisbureau.nl Ministry of Health, Welfare and Sport

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Our reference

Our reference 23I12EY23K16					
Foreign material	Visual	Free from insect other vermi		conf	orm
Microbial contamination	Ph. Eur. (current ed.)				
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gra	m	< 10 ²	cfu/gram
Total combined yeasts/moulds count		≤10¹ cfu/gra	m	< 10 ¹	cfu/gram
(TYMC)					
<i>S. aureus, P. aeruginosa, bile-tolerant gram- negative bacteria</i>		Absent (1 gra	ım)	conf	orm
Aflatoxins	Monograph				
Aflatoxin B ₁		≤ 2 µg/kg			µg/kg
<i>Sum of aflatoxins B₁, B₂,</i> <i>G</i> 1 and <i>G</i> 2		≤ 4 µg/kg		< 4.0	µg/kg
Pesticides	Ph. Eur. (current ed.) 2.8.13	≤ Limits Ph. Eur. :	2.8.13*	conf	orm
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	%	7.4	%
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	22 % [17.6	6 – 26.4]	18.2	%
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 455	5	gram	± 5.14	gram
Expiry date			and to	30 Sep.	2024

*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, 30 May 2024

Amarsch

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