



**Hemp Ingredients
Dietary Supplements
Conventional Food**

PRESENTED BY
Douglas MacKay, SVP of Scientific and Regulatory Affairs
CVSI
FDA Public Meeting
May 31, 2019

HEMP AND MARIJUANA COMPARED, 0.3% THC IS ONLY ONE *small DIFFERENCE*



**Agricultural Commodity
vs.
Controlled Substance**

“For the support you can only use the Cannabis types....listed in the common seed catalog and published according to article 17 of the guideline”

“Cannabis seed types which are not allowed in Germany 2017”

-Hot Crops

INDUSTRIAL HEMP SEED TYPES WHO CAN BE SUPPORTED*

*For the support you can only use the Cannabis types which are till the 15th of march of this year listed in the common seed catalog for agricultural plants and published according to article 17 of the guideline 2002/53/EG.

Cannabis seed types for the regular farming

Antal	KC Dora
Armanca	KC Virtus
Beniko	KC Zuzana
Cannakomp	Kompolti
Carma	Kompolti hibrid TC
Carmaleonte	Lipko
Chamaeleon	Lovrin 110
Codimono	Marcello
CS	Markant
Dacia Secuieni	Monoica
Delta-Ilosa	Rajan
Delta-405	Ratza
Denise	Santhica 23
Diana	Santhica 27
Dioica 88	Santhica 70
Eletta Campana	Secuieni Jubileu
Epsilon 68	Silvana
Fedora 17	Szarvasi
Felina 32	Tiborszallasi
Ferimon	Tisza
Fibranova	Tygra
Fibrol	Uniko B
Finola	Uso-31
Futura 75	Wielkopolskie
Ivory	Wojko
KC Bonusz	Zenit

Cannabis seed types which are not allowed in Germany in 2017:

Bialobrzeskie	Carmagnola
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The average THC content of all samples of Bialobrzeskie and Carmagnola were above the allowed maximal concentration in two years.



FDA regulation allows a naturally derived ingredient to co-exist as conventional food, dietary supplement, and drug

✓ Intended use dictates safety, manufacturing standards, and marketing claims

DISTINCT REGULATED PRODUCT CATEGORIES – food, supplements, drugs

1 Conventional Food - Defined

2

FDA completed three generally recognized as safe (GRAS) notices for hemp seed-derived food ingredients: hulled hemp seed, hemp seed protein powder, and hemp seed oil.

FDA had no questions regarding the safe use of these ingredients in humans.

3

Hemp seed derived products can be legally marketed in human foods, provided they comply with other FD&C requirements.



DISTINCT REGULATED PRODUCT CATEGORIES – food, supplements, drugs

1 Prescription Drug - Defined

2 FDA has approved one cannabis-derived and three cannabis-related drug products. These approved products are only available with a prescription from a licensed healthcare provider.

3 There is active research exploring new cannabis-derived and cannabis-related drugs.



DISTINCT REGULATED PRODUCT CATEGORIES – food, supplements, drugs



1

Dietary Supplement – Guidance for industry needed on the scope of allowed hemp-derived dietary ingredients (purity, potency, and composition)

2

New Dietary Ingredient Notification (NDIN)

1) Describe 'identity' of ingredient (a.k.a., 'the article')

2) Provide evidence of safety for the described ingredient for the intended use

3

Other FD&C requirements for dietary supplements

- cGMP
- Labeling and claims
- Adverse Event Report (AER) record keeping and recording requirements

- Different ➤ **Products (composition, purity and potency)**
- Different ➤ **Intended use**
- Different ➤ **Safety, manufacturing and marketing regulations**



	CONVENTIONAL FOOD	DIETARY SUPPLEMENT	PRESCRIPTION DRUG
Source	Hemp	Hemp	Marijuana, Hemp, and Synthetic
Safety	GRAS	NDIN	pre-market approval
cGMP	21 CFR Part 117	21 CFR Part 111	21 CFR Part 211
Claims	taste, aroma, nutritive value, or technical effect	structure/function	therapeutic (pre-approved)
Scope of allowed cannabis ingredients	hulled hemp seed, hemp seed protein powder, and hemp seed oil	hemp extracts + (hulled hemp seed, hemp seed protein powder, and hemp seed oil)	No limits

Responsible Industry Pillars

- Starting material – food/fiber hemp cultivars from licensed and registered hemp seeds
- Ingredient identity – supplement/food ‘article’ is different composition than drug ‘article’
- Ingredient meets FDA safety standards
- 3rd party cGMP verified manufacturing
- FDA compliant labeling and claims
- Post Market Surveillance (AER record keeping and reporting)

to att:
U.S. Customs and Border Protection /
U. S. Department of Agriculture

23.06.2015

Dear Sirs and Madams!

The phytosanitary certificate DE/FR/PL01437/16 063 15/249 and the delivery note MRN 15DE260417616743E9 from German customs administration reflects the way of transport for the goods stated (3.000 kg hemp seeds Futura 75) from France to Germany and the export of these goods to the US.


Receiver of the goods: U. S. Hemp Oil / CV Corp

Best regards

Wir beeheiligen die Vorlage der Erklärung.
Hinsichtlich des Inhaltes ist Gegenteiliges nicht bekannt.

Düsseldorf, am 23. Juni 2015

Industrie- und Handelskammer
zu Düsseldorf
Der Hauptgeschäftsführer
i.A.
Koen Schol



United States

COMMERCIAL INVOICE

Customer number: 8695 Invoice number: 60361
Invoice date: 07.05.2013

For delivery for the following goods on the aforesaid date we bill:

Pos.	Anz.	Art.-Nr.	Artikel/Dienstleistung	(Mvst.) Preis Rabatt	Gesamt
1	12		Hemp oil (kg) Tariff code 1515.90.80.10	(0)	
2	1	1002r	Transport EXN Duesseldorf	(0) 0.00	0.00

End use: Cosmetics, lotions (will be repacked in US into 8 oz plastic bottles)
Containers: 6 x 2 kg / 70,55 Fl oz. (2155 ml) plastic bucket

Label information:
Product name: Hemp Oil
Batch number: SK0213
Expiry date: 12/2016
Net weight: 12 kg/70,55 Fl oz. (2155 ml)
Manufactured by:
40470 Duesseldorf
Tel. 0049-211-699905610, Fax 0049-211-699905618

Country of origin: Germany

I declare that all the information in this invoice to be true and correct.

05/07/13
Daniel Kruse, CEO, Hempco Int. Duesseldorf

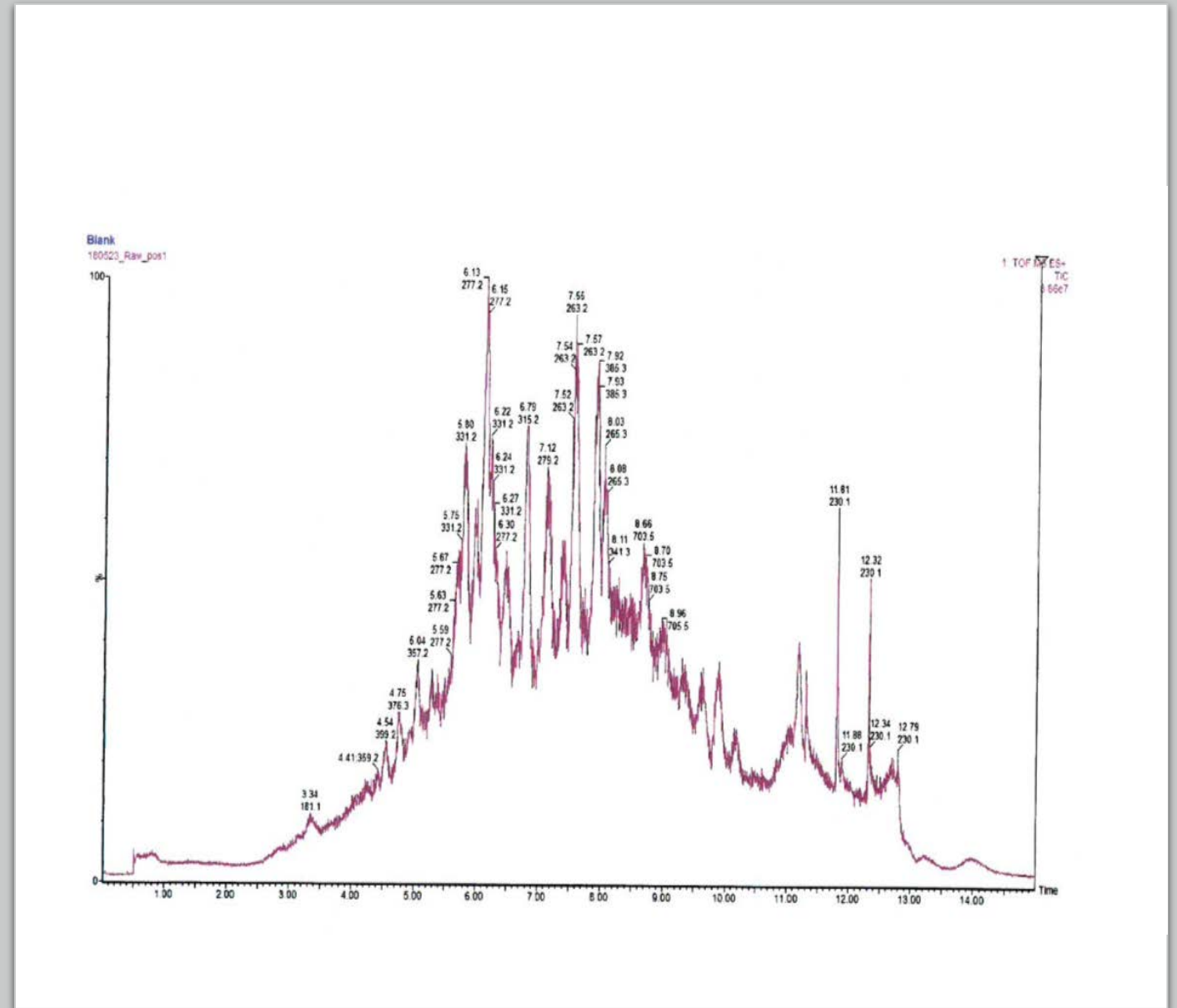
Hinweis: Rechnung o
Nettobetrag EUR
Gesamtbetrag EUR

Hinsichtl. Entgeltminderungen verweisen wir auf aktuelle Zahlungs- und Konditionsvereinbarungen.
Lieferdatum entspricht dem Rechnungsdatum. Es gelten die Allgemeinen Geschäftsbedingungen (AGB).
Oben aufgeführte Ware bleibt bis zur vollständigen Bezahlung Eigentum von Hempco International.

Deutsche Bank, BLZ 251 205 00 24, Kto. 222 55 14
GLS Bank, BLZ 430 609 67, Kto. 40 10 73 71 00
Antsgericht Düsseldorf HR15108
Antsgericht Düsseldorf HR340066
Antsgericht Düsseldorf HR340066
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Hindawi
Journal of Toxicology
Volume 2018, Article ID 8143582, 26 pages
<https://doi.org/10.1155/2018/8143582>

Research Article

An Assessment of the Genotoxicity and Subchronic Toxicity of a Supercritical Fluid Extract of the Aerial Parts of Hemp

Tennille K. Marx ¹, Robin Reddeman ¹, Amy E. Clewell ¹, John R. Endres ¹,
Erzsébet Béres,² Adél Vértesi,² Róbert Glávits,² Gábor Hirka,² and Ilona Pasics Szakonyiné²

¹AIBMR Life Sciences, Inc., 2800 E Madison St., Suite 202, Seattle, WA 98112, USA

²Toxi-Coop Zrt., Magyar Jakobinusok Tere 4/B, Budapest 1122, Hungary

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Academic Editor: Lucio Guido Costa

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A battery of toxicological studies was conducted on a supercritical CO₂ extract of the aerial parts of the *Cannabis sativa* plant, containing approximately 25% cannabinoids. No evidence of genotoxicity was found in a bacterial reverse mutation test (Ames), in an in vitro mammalian chromosomal aberration test, or in an in vivo mouse micronucleus study. A 14-day repeated oral dose-range finding study conducted in Wistar rats at 1000, 2000, and 4000 mg/kg bw/day resulted in effects where a NOAEL could not be concluded. Based on those results, a 90-day repeated dose oral toxicity study was performed in rats using doses of 100, 360, and 720 mg/kg bw/day, followed by a 28-day recovery period for two satellite groups. Significant decreases in body weight, body weight gain, and differences in various organ weights compared to controls were observed. At the end of the recovery period, many of the findings were trending toward normal; thus, the changes appeared to be reversible. The NOAEL for the hemp extract in Hsd.Han Wistar rats was considered to be 100 mg/kg bw/day for males and 360 mg/kg bw/day for females.

1. Introduction

Cannabinoids are chiefly known to act on the cannabi-

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Eurofins Scientific, Inc.
2200 Rittenhouse Street
Des Moines, IA 50321, USA
Ph: (515)299-6979
www.eurofinsus.com/food-safety

AUDIT DATE(S):
8/15/2018

AUDIT SCORE:
99%

EXPIRATION DATE:
8/15/2019

CERTIFICATE NUMBER:
T16242000

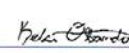
Audit Recognition

This acknowledges that

CV Sciences
10070 Barnes Canyon Rd
San Diego, California, 92121

has successfully completed

**Eurofins Dietary
Supplement Audit**



Kelsi Obando
Certification Specialist



Gary Smith
Director of Food Safety Systems

Credible Results. Incredible Service.™



Certificate of Compliance

Date of Issue:
01-02-2019

Expiration:
01-02-2020

Certificate Number:
701003

Authorized by:



Brian Bennett
Director of Auditing
Services

Issuing Officer:



Ariana Shnurman
Program Manager

Validus Verification Services, LLC

hereby certifies that

CV Sciences Inc.

has been reviewed by an authorized representative of the Validus Verification Services and is certified under the U.S. Hemp Authority Certification Program for the following site:

10070 Barnes Canyon Road, Suite100
San Diego, California 92121, United States

Scope of Registration: U.S. Hemp Authority

Audit was conducted with U.S. Hemp Authority checklist v1.0 in effect 12-2018

*For the validity of the certificate please check www.ushempauthority.com



Validus Verification Services LLC
3331 109th Street
Urbandale, IA 50322

This certificate certifies compliance by the above-named facility with the applicable program requirements of the U.S. Hemp Authority Certification Program. It is not intended to certify or imply the particular operating conditions or product within the facility at any particular time. This certification means that the facility has implemented all U.S. Hemp Authority Certification Program requirements. This certificate must be surrendered upon request by Validus Verification Services in performance with the U.S. Hemp Authority Certification Program.



Thank You!

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Douglas MacKay, SVP of Scientific and Regulatory Affairs
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