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TEA TREE OIL STATEMENT OF PURITY

1. DESCRIPTION

Country of Origin: Eastern Australia
Common Name: Australian Tea Tree Oil
Botanical name: Melaleuca alternifolia
Harvest Method: Mechanical cultivated
Manufacturing process: Steam distillation of leaves and stems.
Period of Harvest/Distillation: Autumn/Winter

MCNE tea tree oil is within the scope of REACH Regulation. The raw material is registered (number: CAS 85085-48-9)

The MCNE Tea Tree Oil meets all the compositional specifications of Pharmaceutical Grade Tea Tree Oil. The Martindale Extra Pharmacopoeia 36 edition 2009, p2338 identifies Melaleuca Oil as a recognized pharmacological substance (under Supplementary Drugs and Other Substances) and details its compositional requirements as per the current ISO4730 and Australian standards. Furthermore MEP references the specs as per the 2008 European Pharmacopoeia Supplement 6. Therefore, the use of this oil is adequate for uses in Pharmaceutical applications.

2. NATURALNESS

MCNE tea tree oil is correctly regarded and classified as being 100% pure and natural.

3. COSMETICS

MCNE tea tree oil is suitable for cosmetic use in accordance with the Cosmetic Directive 76/768/EEC and its various subsequent revisions. It is suitable for use as per the EU Cosmetics regulation (EC) No 1223/2009. The list of IFRA/EU potential allergens is relevant to tea tree oil as per levels shown in the following table.

ALLERGENS	CAS	Percentage in the MCNE tea tree oil
Anisyl alcohol	105-13-5	Not detected (N.D)
Benzyl alcohol	100-51-6	N.D
Cinnamyl alcohol	104-54-1	N.D
Benzyl benzoate	120-51-4	N.D
Benzyl cinnamate	103-41-3	N.D
Benzyl salicylate	118-58-1	N.D
Cinnamaldehyde	104-55-2	N.D
Citral	5392-40-5	N.D
Citronellol	106-22-9	N.D
Coumarin	91-64-5	N.D
D-Limonene	5989-27-5	0.75%
Eugenol	97-53-0	N.D
Farnesol	4602-84-0	N.D
Geraniol	106-24-1	N.D
Isoeugenol	97-54-1	N.D
Linalool	78-70-6	<0.05%
Tree moss	90028-67-4	N.D
Oak moss	90028-68-5	N.D
Phenyl acetaldehyde	122-78-1	N.D
Amyl cinnamic alcohol	101-85-9	N.D
Amyl cinnamaldehyde	122-40-7	N.D
Gamma methyl ionone	127-51-5	N.D
Hexyl cinnamaldehyde	101-86-0	N.D



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Hydroxycitronellal	107-75-5	N.D
Lilial	80-54-6	N.D
Lyral	31906-04-4	N.D
Methyl heptin carbonate	111-12-6	N.D

Furthermore, MCNE tea tree oil contains no detectable levels of compounds from the following list of CMR (carcinogenic, mutagenic, reproductive toxicity) as per the IFRA and EU's Health and Consumer Protection's SCCP.

CAS	INCI (US) NAME	CLASSIFICATION	SUPPLIER / IFRA SELF - CLASSIFICATION
117-81-7	DIETHYL HEXYL PHTHALATE	TOXIC FOR REPRODUCTION CAT.2	
94-59-7	SAFROLE	CARCINOGENIC CAT.2	
75-21-8	ETHYLENE OXIDE	CARCINOGENIC CAT.2 MUTAGENIC CAT.2	
91-22-5	QUINOLINE	CARCINOGENIC CATEGORY 2 MUTAGENIC CATEGORY 3	
75-07-0	ACETALDEHYDE	CARCINOGENIC CATEGORY 3	
98-01-1	FURFURAL	CARCINOGENIC CATEGORY 3	
5146-66-7	GERANYL NITRILE		PROPOSED AS MUTAGENIC CATEGORY 2
98-00-0	FURFURYL ALCOHOL	CARCINOGEN CATEGORY 3	
81-15-2	MUSC XYLENE	CARCINOGENIC CATEGORY 3	
81-14-1	MUSC KETONE	CARCINOGENIC CATEGORY 3	
107-22-2	GLYOXAL	MUTAGENIC CATEGORY 3	
4170-30-3	CROTONALDEHYDE	MUTAGENIC CATEGORY 3	
591-78-6	HEXAN-2-ONE	TOXIC FOR REPRODUCTION CATEGORY 3	
78-59-1	ISOPHORONE	CARCINOGENIC CATEGORY 3	
60-35-5	ACETAMIDE	CARCINOGENIC CATEGORY 3	
91-20-3	NAPHTHALENE	CARCINOGENIC CATEGORY 3	
104-93-8	4-METHYLANISOL		Repro cat.3 R63
80-54-6	P-BMHCA		Repro cat.3 R62
18127-01-0	BOURGEONAL		Repro cat.3 R62
103-95-7	CYCLAMEN ALDEHYDE		Repro cat.3 R62
93-53-8	HYDRATROPIC ALDEHYDE		Repro cat.3 R62
6658-48-6	RHODIAL/SILVIAL		Repro cat.3 R62
7775-00-0	CYCLEMAX		Repro cat.3 R62



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62518-65-4	m-BMHCA		Repro cat.2 R61
77525-18-9	ESTRAGOL		
98-82-8	CUMENE		

Additionally, MCNE tea tree oil does not contain any levels of detectable concern of any of the 791 chemicals suspected of causing cancer or having reproductive toxicity as per the Californian department of public health's Safe Cosmetics Program list – except for the tea tree plant's natural production of ~300mg/kg of tea tree oil of methyl eugenol.

4. IONISATION

MCNE tea tree oil does not undergo any ionisation radiation treatments of any kind.

5. BSE (Mad Cow's Disease)

MCNE tea tree oil does not contain any ingredients obtained from any specified risk materials according to the Regulation 999/2001/EEC.

6. RESIDUAL EXTRACTIVE SOLVENT

MCNE tea tree oil is removed within 24 hours from the harvested plantation trees by steam distillation. A trace amount of water remains dissolved in the product.

7. COMPLIANCE WITH GENERAL CONTAMINANTS REGULATIONS

None of the following contaminants have been detected in MCNE tea tree oil. There are no stages within the farming or processing methods that could possibly give rise to any such contamination(s).



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	Method of Detection	Level of Detection
Heavy metals:		
As	ICP-MS	ND
Cd	ICP-MS	ND Cadmium < 1mg/Kg
Pb	ICP-MS	ND Lead < 3mg/Kg
Hg	ICP-MS	ND Mercury < 0.1mg/Kg
Sb	ICP-MS	ND
Zn	ICP-MS	ND
Ni	ICP-MS	ND
Cu	ICP-MS	ND
Chlorinated organics(CDD/CDF/PCB)	HRGC/MS	ND
Nitrates / Nitrites	Wet Chem	
Mycotoxins:		
Aflatoxin B1	LC-MS/MS	ND
Aflatoxin B1+B2+G1+G2	LC-MS/MS	ND
Patulin	HPLC	ND
Ochratoxine	HPLC	ND
Pesticides: Organophosphate/organochlorine		ND
Phthalates:		
DEHP bis (2-ethylhexyl) phthalate		ND
DBP Dibutyl phthalate		ND
DEP Diethyl phthalate		ND
BBP Butyl Benzil Phthalate		ND
Ethylene Glycol		ND
Musk		ND
Formalin		ND

8. GENETIC MODIFICATION

MCNE tea tree oil is derived from plantation trees grown from selected natural wild seeds. Not genetically modified material organism or enzymes are used or have contacted and part of any components of the cultivation, harvesting or processing stages of the product's production.

9. FOOD ALLERGENS

The following Food Allergens as defined in Directive 2003/89/EEC are not detected in MCNE tea tree oil and are not in any way contacted or exposed to such allergens during any part of the cultivation, harvesting or processing stages of the product's production:



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Cereal with gluten (wheat, rye, barley, oats, lupine, kamut) and products thereof.
Shellfish, crustaceans and products thereof. Eggs and products thereof. Fish and products thereof. Peanuts and products thereof. Soybeans and products thereof. Milk and products thereof (lactose). Nuts - hazel, pistachio, almonds, walnut, acagiu, pecan, brazil and products thereof. Celery and products thereof. Sesame and products thereof. Mustard and products thereof. SO₂ and SO₃ concentration > 10 mg/Kg or 10 mg/l SO₂. BHA E320, BHT E321, Tocopherols E306-E309, Acid benzoic E210- E213, Acid benzoic E210- E213.

Other ingredients, which could cause adverse reaction or considered to be allergens in non EU- countries are not detected in MCNE tea tree oil and are not in any way contacted or exposed to such allergens during any part of the cultivation, harvesting or processing stages of the product's production:

Vegetables (Pulse legumes, garlic, tomato, shiitake mushrooms), Fruits (Kiwi, banana, apple, orange, peach, strawberry), Spices (vanilla beans, cinnamon), Umbellifereae (caraway, dill, anise, coriander, Chervil, lavas, cicerly), Meat (beaf, pork, chicken), Soya, Buckwheat, Sunflowers seeds, Poopy seeds, Pine nuts, Japanese nooddles, Gelatin, Bee pollen/propolis.

10. MELAMINE COMPOUND

MCNE Tea Tree Oil does not contain any Melamine traces. It is Melamine-free.

11. MICROBIOLOGICAL ASSESSMENT

MCNE Tea Tree Oil is tested in accordance to the Therapeutic goods Order No 77, Microbiological Standards for Medicines (topical and oral product use). The following demonstrates the typical Microbiological Analysis;

MICROBIOLOGICAL ANALYSIS	RESULTS	TEST METHOD
Bile Tolerant Gram Negative Bacteria (PN/gram)	<10	Biotest 3.03.01.05
Total Viable Aerobic Count TSA 30°C/5 days (CFU/g)	<10	Biotest 3.01.13
Yeast & Mould Count SGA 20-25°C/5 days (CFU/g)	<10	Biotest 3.02.07
<i>E. Coli</i> (Presence/gram)	Not detected	Biotest 3.03.04.05
<i>S.aureus</i> (Presence/gram)	Not detected	Biotest 3.04.01.01
<i>Salmonella</i> spp. (Presence/10 grams)	Not detected	Biotest 3.05.08
<i>Psuedomonas</i> spp. (Presence/gram)	Not detected	Biotest 3.10.01

12. Pyrrolizidine Alkaloids.

MCNE Tea Tree Oil does not contain any Pyrrolizidine Alkaloids.



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Person Responsible: Yannick Castella
Position: Commercial Manager

Date: 01/02/2018 Signature:

Stamp: Main Camp Natural Extracts Pty Ltd
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