COSMETIC SAFETY DOSSIER

This Third Party Cosmetic Safety Dossier
Is Prepared for **MagicDichol LLC**
251 Little Falls Drive
Wilmington, DE 19808

Regarding **Metasomer™**

FDA 740(10) and EU Art. 7 Compliant

www.CosmeticSafetyDossier.com

Prepared by:
Robert M. Goodman, PhD
Ralph Fucetola JD

INDEX

1. **Report on the Consultation Regarding the Description** required of the "qualitative and quantitative composition."

2. **Report Confirming the Specification**: confirming the required "physic-chemical and microbiological specification" as certified by the responsible person at the Company; the Confirmation Report attests before a Notary that the search of the scientific literature supports the specification as reported.

3. **Report of SOP Consultation** regarding description of the SOPs for method of manufacture complying with cGMPs.

4. **Certified Assessment of Safety**; this Certification Document shall take into consideration the general toxicological profile of the ingredients, their chemical structure and their level of exposure, and shall take particular account of the specific exposure characteristics of the areas on which the product will be applied or of the population for which it is intended.

5. **Proprietary List of Ingredients**

6. **Biographies of Dr. Goodman and Counsel Fucetola**

CERTIFICATE OF SAFETY

This Certification Confirms that
The Named Cosmetic Product
Metasomer™
MagicDichol LLC
251 Little Falls Drive
Wilmington, DE 19808

COSMETIC SAFETY DOSSIER

With the Attached Proprietary
Ingredient List
Is Fully Compliant with
FDA Regulations under 26 USC 740(10) and
European Union Cosmetic Article 7.

The product is not injurious to consumers under conditions of customary use and reasonably foreseeable conditions of misuse.

Certification Dated the 9th Day of June, 2021

Robert M. Goodman, PhD
Robert M. Goodman, PhD Biochemistry

Ralph Fucetola, JD
Ralph Fucetola, JD

Certified True Copy
Ralph Fucetola

RALPH FUCETOLA NOTARY PUBLIC STATE OF NEW JERSEY MY COMMISSION EXPIRES JULY 30 2025 ID # 2398815

www.CosmeticSafetyDossier.com

ATTACHMENTS

1. Report on the Qualitative and Quantitative Description

The third party reviewers confirm the qualitative and quantitative description of the product as set forth in Attachment #5.

2. Report on the physic-chemical and Microbiological Specification Confirmed

This is to confirm the specification of the form of the product as a liquid of pH between 4.3 and 4.7, consisting of a stable, light-scattering aqueous suspension of particles of diameter 70 nanometers or less, packed in a pump spray bottle.

A standard batch analysis showed no bacterial or fungal contamination (below detection limits), and the product's packaging and method of use make accidental contamination during shipment or use very unlikely. However, even if minor microbial contamination were to occur, a standard challenge test by an independent contract laboratory using 6 organisms of concern (bacteria and fungi) showed the liquid as having most favorable antimicrobial profile the test could detect.

3. Report of SOP Consultation

The Standard Operating Procedures (SOP) documentation of the company has been reviewed by the third party reviewers in consultation with the company. We find that the SOPs conform to the specific requirements of Good Manufacturing Practices in the cosmetic industry, as provided under FDA and EU regulations.

4. Certified Assessment: See Pages 5 – 6.

5. Proprietary Ingredient List

Water
Edible Xanthan gum
Vitamin E TPGS
Policosanol
Potassium sorbate
Sucrose monolaurate
Citric Acid

6. Biographies: See Page 7.

ATTACHMENTS CONTINUED

4. Assessment of Safety Certified

The ingredients individually each have uncontroverted evidence of safety for use in the manner intended. The third party reviewers hereby certify the assessment of safety.

Water

This component is well known to be safe on skin, in eyes, and if ingested.

Edible Xanthan gum

This component is GRAS. 21 C.F.R. §172.695

Saccharum officinarum (sugar cane) extract

A comprehensive literature search shows no examples of toxicity to humans or to related organisms. A study in 16 beagles (versus 8 negative controls) force-fed 30 or 180 mg/kg of extract daily for one year showed no toxicity.[1] [1.] An evaluation of the extract for anti-inflammatory effects by two experiments on mouse skin showed at least no worsening of their condition.[2.] CosIng (the cosmetics ingredient database of the European Commission) lists the extract as without cosmetic or other restriction as of June 17, 2017. The likely breakdown products of the extract can be expected to be innocuous as well.

Tocophersolan

According to literature compiled by Antares Health Products, Inc. and Isochem, tocophersolan has for it a standing claim of GRAS status uncontroverted by the US FDA for oral use, has a monograph in the USP-NF; dermal and ocular use of the material is also mentioned as at least investigational. The Antares brochure says of its safety, "Studies in humans included dosing of cholestatic children at 25 IU/kg/day (equivalent to 64 mg TPGS/kg/day) for over two years." CosIing lists tocophersolan as without cosmetic or other restriction as of June 17, 2017. The standing Cosmetics Ingredients Review panel (CIR) of the Personal Care Products Council concluded it was safe under common conditions of use.[3.] Being a polyethylene glycol succinyl ester of vitamin E, the method of manufacture of tocophersolan in its linking of the PEG moiety (rather than direct ethoxylation) is such as to minimize carryover of any 1,4-dioxane that may have formed during polymerization. The likely breakdown products of tocophersolan are innocuous.

Citric Acid

This is an ingredient with a long and well-known history of safe use in cosmetics to adjust pH. Citric acid's presence as a common component of beverages shows that it is safe if ingested even in concentrations well above those used to adjust pH. The CIR report on safety noted that repeat insult

---

1Toxicity of policosanol in beagle dogs: one-year study. Mesa AR1, Más R, Noa M, Hernández C, Rodeiro I, Gámez R, García M, Capote A, Alemán CL. *Toxicol Lett.* 1994 Aug;73(2): 81-90

2 Further studies on a mixture of fatty acids from sugar cane (Saccharum officinarum) wax oil in animal models of hypersensitivity. Ledón N1, Romay Ch, Rodríguez V, Cruz J, Rodríguez S, Ancheta O, González A, González R, Tolón Z, Cano M, Rojas E, Capote A, Valdes T. *Planta Med.* 2005 Feb;71(2):126-9

3. Safety Assessment of Tocopherols and Tocotrienols as Used in Cosmetics, Final Amended Report, April 4, 2014

patch tests of citric acid at 4% without buffering showed an absence of irritation and sensitization.[4.] CosIng lists it without cosmetic or other restriction. The Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, asked to assess the safety of α-hydroxy acids (of which citric acid is one), in its position paper of June 28, 2000, did not take a position on citric acid, while noting its existing use at 0.2 to 4% and pH of 2.67 to 5.38. However, they did suggest that glycolic acid be used only up to 4% and pH $\geqslant$ 3.8 . Citric acid being generally a less aggressive substance, its use in the present product in concentration just sufficient to adjust pH no lower than 4.3 puts it well within parameters of safety for skin.

Sucrose monolaurate

CIR's Safety Assessment of Saccharide Esters as Used in Cosmetics (March 22, 2016) included a literature review reporting an absence of eye damage by 10 mg of sucrose laurate left in rabbit eyes. In a publication on delivery of substances by microemulsion using sucrose laurate, sucrose fatty acid esters are said to be nontoxic, nonsensitizing, and causing no skin irritation.[5.] CosIng lists sucrose laurate without cosmetic or other restriction. The expected breakdown products of sucrose laurate are innocuous.

There is nothing about this combination of ingredients that would cause one to expect its safety to be less than those ingredients separately. They may enhance each other's absorption, but since absorption of the individual ingredients presents no hazard, this enhancement is of no concern.

The low pH of the product would cause it to sting on introduction to the eye. However, it would not be expected to be able to damage the cornea unless the eye was anesthetized and the product introduced deliberately. The surfactants used in this product have not been reported to anesthetize mucous membranes, so together with its propensity to sting eyes and the instruction to use it indirectly rather than spraying when using it in the vicinity of an eye, the product's safety against eye damage is adequate.

I certify that the above stated Assessment is the true and accurate assessment of the third party reviewers, Robert M. Goodman, PhD (Biochemistry) and Ralph Fucetola, JD

Ralph Fucetola

9 June 2021

4 Safety Assessment of Citric Acid, Inorganic Citrate Salts, and Alkyl Citrate Esters as Used in Cosmetics. Fiume MM, Heldreth BA, Bergfeld WF, Belsito DV, Hill RA, Klaassen CD, Liebler DC, Marks JG, Shank RC, Slaga TJ, Snyder PW, Andersen FA. *Int. J. Toxicol.* 2014(33) Supp. 2: 16S-46S

5 Efficient Delivery and Distribution in Skin of Chlorogenic Acid and Resveratrol Induced by Microemulsion Using Sucrose Laurate. Yutani R, Kikuchi T, Teraoka R, Kitagawa S. *Chem. Pharm. Bull.* 62(3) 274–280 (2014)

Biographies

Robert M. Goodman, PhD received his A.B. with a concentration in Chemistry from Columbia University, and followed this with credits in the basic medical sciences and some clinical work at the Chicago Medical School, and finally a Ph.D. in Biochemistry from New York Medical College. Dr. Goodman was later a fellow in Cancer Biology in the Radiology Dept. of the University of Medicine and Dentistry of New Jersey.

He has worked at the Institute of Cancer Research of Columbia University, Schwab Rehabilitation Hospital, and Bronx-Lebanon Hospital, and has taught at Mercy College and Sussex County Community College. He worked with National Medical Care, Inc. as both a hemodialysis technician and a scientist-biomedical engineer in research and development. His publications include two United States patents and a hypothesis on genetics and alcoholism. His consulting clients have included Gary Null, the Global Healing Center, and Divina Biotechnology.

Ralph Fucetola, JD received a B.A. with Distinction from Rutgers University, 1967 and a Juris Doctor (Doctorate in Law) from Rutgers Law School, 1971. Since then he has been active in the business and public service communities and practiced law in New Jersey (from 1971 through 2006) specializing in the Nutrient, Cosmetic and Alternative Health fields. He has basic certifications in human bioacoustics, homeopathy and hololinguistics.

He has varied business background experience, including direct management responsibility with companies in the following fields: Real Estate Management; Construction; Dietary Supplement Products and Alternative Modality Products. www.VitaminConsultancy.com