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COSMETIC PRODUCT SAFETY REPORT

G.M.P. COMPLIANCE: Exists and the company is supervised under international GMP compliance, ISO 17025 / ISO 22716, FDA manufacturing cosmetics license No.55872 accordance with the provisions of Division 104, Chapter 7, Article 4 of the California Health and Safety Code. Complies to Saudi legislation (GSO 1943) or to the European regulation (EU 1223/2009).

Safety Assessment **Safety Evaluation of the Finished Products**

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SECTION 1- PRODUCT NAME / PROFILE

Products Name: Advanced Hand Sanitizer

Size: 2oz/60ml, 4oz/120ml, 6oz/180ml, 8oz/236ml, 16oz/500ml, 1 gallon/3,785ml

A. Product label (front and back/inner out packaging)

Active ingredient	Purpose
Ethyl alcohol SD40B (190 proof) 70%	Antimicrobial

Use. Hand sanitizer to help reduce bacteria on the skin and kill germs.

Warning
Keep away from heat, fire or flame.
For external use only.
Keep away from the eye area. In case of contact, rinse eyes thoroughly with water.
Do not apply to sore or broken skin.
Stop use if irritation occurs. Consult with physician before using this product.

Direction. Place enough product in your palm to thoroughly cover your hands. Run hands together briskly until dry.

Inactive ingredients Water (aqua), isopropyl alcohol, glycerin, isopropyl myristate, tocopheryl acetate, acrylates/C10-30 Allyl acrylate crosspolymer, aloe barbadensis(aloë vera) leaf juice, theobroma cacao (cocoa) seed butter, cannabis sativa (hemp) seed oil, tocopheryl acetate (vitamin E) oil, simmondsia chinensis (jojoba) seed oil, citrus aurantium dulcis (orange) peel oil, cymbopogon schoenanthus (lemongrass) oil, mentha piperita (peppermint) leaf extract, melaleuca alternifolia (tea tree) leaf oil, eucalyptus globulus (eucalyptus) leaf extract, rosmarinus officinalis (rosemary) leaf oil, rosa centifolia (rose) flower oil, pogostemon cablin (patchouli) oil, pelargonium graveolens (geranium) leaf oil, aminomethyl propanol.

Other information. Store below 110°F (43°C). May discolor certain fabrics or surfaces.

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SECTION 2- Ingredients/percentage/CAS numbers/Functions

No.	Ingredient Name	Concentration (%)	CAS Number	EINECS Number	Role of Substance
Active Ingredient					
1	Ethyl Alcohol SD40B	70.0000	64-17-5	200-578-6	Antimicrobial
Inactive Ingredients					
2	Water(aqua)	26.9660	7732-18-5	231-791-2	Solvent
3	Isopropyl alcohol	0.0010	67-63-0	200-661-7	Antimicrobial
4	Glycerin	2.0000	56-81-5	200-289-5	Humectant
5	Isopropyl myristate	0.0010	110-27-0	203-751-4	Skin Conditioning Agent
6	Tocopheryl acetate	0.0020	7695-91-2	231-710-0(1)	Skin Conditioning Agent
7	Acrylates/C10 30 Alkyl acrylate crosspolymer	0.4000	N/A	N/A	Thickening agent
8	Aloe barbadensis(aloe vera) leaf juice	0.0100	85507-69-3	287-390-8	Skin Conditioning Agent
9	Theobroma cacao (cocoa) seed butter	0.0100	N/A	N/A	Skin Conditioning Agent
10	Cannabis sativa (hemp) seed oil	0.0100	89958-21-4	289-644-3	Skin Conditioning Agent
11	Tocopheryl acetate (vitamin E) oil	0.0100	7695-91-2	231-710-0(1)	Skin Conditioning Agent
12	Simmondsia chinensis (jojoba) seed oil	0.0100	90045-98-0	289-964-3	Skin Conditioning Agent
13	Citrus aurantium dulcis (orange) peel oil	0.1000	8028-48-6	232-433-8	Fragrance
14	Cymbopogon schoenanthus (lemongrass) oil	0.0100	89998-16-3	289-754-1	Skin Conditioning Agent
15	Mentha piperita (peppermint) leaf extract	0.0100	84082-70-2	282-015-4	Skin Conditioning Agent
16	Melaleuca alternifolia (tea tree) leaf oil	0.0100	85085-48-9	285-377-1	Antioxidant
17	Eucalyptus globulus (eucalyptus) leaf extract	0.0100	84625-32-1	283-406-2	Skin Conditioning Agent
18	Rosmarinus officinalis (rosemary) leaf oil	0.0100	84604-14-8	283-291-9	Skin Conditioning Agent
19	Rosa centifolia (rose) flower oil	0.0100	84604-12-6	283-289-8	Skin Conditioning Agent
20	Pogostemon cablin (patchouli) oil	0.0100	8014-09-3	282-493-4	Masking Agent
21	Pelargonium graveolens (geranium) leaf oil	0.0100	90082-51-2	290-140-0	Masking Agent
22	Aminomethyl propanol	0.4000	124-68-5	204-709-8	pH adjuster
Total Percentage wt.,%		100.000000			

Ingredients have been reviewed and raw materials known, not forbidden as per Annex II of the Regulation (EC) No 1223/2009 of the European Parliament. Remark: This ingredient list is issued by VSC lab department and is a property of VSC.

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- A. **Specifications of each ingredient from the supplier-** Supplier's specifications for each raw material have been reviewed.
- B. **INCI names of ingredients-** Have been reviewed, Are referred in detail in suppliers raw material MSDS.
- C. CAS number of the ingredients are referred in detail in supplier's raw material MSDS.
- D. Safety data sheet of ingredients (MSDS) have been reviewed especially for the toxicological data.
- E. The product production method and specifications of the final. Products developed under GMP COMPLIANCE – STABILITY OF THE PRODUCT and - PRODUCTION METHOD: Has been reviewed.
- F. SPECIFICATIONS OF FINAL PRODUCT: Have been reviewed.

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STABILITY OF THE PRODUCT: Has been reviewed and it is acceptable.

MICROBIOLOGICAL QUALITY – PRESERVATION EFFICACY TEST

MICROBIOLOGICAL QUALITY: The product, due to the presence of preservatives in the formula is under normal production conditions.

FRAGRANCE COMPOSITION

Perfume contained within the products is covered by this Safety Assessment comply with appropriate IFRA guidance. No allergenic ingredients are present in product.

CHALLENGE TEST: The test has been performed (inside the lab and outside lab as well to consider consumer safety. Each ingredients of the product has been studied and results are satisfactory.

Section 3- PHYSICAL AND CHEMICAL PROPERTIES			
Physical State	Liquid Gel	Color	Clear to slightly hazy liquid
Odor	Alcohol Odor	Specific Gravity	<1.0 @ 25 °C
Boiling Point	Approximately 70°C	Freezing Point	Not available
Vapor Pressure	Not available	Vapor Density	Not available
Flash Point	<20 °C	Flammable Limits	LEL 2.2%v, UEL 12.7%v
Water Solubility	Miscible in all proportions	pH	5.0 – 6.0 neat
Volatile Organic Compounds (VOC)	Not available	Coefficient of Water/Oil Distribution	Not available
Viscosity	Not available	Odor Threshold	Not available
Evaporation Rate	Not available		

Clarification of compliance to tests with respect to Lead (Pb), Arsenic (As), Mercury

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(Hg) and other Heavy Metals as per under international GMP compliance, ISO 17025 / ISO 22716 Standards for all proposed products.

Product safety is of paramount importance to M/s Valley of the Sun Cosmetics LLC located at 535 Patrice Place, Gardena, California 90248. All cosmetic and personal care products must be safe – that's a legal requirement, part of the stringent EU and other international laws surrounding the manufacture of cosmetic products with which M/s Valley of the Sun Cosmetics LLC comply.

Before any product is launched, it undergoes a rigorous safety assessment by a team of professionally qualified toxicologists to ensure the product is safe for consumers. The assessment takes into account the finished product, all of the ingredients and how and where the product is to be used.

All ingredients/ pigments used in our cosmetic products applied for registration in India comply fully with Bureau of international GMP compliance, ISO 17025 / ISO 22716 and to Saudi legislation (GSO 1943) Standards, EU purity specifications and also with the USA FDA purity specifications for cosmetic colours, which state very strict limits to trace impurities of heavy metals which may be present in raw materials. These restrictions are incorporated into our formulation policies and specifications to their suppliers. We do not allow these materials to be used in any formulation so that we are in line with the EU Cosmetics and to Saudi legislation (GSO 1943) Regulation. All products proposed for registration in India, and to Saudi legislation (GSO 1943) comply to the below mentioned specification.

M/s Valley of the Sun Cosmetics LLC takes full responsibility and takes the safety and quality of our cosmetics very seriously and monitors levels of heavy metals very closely to ensure compliance.

SECTION 4- STABILITY AND REACTIVITY

Chemical Stability	Stable at normal temperatures and pressure
Conditions to Avoid	Excessive heat, sources of ignition
Incompatible Materials	Strong oxidizing agents
Hazardous Decomposition	Product can decompose on combustion to form Carbon Dioxide, And other possibly toxic gases and vapors
Hazardous Reactions	None known

SECTION 5- PROPERTIES OF PACKAGING MATERIAL

Part number	Description
CF-20473	8 oz Clear bottle w/ black pump (Cylinder round Pet bottle)

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SPR0043 LB44012- Label	Shippers 11 1/2 x 7 3/4 x 7 7/16 8 oz label Advanced hand Sanitizer
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SECTION 6- EXPOSURE TO THE SUBSTANCES (ORAL)

Eye Safety and Skin Sensibility Testing,

- **The product passed stability test, no separation, appearance, p H and viscosity remained on specifications.**
- **The test was conducted by Valley of the sun cosmetics LLC. Note storage below 45°C. Valley of the sun cosmetics elected to submit all cosmetic products for rigorous human safety and sensibility testing to validate the safety and sensibility on the following product.**

A summary of study details are provided below.

Product	Test	Subject	Methods	Results	Conclusions
Advanced Hand Sanitizer	Modified human repeat insult patch test (HRIPT)	43 adults: 71.3% women; 45.7% Caucasian, 46% Asian; 11.4% other ethnicities. Age: mean 20.5 years, range 20-45years.	Conclusively apply on the skin 6 times a day at 30 to 72h intervals	The Hand Sanitizer product had negative control and was non-irritating. Product did not induce contact sanitation (allergic contact) in any subject who completed the study.	Hand Sanitizer product is not hypo allergic.

SECTION 7- TOXICOLOGICAL INFORMATION

PRODUCT MIXTURE INFORMATION

- **Local Effects-** Mild Irritant: eye, skin, inhalation and ingestion
- **Target Organs-** Eyes, mucous membranes, skin, lungs.

POTENTIAL HEALTH EFFECTS

- **Ingestion short term exposure-** Swallowing large amounts of this product can cause stomach irritation, nausea and diarrhea. Aspiration of liquid into the lungs can produce chemical pneumonia.
- **Ingestion long term exposure-** No information available
- **Skin contact short term exposure-** Properly used wash solutions not expected to be irritating. Prolonged contact with concentrated solutions may have a degreasing effect on skin.
- **Skin contact long term exposure-** Prolonged and repeated skin contact with solutions may induce eczematoid dermatitis in certain individuals.
- **Eye contact short term exposure-** This product may cause eye irritation, watering and redness.

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<ul style="list-style-type: none"> • Eye contact long term exposure- No information available. 	
<ul style="list-style-type: none"> • Inhalation short term exposure- Irritating to respiratory system, drowsiness. Vapor may cause dizziness and headache. Mist may cause breathing problems. • Inhalation long term exposure- No information available. 	
<p>Carcinogen Status</p> <ul style="list-style-type: none"> • NOHSC- No significant ingredient is classified as carcinogenic by NOHSC • NTP- No significant ingredient is classified as carcinogenic by NTP • IARC- No significant ingredient is classified as carcinogenic by IARC. 	
<ul style="list-style-type: none"> • Medical Conditions aggravated by exposure- No information available. 	
<p>SECTION 8- CLASSIFICATION OF INDIVIDUAL INGREDIENTS</p>	
<p>NOTE: This information relates to each individual ingredient, when evaluated a pure undiluted chemical. See SECTION 2 for actual proportions of ingredients present in this product.</p>	
Ingredients	R-Phrases
Isopropanol	R11 Highly flammable. R36 irritating to eyes.
Ethanol	R11 Highly flammable
<p>INDIVIDUAL INGREDIENT INFORMATION</p>	
<p>ETHANOL 100%</p>	
<ul style="list-style-type: none"> • Irritation Data- Moderately irritating to skin and may cause redness. Moderately irritating to eyes and may injure tissue. Moderately irritating to respiratory system and mucous membranes. • Toxicity Data- Excessive chronic absorption may result in liver damage. LD50 oral (rat): 2080 mg/kg. LD50 oral (rat): 13.9 g/kg • Local Effects- Absorbed into the body by inhalation and ingestion. Irritant of sensitive tissues, eyes, mucous membranes and central nervous system. • Target Organs- Eyes, mucous membranes, liver, central nervous system. • Acute Toxicity level- Mild toxicity. Narcotic properties: ingestion. • Mutagenic data- No available information • Reproductive Effects- No available information 	
<p>ISOPROPYL ALCOHOL 100%</p>	
<ul style="list-style-type: none"> • Irritation Data- Vapor concentrations above recommended exposures levels may be irritating to the eyes and the respiratory tract, may cause headaches and dizziness could be anesthetic and may have other central nervous system effects. Eligible hazard at ambient temperature (-18 to 38°C). Skin irritation test (rabbit): Slight irritations. • Toxicity data- Acute oral toxicity: LD50 = 5045 mg/kg (rat). Acute dermal toxicity: LD50= 12500 mg/kg (rabbit). Acute toxicity of the vapor: LC50= 16970 ppm 4hrs (rat). Chronic effects on humans; developmental toxicity, proven the 	

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substance is toxic to kidneys, lungs, the nervous system, the reproductive system, liver, immune system, eyes and skin.

- **Irritant:** Inhalation, skin and eye
- **Mutagenic Data-** Mutagenicity (test of mammal cells): negative. Bacterian Mutagenicity: Salmonella typhimurium: negative. Bacterian Mutagenicity: Ames-Test: negative.
- **Reproductive Date-** There was no indicators of developmental toxicity in the rabbits at any exposure level. Findings from multigeneration oral reproduction study indicate that indicate that infant and immature rats are more sensitive than their parents to the acute oral toxicity induced by high (1000 mg/kg/day) doses of Isopropanol. The effect levels for rats and rabbits were at several times the maximum exposure that would occur at the TLV.

SECTION 9- ECOLOGICAL INFORMATION

- **Fish Toxicity-** None available for specific product. For major ingredient ISOPROPANOL: P. Promelas CL50:9640 mg/l/96h
- **Algae toxicity:** None available for specific product. For major ingredient ISOPROPANOL: Desmodemus subspicatus IC50 > 1000 mg/l/72h
- **Invertebrates Toxicity:** None available for specific product. For major ingredient ISOPROPANOL: Daphnia magna EC50: 13299 mg/l/48h
- **Toxicity to Bacteria-** None available for specific product. For major ingredient ISOPROPANOL: Photobacterium phosphoreum CE50: 22000 mg/l/15min. Microtox test. Bacterial toxic concentration limit: Ps putida CE5: 1050 mg/l/16h. M. Aeruginosa CE5: 1000mg/l/8d.
- **OECD Biological degradation-** Biological degradability: 95%/21d. Biological degradability: good. Individual components stated to be biodegradable.
- **General-** Product miscible in all proportions with water. AS WITH ANY CHEMICAL PRODUCT. DO NOT DISCHARGE BULK QUANTITIES INTO DRAINS, WATERWAYS, SEWER OR ENVIROMENT. Inform local authorities if this occurs. When introduced properly, no impairments in the function of adapted biological waste-water treatment plants are to be expected. No ecological problems are to be expected when the product is handled and used with due care and attention.


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SECTION 10- DISPOSAL CONSIDERATIONS
<ul style="list-style-type: none"> Disposal- To dispose of quantities of undiluted product, refer to State Land Waste Management Authority. Transfer product residues to a labelled, sealed container for disposal or recovery. Waste disposal must be by an accredited contractor. As with any chemical, do not put down the drain in quantity. The small quantities contained in wash solutions (when used as directed) can generally be handled by conventional sewage systems, septics and grey water systems. For larger scale use Commercial laundry operations, a recycled water system is often recommended, or Trade Waste License obtained for disposal to sewer.

SECTION 11- TRANSPORT INFORMATION			
UN Number	1193	ADG Classification	3
Shipping Name	FLAMMABLE LIQUIDS N.O.S (ETHANOL, ISOPROPANOL)	Class	
Hazchem Code	3(Y)E	Packing Group	II
SUSDP Classification	None allocated	ADG Subsidiary Risk	None allocated
Packaging Method	3.8. RT1	Special Provisions	SP109, SP129, SP274
Segregation	<p>Class 3- Flammable liquid shall not be loaded in the same vehicle or packed in the same freight container with:</p> <ul style="list-style-type: none"> Class 1 Explosives Class 2.1 Flammable gases, if both the Class 3 and Class 2.1 dangerous goods are in bulk Class 2.3 Toxic gases Class 4.2 Spontaneously Combustible Substance Class 5.1 Oxidizing Agents and Class 5.2 Organic Peroxides Class 6 Toxic Substances (where the flammable liquid is nitro methane) Class 7 Radioactive Substances 		

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SECTION 12- REGULATORY INFORMATION	
AICS	All ingredients present on AICS
Labeling Details	
HAZARD	FLAMMABLE
RISK PHRASES	R11- Highly flammable
SAFETY PHRASES	S2- Keep out of reach of children S16- Keep away from sources of ignition S45- In case of accident, or if you feel unwell, seek medical advice immediately (show the label whenever possible).
SUSDP	Not scheduled
ADG Code	Class 3 Flammable

SECTION 13- Marking-Labeling
<ul style="list-style-type: none">• Product Warning- For external use only. Keep away from the eye area. Do not apply to sore or broken skin. Stop use if irritation occurs. Keep away from children. Do not ingest. If swallowed, get medical help or contact a Poison Control Center right away. Store below 110°F (43°C). Do not use if seal is broken.• Ways of Use- Place enough product in your palm to thoroughly cover your hands. Run hands together briskly until dry.

SECTION 14- EMERGENCY AND FIRST AID MEASURES
<ul style="list-style-type: none">• Eye (contact): Thorough rinsing for 15-20 minutes of the affected eye with water is recommended. If discomfort or irritation persists, contact a physician.• Skin (contact): Discontinue use of product. Remove contaminated clothing. Flush exposed areas with copious amount of water. If discomfort persists, contact a physician.• Inhalation: If respiratory irritation occurs, remove individual to fresh air. Give artificial respiration if breathing has stopped.• Ingestion: Accidental ingestion of product may necessitate medical attention. In case of accidental ingestion dilute with fluids (water or milk) and treat symptomatically. Do not induce vomiting. Note: After first aid treatment, the caller should be advised that 1) a hospital emergency room or family physician should be consulted if anything unusual occurs or appears necessary in the judgment of the caller, and 2) that the subsequent management of the accident should be dictated by any persistent symptoms and under

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the direction of the physician.

SECTION 15- HANDLING AND STORAGE

- **Precautions for Safe Handling:** Avoid contact with incompatible materials. When Handling, DO NOT eat, drink or smoke. Keep containers closed at all times. Avoid physical damage to containers. Always wash hands with water after handling. Do not breathe vapor, spray and mist. Use local exhaust extraction. Extinguish any naked flames. Remove ignition sources. Avoid sparks. Do not smoke. Take precautionary measures against static discharges. Earth all equipment. Do not empty into drains.
- **Conditions for Safe Storage:** Store in a cool, dry, place with good ventilation. Store away from incompatible materials (Section 10). Keep containers closed at all times, check regularly for leaks. Keep container tightly closed and in a well-ventilated place. Keep away from direct sunlight and other sources of heat or ignition. Do not smoke in storage areas.

SECTION 16- EXPOSURE CONTROLS, PERSONAL PROTECTION

- **Exposure Limits:** National Occupational Exposure limits, as published by National Occupational Health & Safety Commission.
Time-weighted Average (TWA): None established for specific product. See section 3 for exposure limits of individual ingredients.
Short term exposure limit (STEL): None established for specific product. See **SECTION 3** for Exposure Limits of individual ingredients.
- **Biological Limit Value:** None established for product.
- **Engineering Controls:** Ensure ventilation is adequate to maintain air concentrations below exposure standards. Avoid generating mists of the product. Use only in a well-ventilated area. Ensure airflow, where this product is used, is directed away from the operators.
- **Personal Protective Equipment:** Use good occupational work practice. The use of protective clothing and equipment depends upon the degree and nature of exposure. Final choice of appropriate protection will vary according to individual circumstances i.e. methods of handling or engineering controls and according to risk assessments undertaken. The following protective equipment should be available.
- **Eye Protection:** Generally not required to handle the product as per label directions. The

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use of safety glasses with side shield protection, goggles or face shield is recommended to handle in quantity, cleaning up spills, decanting, etc. Contact lenses pose a special hazard soft lenses may absorb irritants and all lenses concentrate them.



- **Skin Protection:** Generally not required to handle the product as per label directions – hand cleaner/sanitizer (as per AS/NZS 2161, or as recommended by supplier) to handle in quantity, cleaning up, spills, decanting, etc.



- **Protective Material Types Respirator:** Material suitable for detergent contact- Butyl rubber, Natural Latex, Neoprene, PVC and Nitrile. Generally not required to handle the product as per label directions. If engineering controls are not effective in controlling airborne exposure then respiratory protective equipment should be used suitable for protecting against airborne contaminants. Final choice of appropriate breathing protection is defendant upon actual airborne concentrations and the type of breathing protection required will vary according to individual circumstances. Expert advice may be required to make this decision. Reference should be made to Australian Standards AS/NZS 1716, Respiratory Protective Devices; and AS/NZS 1716, Respiratory Protective Devices.

SECTION 17- OTHER INFORMATION

- **Product Category-** Alcohol based Gel
- **Name of product manufacturer-**
- **Address of product manufacturer-**
- **Transportation Emergency (24 hour) Contact-** CHEMTREC - Phone # 1-800-424-9300 (U.S. and Canada) or 1-703-527-3887 (for calls originating elsewhere).

Assessor's Credentials

- **Assessor's Name-** Gris Meza (Head of Chemist at VSC) - For signature & date see page (13).
- **Assessor's Qualifications-** MSc by Research in Applied Chemistry, BSc Combined Sciences - First Class Honors (Chemistry), Chartered Chemist (CChem), Chartered Scientist (CSci)
- **Assessors Experience-** 20+ years in chemical and product safety, 15+ years in small scale manufacturing and development of cosmetics

Reasoning taking under Consideration

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- The composition of the product
- The physicochemical properties of the raw material contained in the final product
- The manufacturing process of the product
- The microbial purity of the raw materials and final product Impurities –Traces in the final product or substances Properties of packaging material
- The preservation efficacy of the final product
- The chemical structure and toxicological properties of the raw materials
- Studies on human volunteers / relevant literature
- The level of exposure of the consumer to the final product
- Data on documented undesirable effects to the product (no such data reported/available)
Labeled warnings & instructions of use

Additionally the Product Manufacturer / Responsible person is aware of the following:

All necessary measurements have been followed for the product to comply **ISO 17025 / ISO 22716, FDA manufacturing cosmetics license No.55872 accordance with the provisions of Division 104, Chapter 7, Article 4 of the California Health and Safety Code.**

The Responsible person / Product manufacturer is responsible for the accuracy of primary information contained in the product. All information provided by the technical dossier may be used, for any legal purpose within the USA & EU, and according to the best current scientific knowledge, the product fulfills the requirements for safety for the consumers, under conditions of normal use.

Approved by: _____

Miriam Dalida (Pharmacy Technician)

Date: March 06, 2020

Update date: March 19, 2020

Release by: _____

Gris Meza (Head of Chemist at VSC)

Date: March 06, 2020

Update date: March 19, 2020