Scientific Documentation

ET108, Alcohol, 190 Proof, USP

Not appropriate for regulatory submission. Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp
769 Jersey Avenue
New Brunswick, NJ 08901
Phone 732.214.1300

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ET108, Alcohol, 190 Proof, USP

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Specification for Alcohol, 190 Proof, USP (ET108)

Item Number	ET108
Item	Alcohol, 190 Proof, USP
CAS Number	64-17-5
Molecular Formula	C_2H_5OH
Molecular Weight	46.07
MDL Number	
Synonyms	Ethanol ; Grain Derived Alcohol

Test	Specification	
	Min	Max
ASSAY (by VOLUME)	94.9	96.0 %
CLARITY OF SOLUTION	NO MORE OPALESCENCE THAN STANDARD	
COLOR OF SOLUTION	NOT MORE THAN STANDARD	
SPECIFIC GRAVITY @ 15.56°C	0.812	0.816
ACIDITY OR ALKALINITY	SOLUTION IS COLORLESS THAN PINK	
ULTRAVIOLET ABSORPTION :		
240 nm		0.40
250 - 260 nm		0.30
270 - 340 nm		0.10
NONVOLATILE RESIDUE		2.5 mg
ELEMENTAL IMPURITIES	AS REPORTED	
ORGANIC IMPURITIES:		
METHANOL		200 µL/L
ACETALDEHYDE AND ACETAL		10 µL/L
BENZENE		2 µL/L
SUM OF ALL OTHER IMPURITIES		300 µL/L
IDENTIFICATION (A)	0.812	0.816
IDENTIFICATION (B)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (C) LIMIT OF METHANOL		200 µL/L
CERTIFIED KOSHER		
APPEARANCE		
EXPIRATION DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS		AS REPORTED
CLASS 3 (solvent) / 1-PROPANOL	.	
CLASS 3 (solvent) / 2-PROPANOL	.	
MONOGRAPH EDITION		

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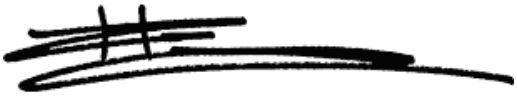
Certificate Of Analysis

Item Number	ET108	Lot Number	1JF1092
Item	Alcohol, 190 Proof, USP		
CAS Number	64-17-5		
Molecular Formula	C_2H_5OH	Molecular Weight	46.07

Test	Specification		Result
	min	max	
ASSAY (by VOLUME)	94.9	96.0 %	95.0 %
CLARITY OF SOLUTION	NO MORE OPALESCENCE THAN STANDARD		NO MORE OPALESCENCE THAN STANDARD
COLOR OF SOLUTION	NOT MORE THAN STANDARD		NOT MORE THAN STANDARD
SPECIFIC GRAVITY @ 15.56°C	0.812	0.816	0.815
ACIDITY OR ALKALINITY	SOLUTION IS COLORLESS THAN PINK		SOLUTION IS COLORLESS THAN PINK
ULTRAVIOLET ABSORPTION :			.
240 nm		0.40	0.15
250 - 260 nm		0.30	0.06
270 - 340 nm		0.10	0.01
NONVOLATILE RESIDUE		2.5 mg	0.0 mg
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
ORGANIC IMPURITIES:			.
METHANOL		200 µL/L	NONE DETECTED
ACETALDEHYDE AND ACETAL		10 µL/L	2 µL/L
BENZENE		2 µL/L	<1 µL/L
SUM OF ALL OTHER IMPURITIES		300 µL/L	<1 µL/L
IDENTIFICATION (A)	0.812	0.816	0.815
IDENTIFICATION (B)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (C) LIMIT OF METHANOL		200 µL/L	NONE DETECTED
CERTIFIED KOSHER			CERTIFIED KOSHER
APPEARANCE			CLEAR COLORLESS LIQUID
EXPIRATION DATE			28-MAY-2023
DATE OF MANUFACTURE			28-MAY-2020
RESIDUAL SOLVENTS		AS REPORTED	.
CLASS 3 (solvent) / 1-PROPANOL	.		<300 ppm
CLASS 3 (solvent) / 2-PROPANOL	.		<300 ppm
MONOGRAPH EDITION			(USP) 42

Spectrum Chemical Mfg Corp
14422 South San Pedro Street
Gardena 90248 CA

Certificate of Analysis Results Certified by:



Himanshu Patel
Quality Control Manager
Spectrum Chemicals & Laboratory Products

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

SAFETY DATA SHEET

Preparation Date: 9/12/2013 **Revision date** 8/19/2019 **Revision Number:** G9

1. IDENTIFICATION

Product identifier

Product code: ET108
Product Name: ALCOHOL, 190 PROOF, USP

Other means of identification
Synonyms: Alcool ethylique 190 proof (French)
Alcohol etílico 190 proof (Spanish)
Ethanol 190 proof
Ethanol, undenatured 190 proof
CAS #: 64-17-5
RTECS # KQ6300000
CI#: Not available

Recommended use of the chemical and restrictions on use
Recommended use: Solvent. Perfuming agent. In pharmaceuticals. Inks. In organic synthesis. In beverages.
Uses advised against No information available

Supplier:
Spectrum Chemical Mfg. Corp
14422 South San Pedro St.
Gardena, CA 90248
(310) 516-8000

Order Online At: https://www.spectrumchemical.com
Emergency telephone number Chemtrec 1-800-424-9300
Contact Person: Tom Tyner (USA - West Coast)
Contact Person: Ibad Tirmiz (USA - East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Serious eye damage/eye irritation	Category 2
Reproductive toxicity	Category 1A
Specific target organ toxicity (single exposure)	Category 3
Specific target organ toxicity (repeated exposure)	Category 1
Flammable liquids	Category 2

Label elements

Danger

Hazard statements

Causes serious eye irritation
May damage fertility or the unborn child
May cause respiratory irritation. May cause drowsiness or dizziness
Causes damage to organs through prolonged or repeated exposure
Highly flammable liquid and vapor

Hazards not otherwise classified (HNOC)
Not Applicable

Other hazards
Causes mild skin irritation
Can burn with an invisible flame

Precautionary Statements - Prevention
Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wash face, hands and any exposed skin thoroughly after handling
Wear protective gloves/protective clothing/eye protection/face protection
Do not breathe dust/fume/gas/mist/vapors/spray
Do not eat, drink or smoke when using this product
Use only outdoors or in a well-ventilated area
Keep away from heat/sparks/open flames/hot surfaces. — No smoking
Keep container tightly closed
Ground container and receiving equipment
Use explosion-proof equipment
Use only non-sparking tools
Take precautionary measures against static discharge
Keep cool

Precautionary Statements - Response
IF exposed or concerned: Get medical attention
In case of fire: Use CO2, dry chemical, or foam to extinguish.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention.
If skin irritation occurs: Get medical attention
IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or physician if you feel unwell.

Precautionary Statements - Storage
Store locked up
Store in a well-ventilated place. Keep container tightly closed

Precautionary Statements - Disposal
Dispose of contents and container to an approved waste disposal plant in accordance with local, regional, national and international regulations as applicable

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight-%
Ethyl Alcohol 200 proof	64-17-5	95
Water	7732-18-5	5

4. FIRST AID MEASURES

First aid measures

General Advice: National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention. If skin irritation persists, call a physician.

Eye Contact: Flush eyes with water for 15 minutes. Get medical attention.

Inhalation: Move to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Get medical attention.

Ingestion: Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.

Most important symptoms and effects, both acute and delayed

Symptoms

Causes eye irritation
May cause skin irritation
May cause irritation of respiratory tract
Dyspnea (Difficulty breathing and shortness of breath)
Central nervous system effects
Dizziness
Drowsiness
Headache
Ataxia
Staggering gait
Nausea
Vomiting
May cause cardiovascular effects

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically.

Protection of first-aiders
First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Carbon dioxide (CO2). Dry chemical. Alcohol-resistant foam. Water spray.

Unsuitable Extinguishing Media: Do not use a solid (straight) water stream as it may scatter and spread fire.

Specific hazards arising from the chemical

Hazardous combustion products Carbon Monoxide, Carbon Dioxide.

Specific hazards Flammable. May be ignited by heat, sparks or flames. Material can burn with invisible flame. Vapor may travel considerable distance to source of ignition and flash back. Vapors may form explosive mixtures with air. Most vapors

are heavier than air. They will spread along the ground and collect in low or confined areas (sewers, basements, tanks). Container explosion may occur under fire conditions or when heated. Fire may produce irritating, corrosive and/or toxic gases.

Special Protective Actions for Firefighters

Specific Methods: No information available

Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Avoid contact with skin, eyes and clothing. Use personal protective equipment. Remove all sources of ignition. Pay attention to flashback. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Use spark-proof tools and explosion-proof equipment. In case of large spill, water spray or vapor suppressing foam may be used to reduce vapors, but may not prevent ignition in closed spaces.

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Absorb spill with inert material (e.g. vermiculite, dry sand or earth), then place in a suitable chemical waste container. In case of large spill, dike if needed. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up Use appropriate tools to put the spilled material in a suitable chemical waste disposal container. Use only non-sparking tools. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:
Provide sufficient air exchange and/or exhaust in work rooms. Remove all sources of ignition. To avoid ignition of vapors by static electricity discharge, all metal parts of the equipment must be grounded. Keep away from incompatible materials.

Safe Handling Advice:
Wear personal protective equipment. Use only in well-ventilated areas. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Do not breathe vapors or spray mist. Do not ingest. When using do not smoke. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:
Hygroscopic. Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Sensitive to light. Store in light-resistant containers. Keep away from heat and sources of

ignition. Store in a segregated and approved area. Store away from incompatible materials.

Incompatible Materials:
Oxidizing agents
Acids
Alkali Metals
Halogens
Caustics
isocyanates
Metals
Bases
Acid anhydrides
Acid chlorides

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Ethyl Alcohol 200 proof	64-17-5	1000 ppm TWA 1900 mg/m³ TWA	1000 ppm TWA 1900 mg/m³ TWA	1000 ppm STEL	None
Water	7732-18-5	None	None	None	None

Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Ethyl Alcohol 200 proof	64-17-5	1000 ppm TWA 1880 mg/m³ TWA	1000 ppm STEL	1000 ppm STEL	1000 ppm TWAEV 1880 mg/m³ TWAEV
Water	7732-18-5	None	None	None	None

Australia and Mexico

Component	CAS No	Australia	Mexico
Ethyl Alcohol 200 proof	64-17-5	1000 ppm TWA 1880 mg/m³ TWA	1000 ppm STEL
Water	7732-18-5	None	None

Appropriate engineering controls

Engineering measures to reduce exposure: Ensure adequate ventilation. Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors and mist below their respective threshold limit value.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection: Goggles or Safety glasses with side-shields.

Skin and body protection: Chemical resistant apron
Long sleeved clothing
Gloves

Respiratory protection: Vapor respirator. Be sure to use an approved/certified respirator or equivalent.

Hygiene measures: Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:
Liquid

Appearance:
Clear.

Color:
Colorless.

Odor:
Pleasant. Alcoholic. Mild. Ethereal. Like wine or whiskey.

Taste
Pungent. Burning.

Formula
C2-H5-OH

Molecular/Formula weight (g/mole):
46.07

Flammability (solid, gas)
no data available

Flashpoint (°C/°F):
17 °C/63 °F

Flash Point Tested according to:
Closed cup

Autoignition Temperature (°C/°F):
363 °C/685.4 °F (For Ethanol 200 proof)

Lower Explosion Limit (%):
3.3% (Eor Ethanol 200 proof)

Upper Explosion Limit (%):
19% (For Ethanol 200 proof)

Melting point/range(°C/°F):
-114.1-117.3 °C/-173.38-179.14 °F (For Ethanol 200 proof)

Decomposition temperature(°C/°F):
No information available

Boiling point/range(°C/°F):
79 °C/174.2 °F

Bulk density:
No information available

Density (g/cm3):
No information available

Specific gravity:
0.8 @ 20 °C

pH
No information available

Vapor pressure @ 20°C (kPa):
5.7-5.866 (For Ethanol 200 proof)

Evaporation rate:
No information available

Vapor density:
1.59

VOC content (g/L):
740

Odor threshold (ppm):
5-10 (recognition)
84 (tolerance)

Partition coefficient (n-octanol/water):
No information available

Viscosity:
No information available

Miscibility:
Miscible with water
Miscible with Acetone
Miscible with Ether
Miscible with Benzene
Miscible with glacial Acetic Acid
Miscible with many organic solvents

Solubility:
Very soluble in water

10. STABILITY AND REACTIVITY

Reactivity

For Ethyl alcohol:
When Ethanol comes in contact with Sodium, it liberates flammable hydrogen gas
It can react vigorously or explosively with acid hydrides or acid chlorides
It reacts with alkali metals to liberate flammable hydrogen gas
It reacts with ammonia + silver nitrate to form silver nitride and silver fulminate
It reacts with acetyl bromide to evolve hydrogen bromide
Ethyl alcohol can react with freshly cut/etched/scratched aluminum with the evolution of heat and release of hydrogen gas. The Ethyl alcohol has to be on the aluminum surface as it is being cut/scratched/etched
Ethyl Alcohol reacts vigorously with acetyl chloride.
Ethyl alcohol reacts with silver (I) oxide + ammonia or hydrazine to form silver nitride and silver fulminate
Ethanol ignites and then explodes on contact with the following compounds: acetic anhydride + sodium hydrosulfate, disulfuric acid + nitric acid, phosphorus (III) oxide, platinum, potassium tert-butoxide + acids

Ethanol rapidly absorbs moisture from the air. Can react vigorously/explosively with oxidizers. Ethanol can react vigorously/explosively with the following: ammonium hydroxide & silver oxide, chlorine or chlorine oxides, perchlorates (barium perchlorate, chloryl perchlorate, magnesium perchlorate (forms ethyl perchlorate), nitrosyl perchlorate , potassium perchlorate, silver perchlorate, uranyl perchlorate), acetic anhydride, acetyl bromide (evolves hydrogen bromide), acetyl chloride, aluminum sesquibromide ethylate, bromine pentafluoride, calcium hypochlorite, chromic anhydride, , chromium trioxide, chromyl chloride, cyanuric acid + water, dichloromethane + sulfuric acid + nitrate (or) nitrite, manganese perchlorate + 2,2-dimethoxy propane, dioxygen difluoride, disulfuryl difluoride, fluorine nitrate, hydrogen peroxide, iodine heptafluoride, manganese heptoxide, iodine + methanol + mercuric oxide, iodine + Phosphorus (forms ethane iodide), mercuric nitrate, nitric acid, perchloric acid, permanganic acid, peroxodisulfuric acid, platinum black, potassium dioxide, potassium permanganate, potassium superoxide, potassium tert-butoxide, ruthenium(VIII) oxide, silver +nitric acid (forms silver fulminate), silver nitrate (forms ethyl nitrate), silver peroxide, sodium hydrazide, hydrogen peroxide + sulfuric acid, sulfuric acid + permanganates, uranium hexafluoride, sulfuric acid + sodium dichromate, tetrachlorisilane + water, silver & nitric acid, tetraphosphorus hexaoxide

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Ignition sources. Incompatible materials.

Incompatible Materials:
Oxidizing agents
Acids
Alkali Metals
Halogens
Caustics
isocyanates
Metals
Bases
Acid anhydrides
Acid chlorides

Hazardous decomposition products: Carbon monoxide. Carbon dioxide. When heated to decomposition it emits acrid smoke and irritating fumes.

Other Information
Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:
Ingestion. Skin. Eyes. Inhalation.

Acute Toxicity

The following values are calculated based on chapter 3.1 of the GHS document
ATEmix (oral) 7432 mg/kg
ATEmix (inhalation-vapor) 131.26 mg/l

Component Information

Ethyl Alcohol 200 proof	
CAS No	64-17-5

LD50/oral/rat = 7060 mg/kg Oral LD50 Rat

LD50/oral/mouse = 3450 mg/kg Oral LD50 Mouse
LD50/dermal/rabbit = No information available
LD50/dermal/rat = No information available
LC50/inhalation/rat = 124.7 mg/L Inhalation LC50 Rat 4 h
LC50/inhalation/mouse = 39000 mg/m^3 4 h
Other LD50 or LC50information = >60000 ppm Inhalation LC50 Mouse 1 h
5900 mg/m^3 Inhalation LC50 Rat 6 h
20000 ppm Inhalation LC50 Rat 10 h
5560 mg/kg Oral LD50 Guinea Pig
6300 mg/kg Oral LD50 Rabbit

Water	
CAS No	7732-18-5

LD50/oral/rat = > 90 mL/kg Oral LD50 Rat
LD50/oral/mouse = No information available
LD50/dermal/rabbit = No information available
LD50/dermal/rat = No information available
LC50/inhalation/rat = No information available
LC50/inhalation/mouse = No information available
Other LD50 or LC50information = No information available

Product Information

LD50/oral/rat =
Value - Acute Toxicity = No information available

LD50/oral/mouse =
Value - Acute Tox = No information available

LD50/dermal/rabbit
Value - Acute Toxicity = No information available

LD50/dermal/rat
VALUE - Acute Tox = No information available

LC50/inhalation/rat
VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse
VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: Mildly to moderately irritating to the skin.

Eye Contact: Causes serious eye irritation.

Inhalation May cause irritation of respiratory tract. Symptoms may include coughing and shortness of breath. May cause nausea and headache. It may affect behavior/central nervous system (ataxia, general anesthetic, drowsiness). May affect respiration (respiratory depression). Inhalation of high concentrations of vapor may cause anesthetic effects. Inhalation of high concentrations of vapors may cause dizziness or suffocation. May affect the brain.

Ingestion Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. May cause gastritis. May cause loss of appetite. May cause flushed skin. May affect the cardiovascular system (change in heart rate). May affect the cardiovascular system (hypotension or hypertension, tachycardia, dysrhythmias). It may affect behavior/central nervous system (excitation, mild euphoria, excessive talking, fatigue, headache, dizziness, drowsiness, staggaring gait, ataxia, hallucinations, slurred speech, amnesia, confusion, release of inhibitions, agressive behavior, convulsions, coma). May affect respiration (dyspnea, respiratory depression). It may affect the brain. May affect liver. May affect the blood. May affect the endocrine system. It may affect the spleen. May affect urinary system (kidneys).

Aspiration hazard No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chronic Toxicity Prolonged or repeated skin contact may cause dermatitis, and dryness and cracking of the skin. Prolonged or repeated ingestion may affect behavior/central nervous system. Prolonged or repeated ingestion may affect metabolism (cause anorexia, weight loss). Prolonged or repeated ingestion may affect the liver (fatty liver degeneration, cirrhosis of the liver. Prolonged or repeated ingestion may affect the cardiovascular system.

Sensitization: No information available.

Mutagenic Effects: For Ethyl alcohol:
May affect genetic material
Mutations in microorganisms
Experiments with bacteria and/or yeast have shown mutagenic effects
Cytogenic analysis - hamster ovary
Cytogenic Analysis (Hamster embryo)
Cytogenic analysis - human leukocyte
Cytogenic Analysis: human lymphocyte
Sister Chromatid Exchange - Hamster ovary
Sister Chromatid Exchange (human lymphocyte)

Carcinogenic effects: May cause cancer based on animal test data. Equivocal tumorigenic agent by RTECS criteria.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Ethyl Alcohol 200 proof	64-17-5	Group 1 - Monograph 100E [2012] in alcoholic beverages Monograph 96 [2010] in alcoholic beverages	A3 Confirmed Animal Carcinogen with Unknown Relevance to Humans	Not listed	Present	Not listed	Not listed
Water	7732-18-5	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

Reproductive toxicity May damage fertility or the unborn child

Reproductive Effects: Causes adverse reproductive effects
Developmental Effects: May cause adverse developmental effects
May cause harm to the unborn child
Teratogenic Effects: Causes birth defects (teratogenic effects)

Specific Target Organ Toxicity

STOT - single exposure respiratory system. central nervous system.
STOT - repeated exposure Causes damage to organs through prolonged or repeated exposure.
Target Organs: Skin. Liver. Central nervous system. Nervous system. Heart.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: Aquatic environment.

Ethyl Alcohol 200 proof - 64-17-5
Fish LC50: 12.0 - 16.0mL/L (96h, Oncorhynchus mykiss) LC50: >100mg/L (96h, Pimephales promelas) LC50: 13400 - 15100mg/L (96h, Pimephales promelas)
Crustacea LC50: 9268 - 14221mg/L (48h, Daphnia magna) EC50: =2mg/L (48h, Daphnia magna) EC50: =10800mg/L (24h, Daphnia magna)

Persistence and degradability: No information available

Bioaccumulative potential: No information available.

Mobility in soil No information available
Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:
Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:
Empty containers should be taken for local recycling, recovery or waste disposal

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Ethyl Alcohol 200 proof	64-17-5	None	None	None	None
Water	7732-18-5	None	None	None	None

14. TRANSPORT INFORMATION

DOT
UN-No: UN1170
Proper Shipping Name: Ethanol solution
Hazard Class 3
Subsidiary Class No information available

Packing group:	II
Emergency Response Guide Number	127
Marine Pollutant	No data available
DOT RQ (lbs):	No information available
Special Provisions	24, IB2, T4, TP1
Symbol(s):	No information available
Description:	UN1170, ETHANOL SOLUTION, 3, II

TDG (Canada)

UN-No:	UN1170
Proper Shipping Name:	Ethanol solution
Hazard Class	3
Subsidiary Risk:	No information available
Packing Group:	II
Marine Pollutant	No Information available
Description:	UN1170, ETHANOL SOLUTION, 3, II

ADR

UN Number	UN1170
Proper Shipping Name:	Ethanol solution
Transport hazard class(es)	3
Packing group	II
Subsidiary Risk:	No information available
Special Provisions	144, 601
Description:	UN1170, ETHANOL SOLUTION, 3, II

IMDG

UN-No:	UN1170
Proper Shipping Name:	Ethanol solution
Hazard Class:	3
Subsidiary Risk:	No information available
Packing Group:	II
Marine Pollutant	No information available
EMS:	F-E
Special Provisions	144
Description	UN1170, ETHANOL SOLUTION, 3, II

RID

UN Number	UN1170
Proper Shipping Name:	Ethanol solution
Transport hazard class(es)	3
Subsidiary Risk:	3
Packing group	II
Special Provisions	144, 601
Description:	UN1170, ETHANOL SOLUTION, 3, II

ICAO (air)

UN-No:	UN1170
Proper Shipping Name:	Ethanol solution
Hazard Class	3
Subsidiary Risk:	No information available
Packing Group:	II
Description:	UN1170, ETHANOL SOLUTION, 3, II
Special Provisions	A58, A180, A3

IATA

UN Number	UN1170

Proper Shipping Name: Ethanol solution
Transport hazard class(es) 3
Subsidiary Risk: No information available
Packing group II
Precautionary Statements - Response 3L
Special Provisions No information available
Description: UN1170, ETHANOL SOLUTION, 3, II

15. REGULATORY INFORMATION

International Inventories

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia (AICS)	EINECS-No.
Ethyl Alcohol 200 proof	64-17-5	Present(ACTIVE)	KE-13217	Present	(2)-202	Present	Present	Present 200-578-6
Water	7732-18-5	PresentACTIVE	Present KE-35400	Present	Not present	Present	Present	Present 231-791-2

U.S. Regulations

Ethyl Alcohol 200 proof

Massachusetts RTK: Present
New Jersey RTK Hazardous Substance List: 0844
Pennsylvania RTK: Present
Minnesota - Hazardous Substance List: Present
Louisana Reportable Quantity List for Pollutants: Present (listed as Volatile Organic Compounds)
California Directors List of Hazardous Substances: Present
FDA - Food Additives Generally Recognized as Safe (GRAS): 21 CFR 184.1293
FDA - 21 CFR - Total Food Additives - List Sourced from EAFUS 169.175, 169.176, 169.177, 169.181, 172.340, 172.560, 172.580, 175.105, 176.180, 176.200, 177.1200, 177.1650, 178.1010, 184.1293, 73.30, 73.345, 73.615

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

Chemicals Known to the State of California to Cause Cancer:

⚠WARNING: This product can expose you to chemicals including (see table below) which is (are) known to the State of California to cause cancer. For more information go to www.p65warnings.ca.gov.

Chemicals Known to the State of California to Cause Reproductive Toxicity:

⚠WARNING: This product can expose you to chemicals including (see table below) which is (are) known to the State of California to cause birth defects or other reproductive harm. For more information go to www.p65warnings.ca.gov.

Component	CAS No	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Ethyl Alcohol 200 proof	64-17-5	carcinogen (Ethanol in alcoholic beverages)	developmental toxicity (Ethyl alcohol in alcoholic beverages)	Not Listed	Not Listed
Water	7732-18-5	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Component	CAS No	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Ethyl Alcohol 200 proof	64-17-5	None	None	None	None	None
Water	7732-18-5	None	None	None	None	None

U.S. TSCA

Component	CAS No	**TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)**	**TSCA 8(d) -Health and Safety Reporting**
Ethyl Alcohol 200 proof	64-17-5	Not Applicable	Not Applicable
Water	7732-18-5	Not Applicable	Not Applicable

Canada

WHIMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information: .

Component
Ethyl Alcohol 200 proof
64-17-5 (95)

Water
7732-18-5 (5)

WHMIS 2015 Hazard Classification
Flammable liquids - Category 2: H225 Highly flammable liquid and vapour.; Serious Eye Damage/Eye Irritation - Category 2B: H320 Causes eye irritation.
Not a dangerous product according to HPR classification criteria

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

DSL/NDSL

Component	CAS No	Canada (DSL)	Canada (NDSL)
Ethyl Alcohol 200 proof	64-17-5	Present	Not Listed
Water	7732-18-5	Present	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Ethyl Alcohol 200 proof	64-17-5	Not listed
Water	7732-18-5	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Ethyl Alcohol 200 proof	64-17-5	Not listed
Water	7732-18-5	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Ethyl Alcohol 200 proof	64-17-5	Flammable liquids - Flam. Liq. 2: H225 Highly flammable liquid and vapour.603-002-00-5
Water	7732-18-5	

EU - CLP (1272/2008)

R-phrase(s)
R11 - Highly flammable

S -phrase(s)
S 7 - Keep container tightly closed.

S16 - Keep away from sources of ignition - No smoking

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Ethyl Alcohol 200 proof	64-17-5	F; R11	No information	S(2) S7 S16
Water	7732-18-5		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:
F - Highly flammable

F

16. OTHER INFORMATION

Preparation Date: 9/12/2013
Revision date 8/19/2019
Prepared by: Sonia Owen

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet

October 16, 2020

Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
ET108	Alcohol, 190 Proof, USP

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824

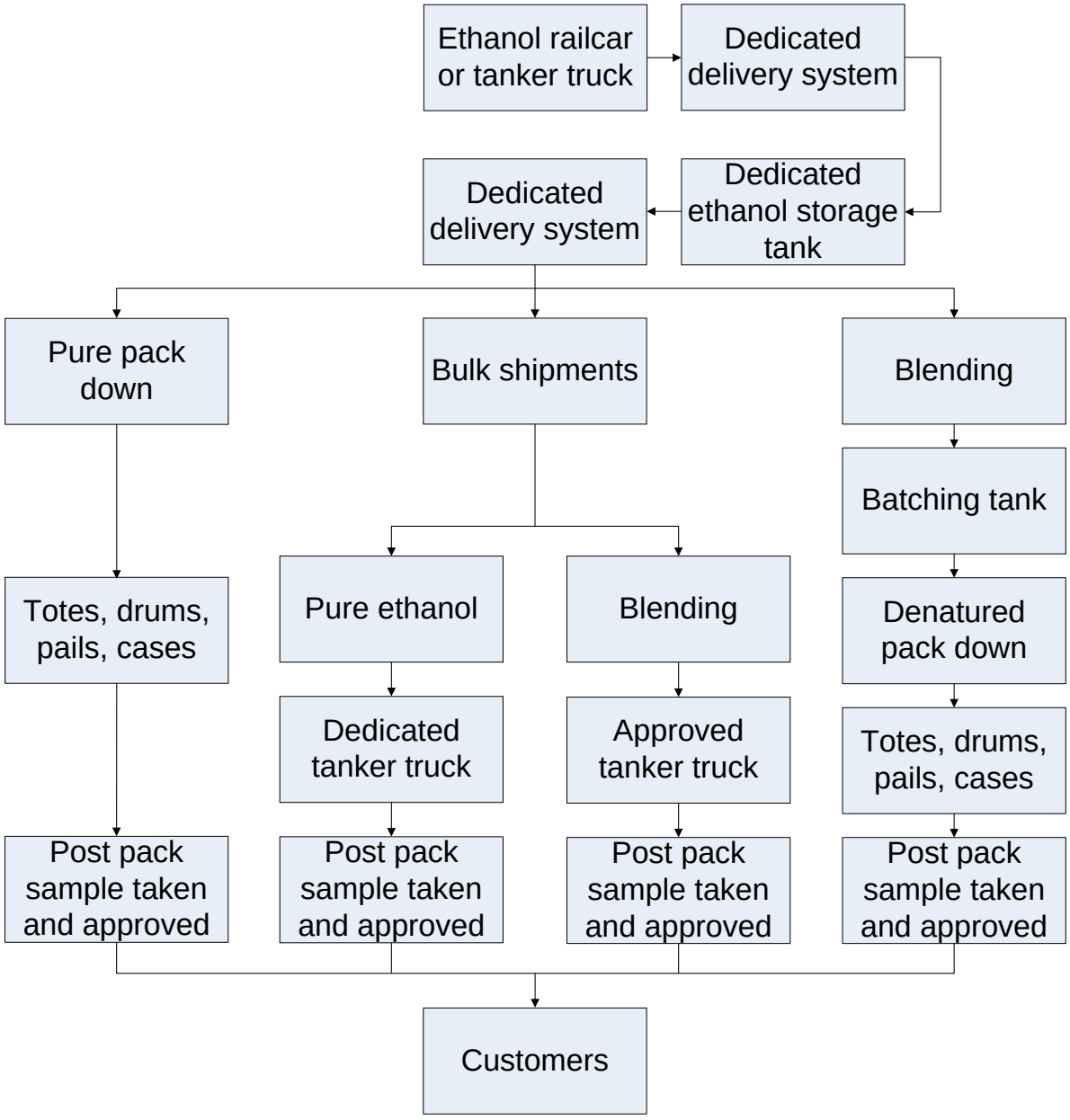
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

Alcohol, 190 Proof, USP - ET108



Spectrum Chemical Mfg Corp

Corporate Headquarters:
769 Jersey Ave.
New Brunswick, NJ 08901
732.214.1300

West Coast Facility:
14422 S. San Pedro St.
Gardena, CA 90248
310.516.8000

ET108, Alcohol, 190 Proof, USP

Source Statement

The above mentioned catalog item is derived from plant derived material, Corn, and fermentation derived material, Enzymes and Yeast. No animal derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Latex
- Sulfites > 10 ppm

EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

GMO Statement

The above mentioned catalog item is manufactured with the use of genetically modified organisms and might contain GMO's, but no detectable levels of GMO's are expected to be present.

Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

Organic Compliance Statement

The above mentioned catalog item has not been produced using irradiation, ethylene oxide (EtO) or sewage sludge.

Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 36 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- Aflatoxins
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances
- Parabens
- Pesticides
- Phthalates
- Preservatives

spectrum®

RE: Elemental Impurities - Alcohol, 190 Proof, USP (Cat# ET108)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

spectrum®

RE: Residual Solvents - Alcohol, 190 Proof, USP (Cat# ET108)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
1-PROPANOL	3	<300 ppm
2-PROPANOL	3	<300 ppm

No Class 1, Class 2 or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

spectrum®
CHEMICAL MFG CORP

Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication.

- **A** Bar Code
- **B** GHS Hazard Pictograms
- **C** Warning, Safety Data and Precautionary Information
- **D** Product Catalog Number
- **E** Item Name, Form, Grade
- **O** Storage Color Band
- **F** Size/Quantity
- **G** Chemical Abstracts Service (CAS) Registry Number
- **H** Caution Information
- **I** DOT Shipping Information
- **J** Toll-Free 24-Hour Chemical Emergency Telephone Number
- **K** Empirical Formula, Formula Weight and Technical Specifications Panel
- **L** Expiration Information
- **M** Lot Number
- **N** Kosher Certified by Kosher Supervision of America (KSA).

This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

- **YELLOW**: Oxidizer
- **RED**: Flammable
- **GREEN**: General Storage
- **BLUE**: Health Hazard
- **WHITE**: Corrosive

Spectrum Chemical Mfg Corp

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769 Jersey Ave.
New Brunswick, NJ 08901
732.214.1300

West Coast Facility:
14422 S. San Pedro St.
Gardena, CA 90248
310.516.8000

spectrum®

May 28, 2020

RE: Lot Numbering System

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products' Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of **six characters**, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum's Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

Example: ZI0928 = The 928th material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of **seven characters**. The first character, a number, represents the production facility:

1 = Gardena, CA Facility
2 = New Brunswick, NJ Facility
3 = China Facility
4 = Pharmacy, NJ Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

Example: 2AA0706 = The 706th material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at quality_assurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Oralia Chavez,
Quality Assurance Specialist

CORPORATE HEADQUARTERS
769 Jersey Avenue
New Brunswick, NJ 08901
PHONE 732.214.1300
FAX 732.246.7132

WEST COAST FACILITY
14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843

KOSHER SUPERVISION OF AMERICA

בס"ד

Feb 03, 2020

The following product(s) prepared by the named company are certified kosher with the stated requirements:

Spectrum Laboratory Products, Inc.
S-0032

14422 S. San Pedro Street
Gardena CA 90248
USA

Product Name	**ET108, Ethyl Alcohol, 190 Proof, USP**
Brand	**Spectrum**
UKD-ID	**KSAV3-F6C6T7**
D/P/M	**P**
Symbol Required	**KSA**
Special Conditions	

This certificate expires on
Feb 01, 2021

Rabbi Binyomin Lisbon
Kashrus Administrator

Placing the KSA logo on products not listed above constitutes an un-authorized use of the KSA symbol, which is a federally registered trademark.

P.O.Box 35721, Los Angeles, Ca 90035 - (310) 282-0444 - Fax (310) 282-0505 - Email info@ksakosher.com - www.ksakosher.com