


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	BANANA CREAM (Flavor)
PRODUCT CODE	1016
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Pharmaceutical Manufacturing
RESTRICTIONS ON USE	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Flammable Liquid (Category 3)	
PICTOGRAM		
SIGNAL WORD	Warning	
HAZARD STATEMENT(S)	Flammable liquid and vapor. Causes skin and eye irritation. May cause allergic reaction.	
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not Applicable.	
PRECAUTIONARY STATEMENT(S)	Prevention	Keep away from heat, sparks, open flames and No smoking Keep container tightly closed Ground/Bond container and receiving equipment Use explosion-proof equipment Use non-sparking tools Take action to prevent static discharges Wear protective gloves, protective clothing, eye and face protection

Response IF ON SKIN (HAIR): Take off immediately all contaminated clothing. Rinse affected areas with water/shower.
 IN CASE OF FIRE: Use alcohol-resistant foam or water spray or fog 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 help.

Storage Store in a well-ventilated place.
 Keep cool.

Disposal Dispose of contents and/or container in accordance with local regulations.

HMS CLASSIFICATION

Health Hazard 2 **Flammability** 3
Reactivity 0 **Personal Protection** C

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME Not applicable
BOTANICAL NAME Not applicable
SYNONYM Not applicable
CHEMICAL FORMULA Not applicable
CHEMICAL FAMILY Not applicable
CAS NUMBER Not applicable
ALTERNATE CAS NUMBER Not applicable
MOLECULAR WEIGHT Not applicable

COMPOSITION

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
ETHYL ALCOHOL	64-17-5	200-578-6	10 - 25
ACETYL METHYL CARBINOL	513-86-0	208-174-1	0.1 - 1.0

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

NOTES

INGREDIENT LISTING: PROPYLENE GLYCOL, ETHYL ALCOHOL, WATER, NATURAL AND ARTIFICIAL FLAVOR, CAMEL COLOR.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

IF SWALLOWED Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

MEDICAL ATTENTION AND SPECIAL TREATMENT Get emergency medical help.

SYMPTOMS CAUSED BY EXPOSURE Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL

Not applicable.

FLAMMABLE PROPERTIES

Flammable.

HAZARDOUS COMBUSTION PRODUCTS

Under fire conditions, hazardous fumes will be present.

SUITABLE & UNSUITABLE EXTINGUISHING MEDIA

Small fire: dry chemical, CO₂ or water spray. **Large fire:** dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS

Wear respiratory protection. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

METHODS & MATERIAL FOR CONTAINMENT

On land, sweep or shovel into suitable containers.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

REFERENCE TO OTHER SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: ACETYL METHYL CARBINOL CAS #: 513-86-0

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

Chemical Name: ETHYL ALCOHOL CAS #: 64-17-5

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	1000	1900	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	A4 (not classifiable as a
NIOSH	USA	1000	1900	N/L	N/L	3300*	N/L	N/A	*10%LEL (See:64175)
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	1000	1880	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	1000	1920	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Austria	1000	1900	2000	3800	N/L	N/L	N/A	N/A
GESTIS	Belgium	1000	1907	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Canada-Ontario	N/L	N/L	1000	N/L	N/L	N/L	N/A	N/A
GESTIS	Canada-Quebec	1000	1880	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Denmark	1000	1900	2000	3800	N/L	N/L	N/A	N/A
GESTIS	Finland	1000	1900	1300(1)	2500(1)	N/L	N/L	N/A	(1) 15 minutes average value
GESTIS	France	1000	1900	5000	9500	N/L	N/L	N/A	N/A
GESTIS	Germany (AGS)	200	380	800(1)	1520(1)	N/L	N/L	N/A	(1) 15 minutes average value
GESTIS	Germany (DFG)	200	380	800(1)	1520(1)	N/L	N/L	N/A	(1) 15 minutes average value
GESTIS	Hungary	N/L	1900	N/L	7600	N/L	N/L	N/A	N/A
GESTIS	Ireland	N/L	N/L	1000(1)	N/L	N/L	N/L	N/A	(1) 15 minutes reference period
GESTIS	Latvia	N/L	1000	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	New Zealand	1000	1880	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Norway	500	950	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Poland	N/L	1900	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Romania	1000	1900	5000(1)	9500(1)	N/L	N/L	N/A	(1) 15 minutes average value
GESTIS	Singapore	1000	1880	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	South Korea	1000	1900	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Spain	N/L	N/L	1000	1910	N/L	N/L	N/A	N/A
GESTIS	Sweden	500	1000	1000(1)	1900(1)	N/L	N/L	N/A	(1) 15 minutes average value
GESTIS	Switzerland	500	960	1000	1920	N/L	N/L	N/A	N/A
GESTIS	Netherlands	N/L	260	N/L	1900	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

 Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

NOTES

ETHYL ALCOHOL
REL 1000 ppm; 1900 mg/m³
IDLH 3300 ppm; 10% LEL

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE

Liquid

DESCRIPTION

Clear, amber-brown liquid with characteristic odor.

SOLUBILITY

Easily soluble in hot and cold water.

ODOR

Characteristic odor

FLAMMABILITY

Flammable

AUTO-IGNITION TEMPERATURE

Not available

BOILING POINT

37 °C, 98.6 °F

DECOMPOSITION TEMPERATURE

Not available

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

FLASH POINT

34°C, 93°F
(Closed Cup)

log P (OCTANOL-WATER)

Not available

LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

MELTING/FREEZING POINT

Not available

PARTICLE CHARACTERISTICS

Not available

OXIDIZING PROPERTY

Not available

pH

7.3

RELATIVE DENSITY (WATER = 1)

Not available

SPECIFIC GRAVITY

0.99 (25°C)

UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

VAPOR DENSITY (AIR = 1)

Not available

VAPOR PRESSURE

Not available

VISCOSITY

Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established.
CHEMICAL STABILITY	Stable under recommended storage conditions.
INCOMPATIBLE MATERIALS	Strong oxidants.
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur.
HAZARDOUS POLYMERIZATION	Will not occur.
POSSIBILITY OF HAZARDOUS REACTION	Not established.
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures.

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): Not available Dermal: Rabbit: LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Based on available data, the classification criteria are not met. Contains ETHYL ALCOHOL: Irritant.
SERIOUS EYE DAMAGE/EYE IRRITATION	Based on available data, the classification criteria are not met. Contains ETHYL ALCOHOL and VANILIN: Irritant.
RESPIRATORY SENSITIZATION	Due to lack of data the classification is not possible.
SKIN SENSITIZATION	Based on available data, the classification criteria are not met. Contains VANILIN: May cause an allergic skin reaction.
GERM CELL MUTAGENICITY	Due to lack of data the classification is not possible.
CARCINOGENICITY	<p>OSHA ETHYL ALCOHOL is listed. Based on the compositional information available from the supplier, no other component of this product is listed.</p> <p>NTP ETHYL ALCOHOL is listed. Based on the compositional information available from the supplier, no other component of this product is listed.</p> <p>IARC ETHYL ALCOHOL is listed in group 1 (carcinogenic to humans). Based on the compositional information available from the supplier, no other component of this product is listed.</p> <p>California Proposition This product contains the following chemical known to the State of California to cause cancer and birth defects or other reproductive harm: ETHYL ALCOHOL. Based on the compositional information available from the supplier, no other component of this product is listed.</p>
ADDITIONAL CARCINOGENICITY INFORMATION	Based on available data, the classification criteria are not met.
REPRODUCTIVE TOXICITY	Based on available data, the classification criteria are not met. Contains ETHYL ALCOHOL: reproductive hazard.
SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE	Due to lack of data the classification is not possible.
SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE	Due to lack of data the classification is not possible.

**ASPIRATION HAZARDS
SIGNS AND SYMPTOMS OF
EXPOSURE**

Due to lack of data the classification is not possible.

ROUTES OF EXPOSURE:

Oral, Dermal, Inhalation, Eye contact

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

Not available

Not expected to present a significant hazard under anticipated conditions of normal use.

POTENTIAL HEALTH EFFECTS

Inhalation	May be harmful if inhaled. May cause irritation to mucous membranes and respiratory tract.
Ingestion	May be harmful if swallowed in large quantities.
Skin	May be harmful if absorbed through skin. May cause skin irritation. May cause allergic reaction.
Eyes	Causes eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY

EC50: 48 Hr: Crustacea: (mg/L): Not available

LC50: 96 Hr: Fish: (mg/L): Not available

EC50: 72 or 96Hr: Algae (or other aqua plants): (mg/L): Not available

**PERSISTENCE AND
DEGRADABILITY**

Not available

BIOACCUMULATIVE POTENTIAL

Not available

MOBILITY IN SOIL

Soluble in water.

OTHER ADVERSE EFFECTS

Not available

This product is not intended to be released into the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME

EXTRACTS, FLAVOURING, LIQUID

UN NUMBER

1197

CLASS

3

PACKING GROUP

III

AUSTRALIA
HAZCHEM

3Y, 3YE

EU

TRANSPORT IN BULK ACCORDING
TO ANNEX II OF MARPOL 73/78
AND THE IBC CODE

Not Listed

ENVIRONMENTAL HAZARDS
SPECIAL SHIPPING
INFORMATION

Not available

Not applicable

SECTION 15: REGULATORY INFORMATION

UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR	EPA 40 CFR Part 355 Appendix A	EPA 40 CFR Part 355 Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
ETHYL ALCOHOL 64-17-5	N/L	N/L	N/L	N/L	X	X	X	X
ACETYL METHYL CARBINOL 513-86-0	N/L	N/L	N/L	N/L	N/L	X	N/L	N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
ETHYL ALCOHOL 64-17-5	N/L	N/L	N/L	N/L	N/L	N/L
ACETYL METHYL CARBINOL 513-86-0	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
ETHYL ALCOHOL 64-17-5	N/L	N/L	N/L	N/L	N/L	N/L	N/L
ACETYL METHYL CARBINOL 513-86-0	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL
AGREEMENT

Not applicable

SECTION 16: OTHER INFORMATION

REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

04/2024

SUPERSEDES

04/2024

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.