

#### **SECTION 1: PRODUCT IDENTIFICATION**

PRODUCT NAME	PALMITOYLETHANOLAMIDE (PEA)
PRODUCT CODE	3052
SUPPLIER	MEDISCA Inc.         Tel.: 1.800.932.1039   Fax.: 1.855.850.5855         661 Route 3, Unit C, Plattsburgh, NY, 12901         6641 N. Belt Line Road, Suite 130, Irving, TX, 75063         MEDISCA Pharmaceutique Inc.         Tel.: 1.800.665.6334   Fax.: 514.338.1693         4509 Rue Dobrin, St. Laurent, QC, H4R 2L8         21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2         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	Manufacturing and Compounding
RESTRICTIONS ON USE	Not applicable

### SECTION 2: HAZARDS IDENTIFICATION

#### GHS CLASSIFICATION

PICTOGRAM

SIGNAL WORD HAZARD STATEMENT(S)

ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS PRECAUTIONARY STATEMENT(S) Skin Irritation (Category 2) Eye Irritation (Category 2A) Chronic Aquatic Toxicity (Category 2)



Causes skin irritation Causes serious eye irritation May cause an allergic skin reaction. Toxic to aquatic life with long lasting effects. Not Applicable.

Prevention

Avoid breathing dust, fume, gas, mist, vapors, spray. Contaminated work clothing should not be allowed out of the workplace. Wash hands thoroughly after handling. Do not touch eyes. Wear protective gloves, eye and face protection. Avoid release to the environment.



	Response	IF ON SKIN: Wash with plenty of water. If skin irritation occurs, get medical help. Take off contaminated clothing and wash it before reuse. 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. COLLECT SPILLAGE.	
	Storage	Not applicable	
	Disposal	Dispose of contents and/or container in accordance with local regulations.	
HMIS CLASSIFICATION	Health Hazard	1 Flammability 0	
	Reactivity	0 Personal Protection E	

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	N-(2-Hydorxyethyl)palmitamide	
BOTANICAL NAME	Not applicable	
SYNONYM	Palmidrol; Palmitoyl Ethanolamide	
CHEMICAL FORMULA	C18H37NO2	
CHEMICAL FAMILY	Lipid compound	
CAS NUMBER	544-31-0	
ALTERNATE CAS NUMBER	Not applicable	
MOLECULAR WEIGHT	299.495	
COMPOSITION	CHEMICAL NAME CAS N	UMBER EC NUMBER % BY WEIGHT
	PALMITOYLETHANOLAMIDE 544	l-31-0 208-867-9 100
	There are no additional ingredients present which with	hin the ourrent knowledge of the cumplior and in the

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.

### **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

May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS

SUITABLE & UNSUITABLE EXTINGUISHING MEDIA

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS

Under fire conditions, hazardous fumes will be present.

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.

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 dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.
METHODS & MATERIAL FOR CONTAINMENT	On land, sweep or shovel into suitable containers. Minimize generation of dust.
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

### 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: PALMITOYLETHANOLAMIDE CAS #: 544-31-0

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m³	ppm	mg/m³				
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
PELs are Ceiling or	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								
EXPOSU	EXPOSURE GUIDELINES Consult local a fraction: 5 mg/r					al or state e	exposure li	mits. Particulates not othen	vise regulated, respirable
PERSON	AL PROTECTIVE E	eye and gloves t <b>Respira</b> EN 149 exceede	face protection o prevent skin tors: Follow W Use a NIOSH ed or if irritation	on regulations i exposure. <b>Clo</b> /HMIS or OSH I/MSHA or Eur n or other sym	in 29 CFR 1 hthing: Wea A respirator ropean Star ptoms are e	1910.133 c r appropria r regulatior ndard EN 1 experience	I safety goggles as describ or European Standard EN16 ate protective clothing to mi ns found in 29 CFR 1910.13 149 approved respirator if e ed. <b>Thermal Hazards:</b> For pr nt should be used.	66. <b>Skin:</b> Wear appropriate nimize contact with skin. 84 or European Standard xposure limits are	
SPECIFIC	IFIC ENGINEERING CONTROLS Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.								
BIOLOGIC	CAL MONITORING		Not available						
CONTRO	L BANDING		Not available						

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE	Solid	Solid									
DESCRIPTION	White	White to off-white, fine, flakey crystal.									
SOLUBILITY	Not a	available									
ODOR	Not a	available									
FLAMMABILITY	May	be combustible at hig	gh ter	nperature							
AUTO-IGNITION TEMPERATURE		Not available		BOILING POINT	Not available			Not available			
EVAPORATION RATE		Not available		EXPLOSIVE LIMIT	Not available	FLASH PC	DINT	Not available			
log P (OCTANOL-WATER)		5.210		LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	MELTING/ POINT	FREEZING	(100-105)°C, (212-221)°F			
PARTICLE CHARACTERISTICS		Not available		OXIDIZING PROPERTY	Not available	pН		Not available			
RELATIVE DENSITY (WATER = 1)		Not available		SPECIFIC GRAVITY	Not available	UPPER FL EXPLOSIV	AMMABLE/ E LIMIT(S)	Not available			
VAPOR DENSITY (AIR = 1)		Not available		VAPOR PRESSURE	Not available	VISCOSIT	(	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.
POSSIBLITY OF HAZARDOUS REACTION	Not established.
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures.
S	SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY       Oral: Rat: LD50: (mg/kg): Not available Dermal: Rabit: LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available         SKIN CORROSION/IRRITATION       Causes skin irritation.         SERIOUS EYE DAMAGE/EYE IRRITATION       Causes skin irritation.         SKIN SENSITIZATION       Due to lack of data the classification is not possible.         SKIN SENSITIZATION       Based on available data, the classification criteria are not met. Suspected skin sensitiser: CAESAR skin sensitisation model in VEGA (Q)SAR platform predicts that the chemical is Sensitizer (moderate reliability).         GERM CELL MUTAGENICITY       Due to lack of data the classification is not possible.         CARCINOGENICITY       Oute to ack of data the classification is not possible.         CARCINOGENICITY       Due to lack of data the classification is not possible.         CARCINOGENICITY       Due to lack of data the classification is not possible.         CARCINOGENICITY       Due to lack of data the classification is not possible.         DEGINITIONAL CARCINOGENICITY       Due to lack of data the classification is not possible.         REPRODUCTIVE TOXICITY       Due to lack of data the classification is not possible.         SPECIFIC TARGET ORGAN TOXICITY- SINGLE EXPOSURE       Due to lack of data the classification is not possible.         SPECIFIC TARGET ORGAN TOXICITY- SINGLE EXPOSURE       Due to lack of data the classification is not possible.         SPECIFIC TARGET ORGAN TOXI							
SERIOUS EYE DAMAGE/EYE       Causes serious eye irritation.         RESPIRATORY SENSITIZATION       Due to lack of data the classification is not possible.         SKIN SENSITIZATION       Based on available data, the classification criteria are not met. Suspected skin sensitiser: CAESAR skin sensitisation model in VEGA (Q)SAR platform predicts that the chemical is Sensitizer (moderate reliability).         GERM CELL MUTAGENICITY       Due to lack of data the classification is not possible.         CARCINOGENICITY       Due to lack of data the classification is not possible.         CARCINOGENICITY       OSHA       PALMITOYLETHANOLAMIDE is not listed.         NTP       PALMITOYLETHANOLAMIDE is not evaluated.       California cancer, birth defects, or any other reproductive harm.         ADDITIONAL CARCINOGENICITY       Due to lack of data the classification is not possible.         REPRODUCTIVE TOXICITY       Due to lack of data the classification is not possible.         SPECIFIC TARGET ORGAN TOXICITY-       Due to lack of data the classification is not possible.         SPECIFIC TARGET ORGAN TOXICITY-       Due to lack of data the classification is not possible.         SPECIFIC TARGET ORGAN TOXICITY-       Due to lack of data the classification is not possible.         SPECIFIC TARGET ORGAN TOXICITY-       Due to lack of data the classification is not possible.         SPECIFIC TARGET ORGAN TOXICITY-       Due to lack of data the classification is not possible.         SPECIF	ACUTE TOXICITY	Dermal: Rabbit: LD50: (mg/kg): Not available					
IRRITATION       Intervention         RESPIRATORY SENSITIZATION       Due to lack of data the classification is not possible.         SKIN SENSITIZATION       Based on available data, the classification criteria are not met. Suspected skin sensitiser: CAESAR skin sensitisation model in VEGA (Q)SAR platform predicts that the chemical is Sensitizer (moderate reliability).         GERM CELL MUTAGENICITY       Due to lack of data the classification is not possible.         CARCINOGENICITY       Due to lack of data the classification is not possible.         NTP       PALMITOYLETHANOLAMIDE is not listed.         NTP       PALMITOYLETHANOLAMIDE is not evaluated.         California       This product does not contain any chemicals known to the State of California to cause Proposition 65         ADDITIONAL CARCINOGENICITY       Due to lack of data the classification is not possible.         REPRODUCITVE TOXICITY       Due to lack of data the classification is not possible.         SPECIFIC TARGET ORGAN TOXICITY-       Due to lack of data the classification is not possible.         SPECIFIC TARGET ORGAN TOXICITY-       Due to lack of data the classification is not possible.         SPECIFIC TARGET ORGAN TOXICITY-       Due to lack of data the classification is not possible.         SPECIFIC TARGET ORGAN TOXICITY-       Due to lack of data the classification is not possible.         SPECIFIC TARGET ORGAN TOXICITY-       Due to lack of data the classification is not possible.	SKIN CORROSION/IRRITATION	Causes skin irrita	ation.				
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NTP       PALMITOYLETHANOLAMIDE is not listed.         IARC       PALMITOYLETHANOLAMIDE is not evaluated.         California       This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.         ADDITIONAL CARCINOGENICITY       Due to lack of data the classification is not possible.         REPRODUCTIVE TOXICITY       Due to lack of data the classification is not possible.         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.	GERM CELL MUTAGENICITY	Due to lack of data the classification is not possible.					
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SINGLE EXPOSURE         SPECIFIC TARGET ORGAN TOXICITY -         REPEATED EXPOSURE    Due to lack of data the classification is not possible.	REPRODUCTIVE TOXICITY	Due to lack of da	ta the classification is not possible.				
REPEATED EXPOSURE		Due to lack of data the classification is not possible.					
ASPIRATION HAZARDS Based on available data, the classification criteria are not met.		Due to lack of data the classification is not possible.					
	ASPIRATION HAZARDS	Based on availal	Based on available data, the classification criteria are not met.				



SIGNS AND SYMPTOMS OF EXPOSURE	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 respiratory tract irritation.			
	Ingestion	May be harmful if swallowed.			
	Skin May be harmful if absorbed through skin. Causes skin irritation. May cause allergic reaction.				
	Eyes	Causes serious eye irritation.			

### SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY	EC50: 48 Hr: Crustacea: Daphnia: (mg/L): <1** LC50: 96 Hr: Fish: (mg/L): 1.57* LC50: 96 Hr: Fish: (mg/L): < 1 *** EC50: 96 Hr: Algae: Green Algae: (mg/L): <1**					
PERSISTENCE AND DEGRADABILITY	Not available					
BIOACCUMULATIVE POTENTIAL	High: Log Pow: 5.210					
MOBILITY IN SOIL	Not available					
OTHER ADVERSE EFFECTS	Suspected hazardous to the aquatic environment.					
	This product is not intended to be released into the environment.					
NOTES	*Fish Acute Toxicity model (KNN/Read-Across) in VEGA (Q)SAR platform prediction (moderate reliability) **Danish QSAR database ***Fish toxicity classification (SarPy/IRFMN) model in VEGA (Q)SAR platform prediction (moderate reliability)					

### 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

Not dangerous good
Not applicable
Not applicable
Not applicable
Not applicable

<u>EU</u>



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 Part 372.65	EPA 40 CF Appendix A	R Part 355 Appendix B	Pennsylvania	Right-to-know New Jersey		California Prop 65
PALMITOYLETHANOLAMIDE 544-31-0	N/L	N/L	N/L	N/L	N/L	N/L	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 Precursors	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemcials
PALMITOYLETHANOLAMIDE 544-31-0	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
PALMITOYLETHANOLAMIDE 544-31-0	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

## SECTION 16: OTHER INFORMATION

#### REFERENCES

Available upon request

Not applicable



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 – Instituto 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	07/2023
SUPERSEDES	11/2021
	For a list of changes to the SDS since the last version, please communicate with MEDISCA at <u>www.medisca.com</u>
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.