


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	ACESULFAME POTASSIUM, NF
PRODUCT CODE	2590
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 661 Route 3, Unit C, Plattsburgh, NY, 12901 3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118 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
USES	Sweetening agent

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Eye Irritation (Category 2A)		
PICTOGRAM			
SIGNAL WORD	Warning		
HAZARD STATEMENT(S)	Causes serious eye irritation.		
AUSTRALIA-ONLY HAZARDS	Repeated exposure may cause skin dryness or cracking.		
PRECAUTIONARY STATEMENT(S)	Prevention	Wear eye and face protection. Wash thoroughly after handling.	
	Response	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 advice/attention.	
	Storage	Not applicable	
	Disposal	Not applicable	
HMS CLASSIFICATION	Health Hazard	1	Flammability 0
	Reactivity	0	Personal Protection B

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	6-Methyl-1, 2, 3-oxathiazine-4(3H)-one-2,2-dioxide Potassium salt
BOTANICAL NAME	Not applicable

SYNONYM Acesulfame K**CHEMICAL FORMULA** C₄H₄NO₄SK**CAS NUMBER** 55589-62-3**ALTERNATE CAS NUMBER** Not applicable**MOLECULAR WEIGHT** 201.2426**COMPOSITION**

CHEMICAL NAME	CAS NUMBER	% BY WEIGHT
ACESULFAME POTASSIUM	55589-62-3	100

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 Chemical family: Acetoacetic acid derivative.

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**SYMPTOMS AND EFFECTS** 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** Under fire conditions, hazardous fumes will be present.**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 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.

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 unlabelled 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. Preserve in a well-closed container, and protect from light. Store at room temperature.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION
Chemical Name: ACESULFAME POTASSIUM CAS #: 55589-62-3

	TWA	Ceiling	STEL	REL	IDLH	Remarks
OSHA PEL	N/L	N/L	-	-	-	-
ACGIH TLV	N/L	N/L	N/L	-	-	-
NIOSH	N/L	N/L	N/L	N/L	N/L	-
AIHA WEEL	N/L	N/L	N/L	-	-	-
Safe Work Australia HSIS	N/L	N/L	N/L	-	-	-
HSE	N/L	N/L	N/L	-	-	-

N/L = Not Listed

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.

SPECIFIC ENGINEERING CONTROLS

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
PHYSICAL STATE

Solid

DESCRIPTION

A white, crystalline powder or colorless crystals.

SOLUBILITY

Soluble in water; very slightly soluble in acetone and in alcohol.

ODOR

Weak odor

FLAMMABILITY

May be combustible at high temperature

ODOR THRESHOLD

Not available

pH

6.5 - 7.5 (1%)

MELTING POINT

 >225°C, >437°F
(decomposes)

BOILING POINT

Not available

FREEZING POINT

>225°C, >437°F

FLASH POINT

Not available

YOUR TRUSTED PARTNER IN COMPOUNDING

SPECIFIC GRAVITY	1.81	EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available
UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	VAPOR PRESSURE	< 0.0000001 kPa (25°C)
VAPOR DENSITY (AIR = 1)	Not available	RELATIVE DENSITY (WATER = 1)	Not available	log P (OCTANOL-WATER)	Not available
AUTO-IGNITION TEMPERATURE	>210°C, >410°F	DECOMPOSITION TEMPERATURE	>225°C, >437°F	VISCOSITY	Not available

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

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
STABILITY	Stable under recommended storage conditions
MATERIALS TO AVOID	Strong oxidizing agents, metals, and acids.
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): 7431 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Due to lack of data the classification is not possible.
SERIOUS EYE DAMAGE/EYE IRRITATION	Causes serious eye irritation.
RESPIRATORY OR SKIN SENSITIZATION	Due to lack of data the classification is not possible.
GERM CELL MUTAGENICITY CARCINOGENICITY	Based on available data, the classification criteria are not met. OSHA ACESULFAME POTASSIUM is not listed. NTP ACESULFAME POTASSIUM is not listed. IARC ACESULFAME POTASSIUM is not evaluated. California Proposition 65 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 INFORMATION	Based on available data, the classification criteria are not met.
REPRODUCTIVE TOXICITY	Based on available data, the classification criteria are not met.

YOUR TRUSTED PARTNER IN COMPOUNDING

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	Based on available data, the classification criteria are not met.								
SIGNS AND SYMPTOMS OF EXPOSURE	Not expected to present a significant hazard under anticipated conditions of normal use.								
POTENTIAL HEALTH EFFECTS	<table border="0"> <tr> <td>Inhalation</td> <td>May be harmful if inhaled. May cause respiratory tract irritation.</td> </tr> <tr> <td>Ingestion</td> <td>May be harmful if swallowed.</td> </tr> <tr> <td>Skin</td> <td>May be harmful if absorbed through skin. May cause skin irritation</td> </tr> <tr> <td>Eyes</td> <td>Causes serious eye irritation.</td> </tr> </table>	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. May cause skin irritation	Eyes	Causes serious eye irritation.
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Ingestion	May be harmful if swallowed.								
Skin	May be harmful if absorbed through skin. May cause skin irritation								
Eyes	Causes serious eye irritation.								

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY	<p>EC50: 48 Hr: Crustacea: (mg/L): Not available LC50: 96 Hr: Fish: (mg/L): > 1000 EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available</p>
PERSISTENCE AND DEGRADABILITY	Biodegradation: 8
BIOACCUMULATIVE POTENTIAL	Not available
MOBILITY IN SOIL	Soluble in water
OTHER ADVERSE EFFECTS	<p>Not available</p> <p>This product is not intended to be released into the environment</p>

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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SECTION 14: TRANSPORT INFORMATION

UNITED STATES & CANADA

UN PROPER SHIPPING NAME	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable

AUSTRALIA

UN PROPER SHIPPING NAME	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable
HAZCHEM	

ENVIRONMENTAL HAZARDS	Not available
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SPECIAL SHIPPING INFORMATION

Not applicable

SECTION 15: REGULATORY INFORMATION

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
ACESULFAME POTASSIUM 55589-62-3	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 Regulation	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors
ACESULFAME POTASSIUM 55589-62-3	N/L	N/L	N/L

SECTION 16: OTHER INFORMATION
REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

CAS – Chemical Abstract Service; **GHS** – Global Harmonized System; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **TWA** – Time Weighted Average; **HSIS** – Hazardous Substances Information System; **STEL** – Short Term Exposure Limit; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **LD50** – Lethal Dose, 50%; **IARC** – International Agency for Research on Cancer; **NTP** – National Toxicology Program; **WHMIS** – Workplace Hazardous Materials Information System; **SARA** – Superfund Amendments and Reauthorization Act; **EPA** – Environmental Protection Agency; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **HMIS** – Hazardous Materials Information System; **NIOSH** – National Institute for Occupational Safety and Health; **MSHA** - Mine Safety and Health Administration; **ACGIH** - American Conference of Governmental Industrial Hygienists; **IDHL** - Immediately Dangerous to Health or Life; **TLV** – Threshold Limit Value; **HSE** – Health and Safety Executive; **REL** - Recommended Exposure Limit

LAST REVISION

06/2018

SUPERSEDES

06/2015

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.