


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	ACETYL SALICYLIC ACID, USP
PRODUCT CODE	0955
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	Skin Irritation (Category 2) Eye Irritation (Category 2A) Sensitization - Respiratory (Category 1) Sensitization - Skin (Category 1) Toxic to Reproduction (Category 2) Acute Toxicity - Oral (Category 4)
PICTOGRAM	
SIGNAL WORD	Danger
HAZARD STATEMENT(S)	Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Suspected of damaging fertility or the unborn child. Harmful if swallowed.
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not Applicable.

PRECAUTIONARY STATEMENT(S)
Prevention

Wash thoroughly after handling.
Do not eat, drink or smoke when using this product.
Avoid breathing dust/fume/gas/mist/ vapors/spray.
Obtain, read and follow all special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wear protective gloves, protective clothing, eye and face protection and hearing protection.
In case of inadequate ventilation, wear respiratory protection.
Contaminated work clothing must not be allowed out of the workplace.

Response

IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. 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 advice/attention.
IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor.
IF EXPOSED OR CONCERNED: Get medical advice/attention.
IF SWALLOWED: Immediately call a poison center. Get medical help. Rinse mouth.

Storage

Store locked up.

Disposal

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

HMIS CLASSIFICATION
Health Hazard

2

Flammability

1

Reactivity

0

Personal Protection

E

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS
CHEMICAL NAME

Benzoic acid, 2-(acetyloxy)-

BOTANICAL NAME

Not applicable

SYNONYM

Aspirin; salicylic acid acetate

CHEMICAL FORMULA

C₉H₈O₄

CHEMICAL FAMILY

Aromatic carboxylic acid

CAS NUMBER

50-78-2

ALTERNATE CAS NUMBER

Not applicable

MOLECULAR WEIGHT

180.1582

COMPOSITION

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
ACETYL SALICYLIC ACID	50-78-2	200-064-1	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.

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 ingestion of a large amount does occur, call a poison control center immediately.

IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
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	Finely dispersed particles form explosive mixtures in air.
FLAMMABLE PROPERTIES	Combustible Powder; explosion hazard if dispersed in air.
HAZARDOUS COMBUSTION PRODUCTS	Under fire conditions, hazardous fumes will be present.
SUITABLE & UNSUITABLE EXTINGUISHING MEDIA	Small fire: dry chemical, CO ₂ or water spray. Large fire: dry chemical, CO ₂ , 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.
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.

Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40°C are acceptable.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: ACETYL SALICYLIC ACID CAS #: 50-78-2

	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	5	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	5	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	5	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	5	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Austria	N/L	5(1)	N/L	10 (1) (2)	N/L	N/L	N/A	(1) inhalable aerosol (2) 15 minutes average value
GESTIS	Belgium	N/L	5	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Canada - Ontario	N/L	5	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Canada - Québec	N/L	5	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Denmark	N/L	5	N/L	10	N/L	N/L	N/A	N/A
GESTIS	Ireland	N/L	5	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Latvia	N/L	0.5	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	New Zealand	N/L	5	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Norway	N/L	5	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	People's Republic of China	N/L	5	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	South Africa	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	South Africa Mining	N/L	5	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	South Korea	N/L	5	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Spain	N/L	5	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Switzerland	N/L	5(1)	N/L	N/L	N/L	N/L	N/A	(1) inhalable aerosol

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE

Solid

DESCRIPTION

White crystals, commonly tabular or needle-like, or white crystalline powder. Is odorless or has a faint odor. Is stable in dry air; in moist air it gradually hydrolyzes to salicylic and acetic acids. Slightly hygroscopic.

SOLUBILITY

Slightly soluble in water, freely soluble in alcohol; soluble in chloroform and in ether; sparingly soluble in absolute ether.

ODOR

Odorless (Develops the vinegar-like odor of acetic acid on contact with moisture)

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE

490°C, 914°F

BOILING POINT

140°C, 284°F (decomposes)

DECOMPOSITION TEMPERATURE

140 °C, 284 °F

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

FLASH POINT

250.00°C, 482.00°F

log P (OCTANOL-WATER)

1.19

LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

MELTING/FREEZING POINT

135 - 144°C, 275 - 291.2°F

PARTICLE CHARACTERISTICS

Not available

OXIDIZING PROPERTY

Not available

pH

Not available

RELATIVE DENSITY (WATER = 1)

Not available

SPECIFIC GRAVITY

1.4

UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

VAPOR DENSITY (AIR = 1)

Not available

VAPOR PRESSURE

0.0000034 kPa (25°C)

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	The solution in water is a weak acid. Slowly hydrolyzes in moist air. Has been involved in dust cloud explosions. Water insoluble. Solution in water is acid to methyl red indicator. May react with water or nucleophiles (e.g. amines and hydroxy groups). May also react with acetanilide, amidopyrine, phenazone, hexamine, iron salts, phenobarbitone sodium, quinine salts, potassium and sodium iodides, alkali hydroxides, carbonates, stearates and paracetamol.
CHEMICAL STABILITY	Stable under recommended storage conditions
INCOMPATIBLE MATERIALS	Strong oxidants. Strong acids. Strong bases. Solutions of alkali hydroxides or carbonates.
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): 1500 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available								
SKIN CORROSION/IRRITATION	Irritancy test. Result: Irritant. Species: Rabbit. Organ: Skin. Severity: Mild.								
SERIOUS EYE DAMAGE/EYE IRRITATION	Irritancy test. Result: Irritant. Species: Rabbit. Organ: Eye. Severity: Moderate.								
RESPIRATORY SENSITIZATION	May cause allergy or asthma symptoms or breathing difficulties if inhaled.								
SKIN SENSITIZATION	May cause an allergic skin reaction.								
GERM CELL MUTAGENICITY	Due to lack of data the classification is not possible.								
CARCINOGENICITY	<table border="0"> <tr> <td style="vertical-align: top;">OSHA</td> <td>ACETYL SALICYLIC ACID is not listed.</td> </tr> <tr> <td style="vertical-align: top;">NTP</td> <td>ACETYL SALICYLIC ACID is not listed.</td> </tr> <tr> <td style="vertical-align: top;">IARC</td> <td>ACETYL SALICYLIC ACID is not evaluated.</td> </tr> <tr> <td style="vertical-align: top;">California Proposition</td> <td>This product contains the following chemical known to the State of California to cause birth defects or other reproductive harm: ACETYL SALICYLIC ACID.</td> </tr> </table>	OSHA	ACETYL SALICYLIC ACID is not listed.	NTP	ACETYL SALICYLIC ACID is not listed.	IARC	ACETYL SALICYLIC ACID is not evaluated.	California Proposition	This product contains the following chemical known to the State of California to cause birth defects or other reproductive harm: ACETYL SALICYLIC ACID.
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California Proposition	This product contains the following chemical known to the State of California to cause birth defects or other reproductive harm: ACETYL SALICYLIC ACID.								
ADDITIONAL CARCINOGENICITY INFORMATION	200 mg/kg/day Carcinogenicity study (oral). Result: No gastrointestinal tumors were observed. Species: Rat. Test Duration: 18 months. Carcinogenicity study (0.5% in feed). Result: No carcinogenic effects. Species: Rat. Test Duration: 68 weeks.								

REPRODUCTIVE TOXICITY

Suspected of damaging fertility or the unborn child. Salicylates are associated with increased prenatal and newborn mortality, anemia, prolonged pregnancy, maternal bleeding complications, and prolonged or complicated deliveries when used therapeutically in the third trimester of pregnancy. It has been suggested that maternal ingestion of salicylates may cause premature closure of the fetal ductus arteriosus and lead to pulmonary hypertension in some infants.

30 mg/kg/day Reproductivity study. Result: Inhibited spermiogenesis in male rats. Species: Rat.

600 mg/kg/day Reproductivity study. Result: No viable litter. Species: Rat.

Reproductivity study (during gestation).Result: Doses of 300 mg/kg showed no increase in incidence of birth defects, but doses of 400 and 500 mg/kg did cause an increase.

250 mg/kg/day Developmental study (NOAEL) Result: Maternal toxicity and reduced fetal weights.

Species: Rabbit.

125 mg/kg/day Reproductivity study (NOAEL) Result: Maternal toxicity. Species: Rabbit.

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
ROUTES OF EXPOSURE:

Oral, Dermal, Inhalation, Eye contact

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

Salicylates: Coma. Respiratory failure. Cardiovascular collapse. Kidney, liver, and pancreas damage. Gastrointestinal bleeding. Death.

Symptoms related to the physical, chemical, and toxicological characteristics:

Salicylates: Gastrointestinal disturbances. Ringing in ears. Headache. Dizziness. Drowsiness. Visual disturbances. Flushing. Sweating. Thirst. Agitation. Confusion. Fast breathing. Mental status changes. Delirium. Seizures.

Cross sensitivity:

Persons sensitive to other salicylates, other nonsteroidal anti-inflammatory agents, or to tartrazine dye may be sensitive to this material also.

Medical conditions aggravated by exposure:

Salicylates: Anemia. Bleeding disorders. Impaired liver function. Impaired kidney function. Diabetes. Asthma. Circulatory disorders.

POTENTIAL HEALTH EFFECTS

Inhalation	May be harmful if inhaled. May cause respiratory tract irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Ingestion	Harmful if swallowed.
Skin	May be harmful if absorbed through skin. May cause an allergic skin reaction. Causes skin irritation.
Eyes	Causes serious eye irritation.

NOTES

Pharmacologically active material. Occupational exposure may cause physiological effects.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY	EC50: 48 Hr: Crustacea: (mg/L): Not available LC50: 96 Hr: Fish: (mg/L): Not available EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available
PERSISTENCE AND DEGRADABILITY	Not available
BIOACCUMULATIVE POTENTIAL	logPow: 1.19
MOBILITY IN SOIL	Water Solubility: 4600 mg/L (25 °C) Henry's Law Constant: 1.30E-09 atm-m ³ /mol (25 °C)
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.
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SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable
AUSTRALIA HAZCHEM	Not Applicable
EU TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE	Not Listed
ENVIRONMENTAL HAZARDS	Not available
SPECIAL SHIPPING INFORMATION	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
ACETYL SALICYLIC ACID 50-78-2	N/L	N/L	N/L	N/L	X	N/L	X	X

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
ACETYL SALICYLIC ACID 50-78-2	N/L	Listed as Schedule 4	N/L	Listed	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
ACETYL SALICYLIC ACID 50-78-2	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
ABBREVIATIONS AND ACRONYMS

Available upon request

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

08/2024

SUPERSEDES

02/2023

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.