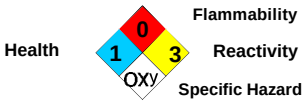
Agrium Material Safety Data Sheet

NFPA Classification	DOT / TDG Pictograms	WHMIS Classification	PROTECTIVE CLOTHING
			

Section I. Chemical Product and Company Identification

PRODUCT NAME/ TRADE NAME	**Ammonium Nitrate, Prilled Fertilizer Grade 34.5-0-0**
SYNONYM	34.5-0-0 Prilled Ammonium Nitrate Fertilizer
CHEMICAL NAME	Ammonium nitrate.
CHEMICAL FAMILY	Nitrate salt. (Oxidizing agent)
CHEMICAL FORMULA	NH_4NO_3
MATERIAL USES	Agricultural industry: Fertilizer. Industrial applications: Manufacture of chemicals. Manufacture of specialty fertilizers.

MSDS NUMBER:	**14082**
REVISION NUMBER	4.6
MSDS prepared by the Environment, Health and Safety Department on:	**March 25, 2003**

24 HR EMERGENCY TELEPHONE NUMBER:

Transportation: 1-800-792-8311
Medical: 1-888-670-8123

MANUFACTURER

Agrium
North American Wholesale
13131 Lake Fraser Drive, S.E.
Calgary, Alberta, Canada
T2J 7E8

SUPPLIER

Agrium
North American Wholesale
13131 Lake Fraser Drive, S.E.
Calgary, Alberta, Canada, T2J 7E8

Agrium U.S. Inc.
Suite 1700, 4582 South Ulster St.
Denver, Colorado, U.S.A., 80237

Section II. Hazardous Ingredients

		Exposure Limits (ACGIH)						
NAME	**CAS #**	**TLV-TWA mg/m³**	**TLV-TWA ppm**	**STEL mg/m³**	**STEL ppm**	**CEIL mg/m³**	**CEIL ppm**	**% by Weight**
Ammonium nitrate	6484-52-2	10						99.8

TOXICOLOGICAL DATA ON INGREDIENTS

Ammonium Nitrate:^

Rat oral LD50: 4500 mg/kg. [Peer Reviewed] [Environment Canada;Tech Info for Problem Spills: Ammonium Nitrate (Draft) p.59 (1981)]
Rat oral LD50: 2217 mg/kg (Rat) [Gigiena i Sanitariya. For English translation, see HYSAAV. (V/O Mezhdunarodnaya Kniga, 113095 Moscow, USSR) V.1- 1936- (52(8),25,1987)]
Huntingdon Research Center Testing Results (3 studies), OECD Guide 401: 2462- 2900 mg/kg (rat oral)
TFI Product Testing Results, OECD Guideline 402: > 5,000 mg/kg acute dermal LD_{50}, rat,
Bacterial reverse mutation assay: negative, with and without metabolic activation, (Salmonella)
Developmental terotogenicity: Not teratogenic to rats. NOAEL >57 mg/kg

Ecotoxicity Values:
Acute fish toxicity: Chinook salmon, rainbow trout, bluegill: 96hr LC_{50} = 420-1360 mg NO_3/L
Acute toxicity to aquatic invertibrates: Daphnia magna EC_{50} = 555mg/L
Acute toxicity to aquatic plants (algae): Scenedesmus quadricauda EC_{50} = 83mg/L
LD50 Aspergillus niger (fungus) 15 mg/l/40 hr (36 deg C). [Peer Reviewed] [Environment Canada; Tech Info]

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Section III. Hazards Identification.

POTENTIAL ACUTE HEALTH EFFECTS	May interfere with the oxygen carrying capacity of the blood if ingested in large quantities or over a prolonged period of time. Persons with anemia, bowel diseases, or infants, are more likely to develop effects. Over-exposure by ingestion is unlikely under normal working conditions. Inhalation of dusts may cause respiratory irritation. This product may irritate eyes and skin upon contact but is unlikely to injure tissue. Symptoms of overexposure may include: Cardiovascular: methemoglobinemia, low blood pressure (hypotension), irregular heart beat (arrhythmia), shock (vasodilation) CNS: headache, dizziness, generalized tingling sensation (parasthesia) Gastrointestinal: nausea, vomiting, diarrhea, abdominal pain Eye: redness and inflammation (conjunctivitis) Skin: bluish discoloration (cyanosis) with profuse sweating following ingestion or irritation and flushed skin following contact with moist skin surfaces.
POTENTIAL CHRONIC HEALTH EFFECTS	**CARCINOGENIC EFFECTS**: NONE by ACGIH, EPA, IARC, NTP, OSHA. **MUTAGENIC EFFECTS**: NONE by ACGIH, EPA, IARC, NTP, OSHA. **TERATOGENIC EFFECTS**: NONE by ACGIH, EPA, IARC, NTP, OSHA. Repeated or prolonged overexposure by ingestion can reduce the oxygen carrying capacity of the blood producing anoxia in infants or individuals with preexisting bowel or blood diseases. Ensure that nitrate containing fertilizers are not applied near wells where contamination may occur. Consult your agronomist regarding the advisability and precautions for use of nitrate fertilizers on fruit or vegetable crops.

Section IV. First Aid Measures

EYE CONTACT	Immediately flush eyes with running water for at least 15 minutes, keeping eyelids open. Obtain medical attention if irritation persists.
MINOR SKIN CONTACT	May cause skin irritation. Wash contaminated skin with soap and water. Cover dry or irritated skin with a good quality skin lotion. If irritation persists, seek medical attention.
EXTENSIVE SKIN CONTACT	No additional information.
MINOR INHALATION	Inhalation of dust may produce irritation, burning, sneezing and coughing. Long term exposure may cause headache, nausea or weakness. Loosen tight clothing. Allow affected persons to rest in a well ventilated area. Obtain medical attention if irritation persists.
SEVERE INHALATION	In emergency situations use proper respiratory protection to evacuate affected individuals to a safe area as soon as possible. Loosen tight clothing around the person's neck and waist. Oxygen may be administered if breathing is difficult. If the person is not breathing, perform artificial respiration. Obtain immediate medical attention.
SLIGHT INGESTION	If conscious, have person drink several glasses of water or milk and induce vomiting. Never give anything by mouth to an unconscious person. Lower the head so that the vomit will not reenter the mouth and throat. Obtain medical attention.
EXTENSIVE INGESTION	No additional information.

Section V. Fire and Explosion Data

THE PRODUCT IS	Non-flammable.
AUTO-IGNITION TEMPERATURE	Not applicable.
FLASH POINT	Not applicable.
FLAMMABILITY LIMITS	Not applicable.
PRODUCTS OF COMBUSTION	Material will not burn, but thermal decomposition may result in flammable/toxic gases being formed. These products are nitrogen oxides and ammonia (NO, NO_2, NH_3).

Continued on Next Page

FIRE HAZARD IN THE PRESENCE OF VARIOUS SUBSTANCES	Not applicable.
EXPLOSION HAZARD IN THE PRESENCE OF VARIOUS SUBSTANCES	Oxidizer: Material is an oxidizer which may react readily with other materials, especially upon heating. In confinement and in the presence of a strong detonation source, the material can explode when subject to sudden shock, pressure, or high temperature. Avoid temperatures above 210 °C (410 °F) which may cause thermal decomposition or explosion, especially in confined or poorly ventilated spaces. Incompatible with sulfur, chlorides, reducing agents, or other oxidizers. Incompatible with finely powdered metals (cadmium, copper, lead, cobalt, nickel, bismuth, chromium, magnesium, zinc, sodium, potassium and aluminum).
FIRE FIGHTING MEDIA AND INSTRUCTIONS	Oxidizing material. Cool containing vessels with water jet in order to prevent pressure build-up, or explosion. Use flooding quantities of water. Evacuate surrounding area. Material will not burn. Melts and undergoes thermal decomposition at elevated temperatures to release visible clouds of toxic and combustible gases (ammonia, carbon dioxide, and oxides of nitrogen). If fumes or gases may be present, fire fighters should wear self-contained breathing apparatus.
SPECIAL REMARKS ON FIRE HAZARDS	Material supports combustion. Powerful oxidizing agent, supports combustion by liberating oxygen even if smothered. Avoid temperatures above 210°C (410°F) in confined or poorly ventilated spaces. Explosive when exposed to heat or flame under confinement. Avoid pressure build-up. Thermal decomposition or explosion may result. Ventilate to cool and flood with water to stop decomposition reaction. Contain and collect all runoff for treatment. Prevent fire water from reaching water courses or aquifers.
SPECIAL REMARKS ON EXPLOSION HAZARDS	Industry studies have proposed the following rules for blends of ammonium nitrate with phosphate and potassium containing fertilizers: a) Ammonium nitrate fertilizers are reported not to detonate unless the fertilizer contains at least 70% ammonium nitrate, unless ammonium sulfate is present in the blend. Blended ammonium nitrate - ammonium sulfate fertilizers may detonate with as little as 45% ammonium nitrate present. b) It has been reported that it is desirable to keep the ammonium to nitrate ratio above 1.5 in fertilizer blends in order to minimize toxic gas release during "cigar burn" fires. c) "Cigar burn" is considered to be a hazard primarily when the ammonium nitrate content of a blend is between 20-40%. Cigar burn is a rare phenomenon which requires the combustion of a separate combustable material such as sulfur which can cause thermal decomposition of nearby ammonium nitrate.

Section VI. Accidental Release Measures

SMALL SPILL	Use appropriate tools or equipment to place the spilled solid in a suitable container for reuse or disposal.
LARGE SPILL	In the event of a spill, prevent additional discharge of material, if possible to do so without hazard. Prevent spills from entering sewers, watercourses, wells, etc. Product will promote algae growth which may degrade water quality and taste. Notify downstream water users. Nitrate in potable drinking water should be maintained below 10 mg/L. Will dissolve and disperse in water. Put the material into a suitable container for reuse or disposal.

Section VII. Handling and Storage

PRECAUTIONS	Keep away from heat, combustible materials, and reducing agents. Avoid contact with skin and eyes. DO NOT ingest or breathe dust. Take precautions against electrostatic discharges. Keep out of reach of children. Keep away from food, drink and animal feed.
STORAGE	Store in a dry, cool and well ventilated area. Keep away from food, drink and animal feeds. Keep away from combustible materials. Keep away from incompatible materials. Do not blend or store in contact with urea. Dry urea and dry ammonium nitrate will react together to produce a slurry.

Continued on Next Page

Section VIII. Exposure Controls/Personal Protection

ENGINEERING CONTROLS	Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, use ventilation to keep exposure to airborne contaminants below the exposure limit.
PERSONAL PROTECTION	The selection of personal protective equipment varies, depending upon conditions of use. Wear appropriate respiratory protection for dust/mist when ventilation is inadequate. A filtering facepiece dust mask is recommended for most applications if respiratory protection is needed. Where skin and eye contact may occur as a result of brief periodic exposures, wear long sleeved clothing, coveralls, chemical resistant gloves, and safety glasses with side shields.
PERSONAL PROTECTION IN CASE OF LARGE RELEASE	No additional information.
EXPOSURE LIMITS	U.S. OSHA PEL: 15mg/m^3 as particulate not otherwise regulated. Permissible exposures may vary from juresdiction to juresdiction. Consult local authorities for acceptable exposure limits in your area.

Section IX. Physical and Chemical Properties

PHYSICAL STATE AND APPEARANCE	Solid prills		
MOLECULAR WEIGHT	Not available.	**COLOR**	White.
pH (10% SOLN/WATER)	6 [Acidic.]	**ODOR**	Odorless.
BOILING POINT	Decomposes.	**ODOR THRESHOLD**	Not available.
MELTING POINT	170°C (338°F)	**TASTE**	Disagreeable. Acrid. (Strong.)
CRITICAL TEMPERATURE	Not available.	**VOLATILITY**	0% (v/v). 0% (w/w).
SPECIFIC GRAVITY g/cc	0.92 (Water = 1)	**SOLUBILITY**	Easily soluble in cold water, hot water. Soluble in acetone. Partially soluble in methanol.
BULK DENSITY kg/m^3 ; lbs/ft^3	Loose: 913; 57.7	**DISPERSION PROPERTIES**	See solubility in water, methanol, acetone.
VAPOR PRESSURE	0 mm of Hg (@ 20°C)	**WATER/OIL DIST. COEFF.**	Not available.
VAPOR DENSITY	Not available.		

Section X. Stability and Reactivity Data

STABILITY	The product is stable.
INSTABILITY TEMPERATURE	Not available.
CONDITIONS OF INSTABILITY	No additional information.
INCOMPATABILITY WITH VARIOUS SUBSTANCES	Reactive with combustible materials. Slightly reactive to reactive with reducing agents, organic materials, metals, moisture. Very slightly to slightly reactive with alkalis. Non-reactive with acids.
CORROSIVITY	Slightly corrosive to aluminum, zinc, and copper. Non-corrosive to steel and stainless steel (304 or 316).
SPECIAL REMARKS ON REACTIVITY	Absorbs moisture from the air. Incompatible with magnesium, zinc, sodium, potassium, and other finely powdered metals. May explode by detonation, heat or shock.
SPECIAL REMARKS ON CORROSIVITY	Avoid contact with moisture. Slow hydrolysis will produce acids which may slowly corrode metals. Contact your sales representative or a metallurgical specialist to ensure compatability with system equipment.

Continued on Next Page

Section XI. Toxicological Information

SIGNIFICANT ROUTES OF EXPOSURE	Ingestion. Inhalation.
TOXICITY TO ANIMALS	See Section II.
SPECIAL REMARKS ON TOXICITY TO ANIMALS	Toxic to livestock, wildlife, and domestic animals if directly ingested. Ensure that all spillage is cleaned up and that top dressing on pasture lands is applied uniformly. Allow 2 - 4 days to pass after application before returning livestock to pasture. The product itself and its products of degradation are not harmful under normal conditions of careful and responsible use.
OTHER EFFECTS ON HUMANS	Recent studies undertaken by the U.S. Government using Canadian and American databases have determined that ammonium nitrate fertilizer does not demonstrate any risk of gastrointestinal cancer.
SPECIAL REMARKS ON CHRONIC EFFECTS ON HUMANS	Exposure can cause headache, stomach pains, vomiting and diarrhea. Produces methemoglobin which reduces oxygen supply in the circulating blood. Although predominantly affecting infants, nitrate induced methemoglobinemia has also been documented in adults.
SPECIAL REMARKS ON OTHER EFFECTS ON HUMANS	No additional remark.

Section XII. Ecological Information

ECOTOXICITY	Non-persistent. Non-cumulative when applied using normal agricultural practises. Low toxicity for humans or animals under normal conditions of use. May be harmful to livestock and wildlife if ingested. Clean up all spilled material, especially where bulk fertilizer loading of equipment occurs to prevent animal exposure. Aquatic/Marine Toxicity: Will release ammonium ions. Ammonia is a toxic hazard to fish. Avoid spills or release to watercourses. Will disperse with current. Release to watercourses may cause effects down stream from the point of release. U.S. D.O.T.: This material NOT listed as a Marine pollutant.
BOD and COD	Not available.
PRODUCTS OF DEGRADATION	Not applicable.
TOXICITY OF THE PRODUCTS OF DEGRADATION	The product itself and its products of degradation are not harmful under normal conditions of use. Avoid spills or releases to watercourses.
SPECIAL REMARKS ON THE PRODUCTS OF DEGRADATION	Product will promote algae growth which may degrade water quality and taste. Notify downstream water users. Nitrate in potable drinking water should be maintained below 10mg/L. Will dissolve and disperse in water.

Section XIII. Disposal Considerations

WASTE DISPOSAL OR RECYCLING	Recycle to process, if possible. Recover and place material in a suitable container for intended use or disposal. Ensure disposal complies with government requirements and local regulations.

Section XIV. Transport Information

DOT / TDG CLASSIFICATION	TDG/DOT CLASS 5.1: Oxidizing substance.
PIN and Shipping Name	Proper shipping name: Ammonium nitrate PIN #: UN1942
SPECIAL PROVISIONS FOR TRANSPORT	U.S. DOT: A1, A29, IB8, IP3

Continued on Next Page

DOT (U.S.A) (Pictograms)

Section XV. Other Regulatory Information and Pictograms

OTHER REGULATIONS

U.S. Allowable Tolerances (FIFRA Requirements):
1. Ammonium nitrate is exempted from the requirement of a tolerance when used as a desiccant or defoliant in the production of cottonseed, grain sorghum, peppers, potatoes, sweet potatoes. 40 CFR 180.1018 (7/1/91)
2. Ammonium nitrate is exempted from the requirement of a tolerance when used as an adjuvant/intensifier for herbicides in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops only. 40 CFR 180.1001(d) (7/1/91)

FDA Requirements:
1. Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in paragraph (d)(1)(ii) of this section, meet the standards of chemical quality and shall not contain nitrate, as nitrogen, in excess of 10.0 mg/l. /Nitrate, as nitrogen. 21 CFR 103.35 (4/1/91)

TSCA - Sect. 8(b) Inventory: XU

California - Air Bill 2588 (Air Toxics Hot Spots) Appendix A-I: 6/91; ADOA 100.0 lbs/yr
California - Toxic Air Contaminant List Category III (AB 1807, AB 2728)
Massachusetts RTK List - Present
NJ Department of Health RTK List: sn 0106
NJ Special Hazardous Substances: (reactive - third degree)
Pennsylvania RTK List: environmental hazard
Rhode Island Hazardous Substance List - Present

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA): This product or its ingredients is on the Domestic Substances List (DSL), and acceptable for use under the provisions of CEPA.
Canada - Domestic Substances List - Present
Canada - WHMIS Classification of Substances: C; D2B
EINECS Inventory: 229-347-8

Japan - Existing and New Chemical Substances Inventory: 1-395
Korea - Existing and Evaluated Chemical Substances Inventory: KE-01715
Taiwan - Dangerous and Toxic Materials List: Dangerous material - Oxidizer
CERCLA/SUPERFUND, 40 CFR 117, 302: This product contains no Reportable Quantity (RQ) Substances.

SARA HAZARD CATEGORY: This product has been revised according to the EPA "Hazard Categories" promulgated under Sections 311 and 312 of the Superfund Amendment and Reauthorization Act of 1986 (SARA Title III) and is considered, under applicable definitions, to meet the following category(ies):
Immediate Health, Fire, Reactive
The following product is listed in SARA Section 313 (40 CFR Part 372):
Ammonium nitrate, CAS # 6484-52-2 (if in solution and dissociated). Refer to EPA guidance document 745-R-00-006 for information on TRI reporting for nitrates.

This product is not considered as a priority pollutant as regulated under the Clean Water Act.
OSHA: Hazardous by definition of Hazard Communication Standard (29 CFR 1910.1200).

OTHER CLASSIFICATIONS

HCS (U.S.A.)	HCS CLASS: Oxidizer.
DSCL (EEC)	R2- Risk of explosion by shock, friction, fire or other sources of ignition. R8- Contact with combustible material may cause fire. R9- Explosive when mixed with combustible material.

National Fire Protection Association (U.S.A.)

Hazards presented under acute emergency conditions only:

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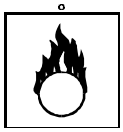
TDG (Pictograms - Canada)

DSCL (Europe) (Pictograms)



ADR (Europe) (Pictograms)

Section XVI. Other Information

REFERENCES

-Transportation of Dangerous Goods Act and Clear Language Regulations.
-Canada Gazette Part II, Vol. 122, No. 2 Registration SOR/88-64 31 December, 1987 Hazardous Products Act "Ingredient Disclosure List".
-Domestic Substances List, Canadian Environmental Protection Act.
-Canadian Centre for Occupational Health and Safety Infodisk Series
-29 CFR Part 1910
-33 CFR Parts 151, 153, 154, 156
-40 CFR Parts 1-799
-46 CFR Part 153
-49 CFR Parts 1-199
-American Conference of Governmental Industrial Hygienists, Threshold Limit Values for Chemical Substances, 2002.
-Fire Protection Guide to Hazardous Materials, (NFPA49, 325M, 491M, and 704), National Fire Protection Association, 10th Ed, 1991
-Corrosion Data Survey, Sixth Edition, 1985, National Association of Corrosion Engineers
-TOMES® System: Heitland G & Hurlbut KM (Eds) (electronic version): MICROMEDEX, Greenwood Village, Colorado, USA. Available at: http://csi.micromedex.com (2002). The TOMES® System includes MEDITEXT® Medical Management; HAZARDTEXT® Hazard Management; INFOTEXT® Documents; ERG2000 Emergency Response Guidebook Documents; REPROTEXT®: Heitland G & Hurlbut KM (Eds); CHRIS Hazardous Chemical Data: U.S. Department of Transportation, U.S. Coast Guard, Washington, D.C. (2002); HSDB: Hazardous Substances Data Bank. National Library of Medicine, Bethesda, Maryland (2002); IRIS: Integrated Risk Information System. U.S. Environmental Protection Agency, Washington, D.C. (2002); NIOSH: Pocket Guide to Chemical Hazards. National Institute for Occupational Safety and Health, Cincinnati, Ohio (2002); OHM/TADS: Oil and Hazardous Materials Technical Assistance Data System. U.S. Environmental Protection Agency, Washington, D.C. (2002); REPROTOX®: Scialli A.R. Georgetown University Medical Center and Reproductive Toxicology Center, Columbia Hospital for Women Medical Center, Washington, D.C. (2002); RTECS®: Registry of Toxic Effects of Chemical Substances. National Institute for Occupational Safety and Health, Cincinnati, Ohio (2002); and SHEPARDS: Shepard T.H.: Shepard's Catalog of Teratogenic Agents (2002).
-The Fertilizer Institute Product Testing Program Results, March 2003

OTHER SPECIAL CONSIDERATIONS

Not applicable.

FOR FURTHER SAFETY, HEALTH, OR ENVIRONMENTAL INFORMATION ON THIS PRODUCT, CONTACT

AGRIUM
Environment, Health and Safety Department
Telephone (403) 225-7380 or Fax (403) 225-7608

NOTICE TO READER

MATERIAL SAFETY DATA SHEET

NICE - PAK PRODUCTS, INC
TWO NICE-PAK PARK
ORANGEBURG NY 10962-1376
845-365-1700

REVISION DATE: 3/06

I. PRODUCT IDENTIFICATION

PRODUCT/TRADE NAME: INSECT STING RELIEF - B68789 B63695

HAZARD RATING (NFPA)
HEALTH: 1
FLAMMABILITY: 3
REACTIVITY: 0
SPECIFIC: NONE

EMERGENCY OR INFORMATION TELEPHONE NO: 845-365-1700 (M-F DAYTIME) AT OTHER TIMES, CONTACT THE LOCAL POISON CONTROL CENTER

CHEMICAL NAME: PROPRIETARY MIXTURE

II HAZARDOUS INGREDIENTS PER 29 CFR 1910.1200

Hazardous Ingredients	%	ACGIH TLV	CAS NUMBER
SD ALCOHOL 40	60	1000 PPM	64-17-5
BENZOCAINE	6	NOT ESTABLISHED	94-09-7

III PHYSICAL/CHEMICAL CHARACTERISTICS

COLOR/ODOR/APPEARANCE: TOWELETTE/PAD SATURATED WITH CLEAR COLORLESS LIQUID WITH ALCOHOL ODOR
BOILING POINT: N/A
FLASH POINT: 82^{o}F
VAPOR DENSITY: N/A
EVAPORATION RATE: N/A
SOLUBILITY IN WATER: COMPLETE

SPECIFIC GRAVITY (H_2O = 1): 0.905

IV FIRE & EXPLOSION HAZARD DATA

FLASH POINT(Method Used): 82^{O}F (CC) LEL: N/A UEL: N/A
EXTINGUISHING MEDIA: DRY CHEMICAL OR ALCOHOL TYPE FOAM; CARBON DIOXIDE
SPECIAL FIRE FIGHTING PROCEDURES: HANDLE AS FLAMMABLE LIQUID

UNUSUAL FIRE AND EXPLOSION HAZARDS: RESPIRATORY PROTECTION REQUIRED FOR FIRE FIGHTING PERSONNEL.

V-REACTIVITY DATA

STABILITY: STABLE
CONDITIONS TO AVOID: NONE KNOWN
INCOMPATIBILITY: NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS: NONE KNOWN
POLYMERIZATION: WILL NOT OCCUR
CONDITIONS TO AVOID: NONE KNOWN

INSECT STING RELIEF

VI-HEALTH HAZARD DATA

EFFECTS OF OVER EXPOSURE
SKIN : TOPICALLY APPLIED
EYES : WILL STING IF SPLASHED IN EYES
INHALATION: NONE KNOWN
INGESTION: NONE

EMERGENCY AND FIRST AID PROCEDURES:
SKIN CONTACT: IF RASH OR IRRITATION DEVELOP, DISCONTINUE USE
EYE CONTACT: RINSE WITH COOL WATER
INHALATION: NONE
INGESTION: IF INGESTED, SEEK MEDICAL ATTENTION
TARGET ORGANS: NONE KNOWN

VII-SPILL AND DISPOSAL PROCEDURE
SPILL CONTROL: ELIMINATE ALL SOURCES OF IGNITION. ABSORB WITH ABSORBENT MATERIAL.
WASTE DISPOSAL METHOD: PER LOCAL, STATE AND FEDERAL REGULATIONS

HANDLING AND STORAGE: STORE IN TIGHTLY CLOSED CONTAINERS AWAY FROM HEAT AND SOURCES OF IGNITION.

VIII-CONTROL MEASURES/PROTECTION
RESPIRATION: NONE REQUIRED
VENTILATION: NONE REQUIRED
PROTECTIVE GLOVES: YES. FOR BULK LIQUID
EYE PROTECTION: YES. FOR BULK LIQUID
HYGIENIC PRACTICES: FOLLOW GOOD HOUSEKEEPING PRACTICES
OTHER: NONE

IX TRANSPORT/SHIPPING

DOT SHIPPING NAME: CONSUMER COMMODITY
TECHNICAL SHIPPING NAME: N/A
DOT SHIPPING CLASSIFICATION: "ORM-D"
DOT ID NO.:N/A
DOT LABEL REQUIREMENTS: N/A
UN/NA NUMBER REGULATIONS: N/A
REPORTABLE QUANTITY: N/A

X DISCLAIMER
THE INFORMATION FURNISHED HEREIN IS BELIEVED TO BE ACCURATE AND REPRESENTS THE BEST DATA CURRENTLY AVAILABLE TO US. NO WARRANTY, EXPRESSED OR IMPLIED IS MADE AND NICE-PAK PRODUCTS, INC. ASSUMES NO LEGAL RESPONSIBILITY OR LIABILITY RESULTING FROM ITS USE.

SAFETY DATA SHEET

1. IDENTIFICATION

Product Name: BZK Antiseptic Towelettes **SDS 0055-00**

Finished Product Number: D35185

Formula Item Number: 4XD35101

Date of Preparation: June 20, 2018

Recommended use of the chemical and restrictions on use:

Recommended use: Antiseptic

Restrictions on use: For Professional and Hospital Use.

Manufacturer/Supplier: Nice-Pak/PDI, Inc.
Two Nice-Pak Park
Orangeburg, NY 10962-1376

Phone Number: 1-845-365-1700

Emergency Phone Number: **PERS**: 1-800-633-8253 (Domestic/Canada)
1-801-629-0667 (International)

2. HAZARD(S) IDENTIFICATION

This product is a odorless colorless to light yellow liquid impregnated on a wipe in a single packet.

GHS Classification:

Physical	Health	Environmental
Not Classified	Not Classified	Not Classified

Label Elements:
None Required

Hazard Statements:
Not Required

Precautionary Statements:
Not Required

Other Hazards: None known.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride	68424-85-1	0.13%

The specific identity and/or exact percentage of composition has been withheld as a trade secret.

4. FIRST-AID MEASURES

Description of First Aid Measures:

Eye: Rinse thoroughly with water. Get medical attention if irritation occurs and persists.
Skin: No first aid should be required. Wash skin with water. Get medical attention if irritation develops or persists.
Inhalation: If symptoms develop move victim to fresh air. Get medical attention if irritation or other symptoms persists.
Ingestion: Ingestion is unlikely for solid products. No first aid is required for small amounts transferred from hands to mouth.

Most Important Symptoms/Effects, Acute and Delayed: Direct contact may cause mild eye irritation.

Indication of Immediate Medical Attention and Special Treatment, If Necessary: None required under normal conditions of use.

5. FIRE-FIGHTING MEASURES

Suitable (and Unsuitable) Extinguishing Media: Use media appropriate for surrounding fire.

Specific Hazards Arising From the Chemical: Product will burn under fire conditions. Combustion may produce oxides of carbon and nitrogen, hydrogen chloride, and ammonia.

Special Protective Equipment and Precautions for Fire-Fighters: Firefighters should always wear self-contained breathing apparatus and full protective clothing for fires involving chemicals or in confined spaces.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures: None required.

Environmental Hazards: Report spill as required by local and federal regulations.

Methods and Materials for Containment and Cleaning Up: Pick up wipe and place in an appropriate container for disposal.

7. HANDLING AND STORAGE

Precautions for Safe Handling: Avoid prolonged contact with eyes. Wash hands with soap and water after use.

Conditions for Safe Storage, Including Any Incompatibilities: Store in a cool, dry location. Protect container from physical damage. Keep containers closed when not in use.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines:

Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride	None Established

Appropriate Engineering Controls: General ventilation is adequate under normal conditions of use.

Individual Protection Measures, Such As Personal Protective Equipment:
Respiratory Protection: None required for normal use.
Skin Protection: None required under normal use conditions.
Eye Protection: None required under normal use conditions.
Other: None required under normal conditions of use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Colorless to light yellow liquid impregnated on a lint free wipe	**Flammable limits: LEL:** Not applicable **UEL:** Not applicable
Odor: Odorless	**Vapor pressure:** Not available
Odor Threshold: Not applicable	**Vapor density:** Not available
pH: 5.5 (+/-0.5) (Saturant)	**Relative density:** Not available
Melting point/freezing point: 0°C (32°F) (Saturant)	**Solubility(ies):** Saturant- infinite
Boiling point/range: 100°C (212°F) (Saturant)	**Partition coefficient (n-octanol/water):** Not available
Flash point: Not available	**Auto-ignition temperature:** Not available
Evaporation rate: Not available	**Decomposition temperature:** Not available
Flammability (solid, gas): Not applicable	

10. STABILITY AND REACTIVITY

Reactivity: This product may react with oxidizing agents.
Chemical Stability: Stable under normal storage and handling conditions.
Possibility of Hazardous Reactions: Hazardous polymerization will not occur.
Conditions To Avoid: Keep away from heat and open flames.
Incompatible Materials: Avoid contact with strong oxidizing agents, strong acids, and bases.
Hazardous Decomposition Products: Thermal decomposition may produce oxides of carbon and nitrogen, hydrogen chloride, and ammonia.

11. TOXICOLOGICAL INFORMATION

Potential Health Effects:

Eye: Direct contact with liquid may cause mild eye irritation.
Skin: No adverse effects are expected.
Inhalation: No adverse effects are expected.
Ingestion: Ingestion is unlikely for solid products. This product contains only a small amount of liquid. No adverse effects are expected.

Chronic Effects: None known.

Carcinogenicity: None of the components of this product are listed as a carcinogen or suspected carcinogen by OSHA, IARC, and NTP.

Reproductive Effects: Reproductive harm is not expected from this product.

Mutagenic Effects: Not expected to cause mutagenic activity.

Acute Toxicity:
Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride: Oral rat LD50: 344 mg/kg, Skin rabbit LD50: 3340 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity:
Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride: 96 hr LC50 Fathead minnow: 0.28 mg/L, 48 hr EC50 Daphnia magna: 0.016 mg/L, 72 hr ErC50 Green Algae: 0.049 mg/L, 96 hr ErC50 Algae: 0.089 mg/L, 34 days NOEC Fathead minnow: 0.032 mg/L, 21 days NOEC Daphnia magna: 0.0042 mg/L (Acute M-Factor: 10, Chronic M-Factor: 1)

This product is expected to be toxic to the aquatic environment and harmful to the aquatic environment with long lasting effects. Releases to the environment should be avoided.

Persistence and Degradability: Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride: Readily biodegradable- 95.5% in 28 days.
Bioaccumulative Potential: No data available
Mobility in Soil: No data available
Other Adverse Effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
US DOT	None	Not Regulated	None	None	Not applicable
Canadian TDG	None	Not Regulated	None	None	Not applicable
IMDG	None	Not Regulated	None	None	Not applicable
IATA	None	Not Regulated	None	None	Not applicable

Special precautions: None known

15. REGULATORY INFORMATION

Safety, Health, and Environmental Regulations Specific for the Product In Question:

U.S. FEDERAL REGULATIONS:

CERCLA 103 Reportable Quantity: This product is not subject to reporting under CERCLA. Some states have more stringent reporting requirements. Report all spills in accordance with local, state, and federal regulations.

SARA TITLE III:

Hazard Category for Section 311/312: See OSHA Hazard Classification in Section 2.

Section 313 Toxic Chemicals: This product contains the following chemicals subject to SARA Title III Section 313 Reporting requirements: None

Section 302 Extremely Hazardous Substances (TPQ): None

EPA Toxic Substances Control Act (TSCA) Status: All of the ingredients of this product are listed on the TSCA inventory or exempt.

STATE REGULATIONS:

California Proposition 65: This product does not contain substances known in the State of California to cause cancer and/or reproductive harm.

Massachusetts RTK: None listed.

Pennsylvania RTK: None listed.

Rhode Island RTK: None listed.

New Jersey RTK: None listed.

CANADIAN REGULATIONS:

Canadian Environmental Protection Act: All of the components in this product are listed on the Domestic Substances List (DSL) or exempt.

16. OTHER INFORMATION

HMIS Ratings: Health – 1	Flammability – 0	Physical Hazard - 0
NFPA Ratings: Health – 0	Flammability – 0	Instability – 0

SDS Revision History: December 16, 2014
Date of preparation: June 20, 2018

SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

Product:	Alcohol Prep Pads
Product Label Name:	Dukal Alcohol Prep Pads (private label included)
CAS#:	(Alcohol) 67-63-0
EC#:	(Alcohol) 200-661-7
Relevant Product Use:	Antiseptic Cleanser
Company Name and Address:	Dukal Corporation 2 Fleetwood Court Ronkonkoma, NY 11779
Emergency Telephone Number:	631-656-3800
Contact Outside USA:	+1-800-243-0741 QA-RA-NY@dukal.com
Last Revision Date:	21-August-2019

SECTION 2: HAZARDOUS IDENTIFICATION

Hazard Class/Category:	Flammable Liquid – 2 Eye Irritation – 2 STOT SE – 3
Hazard Symbol:	
Signal Word:	Danger
Hazard Statements:	Highly flammable liquid and vapor. (H225) Causes serious eye irritation. (H319) May cause drowsiness or dizziness. (H336)
Precautionary statements:	
General:	Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Keep out of reach of children. (P210) (P102)
Eyes:	IF IN EYES: Rinse cautiously with water for several minutes. If eye irritation persists: Get medical advice/attention. (P305+P338) (P337+P313)
Inhalation:	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. (P304+P340)

SECTION 3: INFORMATION ON INGREDIENTS

Component Name	CAS #	EC #	Concentration	R Phrase
Isopropyl Alcohol	67-63-0	200-661-7	>60%	R11

SECTION 4: FIRST-AID MEASURES

Emergency first aid procedures by route of exposure:

Inhalation: If symptoms are experienced, remove source of contamination or move victim to fresh air. If affected person is not breathing, apply artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

Ingestion: Do not induce vomiting. If the material is swallowed have victim drink 1-3 glasses of water to dilute stomach contents. Seek medical attention or advice.

Skin: If irritation is experienced, rinse with water. If irritation persists, seek medical attention.

Eyes: Rinse eyes with water for 15 minutes holding the eye open. Seek medical attention if irritation persists

SECTION 5: FIRE-FIGHTING MEASURES

Flammability Classification: Flammable Liquid IB Extinguishing Media: Use methods appropriate for the surrounding fire. Consider water spray or fog, carbon dioxide, dry chemical powder, or alcohol resistant foam.

Products of Combustion: Upon decomposition this product may emit carbon dioxide, carbon monoxide and/or low molecular weight hydrocarbons.

Fire Fighting Equipment/Instructions: Wear protective clothing and equipment suitable for the surrounding fire, including helmet, facemask, and self-contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions: For large spills wear gloves, safety glasses and when levels exceed OSHA PEL use appropriate NIOSH approved respiratory protection. Keep unnecessary personnel away. Eliminate all sources of ignition or flammables that may come into contact with a spill of this material.

Environmental Precautions: Prevent discharge to open waters.

Method for Containment: Absorb spilled liquid in suitable non-flammable inert material such as clay, vermiculite or diatomaceous earth.

Methods for Clean-Up: Ventilate area of leak or spill. Use spark-proof tools to sweep or scrape up and containerize in approved chemical waste container. Wash spill area with water.

SECTION 7: HANDLING AND STORAGE

Handling: Keep away from heat, sparks and flame. Prevent contact with eyes. Use in well ventilated area.

Storage: Keep the container tightly closed and in a cool, well ventilated place.

SECTION 8: EXPOSURE CONTROLS

Isopropyl Alcohol (67-63-0)

ACGIH: 200 ppm TWA
OSHA: 400 ppm TWA; 980 mg/m3 TWA

Engineering Controls: Normal room ventilation is usually adequate.

Personal Protective Equipment (PPE):

Eye/Face Protection: None needed under normal use – Wear goggles is exposed to unusual amount and splashing

Skin Protection: None needed under normal use -- Wear overalls or apron if splashing is possible

Respiratory Protection: Use when vapor concentrations are high or in an enclosed space. Avoid inhalation of vapor.

General Hygiene Considerations: No smoking. Normal hygienic practices.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Non-woven cloth saturated with liquid. No free liquid inside packaging.
Appearance/Color: Clear
Odor: Alcohol
PH: Not Available.
Vapor Density: 2.1 (air=1)
Boiling Point: 80°C
Vapor Pressure: No data
Melting Point: No data
Freezing Point: Not Available
Flash Point: 11.7°C for 70% Isopropanol Solution
Solubility (in water): Soluble
Specific Gravity @ 25°C: 0.88-0.92
Evaporation Rate: Not Available
Octanol/Water partition coefficient : Not Available
Auto-ignition temperature: Not Available
Decomposition temperature: Not Available

SECTION 10: STABILITY AND REACTIVITY

Stability: Stable under normal ambient temperatures 70°C (21°C)
Condition to Avoid: Avoid excessive heat or sources of ignition.
Incompatible Materials: This product reacts with strong acid, strong bases, and oxidizing agents.
Hazardous Decomposition: Upon decomposition, this product evolves carbon monoxide, carbon dioxide, and/or low weight hydrocarbons.
Hazardous Reactions: Hazardous polymerization will not occur.

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE EFFECTS:
A: General Product information
Product contains isopropyl alcohol.
B: Acute Toxicity
Low order of acute toxicity is possible.
CHRONIC EFFECTS: Component
Isopropyl Alcohol (67-63-0) -- This product is not expected to cause long term adverse effects
Carcinogenicity: ACGIH A4 – Not Classifiable as a Human Carcinogen
Neurotoxicity: No information available
Mutagenicity: No information available for product.
Reproductive: This product is not expected to cause reproductive health effects
Developmental: This product is not expected to cause reproductive health effects.
Target Organs: When consumed, ethyl alcohol can target the respiratory system, skin, eyes, CNS, liver, blood and reproductive system.

SECTION 12: ECOLOGICAL INFORMATION

Solutions of alcohols are toxic to aquatic life at moderate to low concentrations. No long-term ecological effects are likely. Concentrated solutions of alcohols and surfactants may cause damage to aquatic and terrestrial plants.

SECTION 13: DISPOSAL CONSIDERATIONS

Dispose in accordance with national and local regulations. Labels should not be removed from containers until they have been cleaned. Do not cut, puncture or weld near container. Do not incinerate closed containers. Empty containers may contain hazardous residues. Dispose of containers with care.

SECTION 14: TRANSPORATION INFORMATION

DOT	Not Regulated as Hazardous Material under DOT 49 CFR 172.102 Special Provision 47
UN (EU: ADR/RID/ADN)	Not Regulated as Hazardous Material under UN Dangerous Goods Ch. 3.3 Special Provision 216
IATA/ IACAO	Not Regulated as Hazardous Material under IATA Sec. 4.4 Special Provision A46, IACAO DPG SP A46
IMDG/ IMO	Not Regulated as Hazardous Material under IMDG Ch. 3.3 Special Provision 216

Special Provisions Verbiage: (DOT) Mixtures of solids that are not subject to this subchapter and flammable liquids may be transported under this entry without first applying the classification criteria of Division 4.1, provided there is no free liquid visible at the time the material is loaded or at the time the packaging or transport unit is closed. Except when the liquids are fully absorbed in solid material contained in sealed bags, for single packagings, each packaging must correspond to a design type that has passed a leakproofness test at the Packing Group II level. Small inner packagings consisting of sealed packets and articles containing less than 10 mL of a Class 3 liquid in Packing Group II or III absorbed onto a solid material are not subject to this subchapter provided there is no free liquid in the packet or article. (UN: ARD/RID/ADN) SP216: Mixtures of solids which are not subjects to these Regulations and flammable liquids may be transported under this entry without first applying the classification criteria of Division 4.1, provided there is no free liquid visible at the time the substance is loaded or at the time the packaging or cargo transport unit is closed. Each cargo transport unit shall be leakproof when used as a bulk packaging. Sealed packets and articles containing less than 10 ml of a packing group II or III flammable liquid absorbed into a solid are not subject to these Regulations provided there is no free liquid in the packet or article. SP313: Sealed packets and articles containing less than 10 ml of an environmentally hazardous liquid, absorbed into a solid material but with no free liquid in the packet or article, or containing less than 10 g of an environmentally hazardous solid, are not subject to these Regulations. (IATA) Small inner packagings consisting of sealed packets or articles containing less than 10 mL of a Packing Group II or III flammable liquid absorbed into a solid material are not subject to these Regulations provided there is no free liquid in the packet or article (IACAO) Mixtures of solids which are not subject to these Instructions and flammable liquids may be transported under this entry without first applying the classification criteria of Division 4.1, providing there is no free liquid visible at the time the substance is packaged and the packaging must pass a leakproofness test at the Packing Group II level. Small inner packagings consisting of sealed packets or articles containing less than 10 mL of a Packing Group II or III flammable liquid absorbed into a solid material are not subject to these Instructions provided there is no free liquid in the packet or articles. (IMDG) Sealed packets containing 10 ml or less of Class 3 flammable liquids in Packing Group II or III which are absorbed into a solid with no free liquid at the time of shipment are not regulated.

SECTION 15: REGULATORY INFORMATION

EPA: SARA

CAS	Chemical	De Minimis
67-63-0	Isopropyl alcohol (only persons who manufacture by the strong acid process are subject, no supplier notification)	1.0%

EC:

Directive 2010/75/EU (VOC): 60 - 80 % (Liquid)

SECTION 16: OTHER INFORMATION

Issue Date: **03-26-2014**
Revision Date: **08-21-2019**

Disclaimer:

The information provided in this SDS is correct and is to the best of our knowledge, at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, REACH, European Union CLP EC 1272/2008 and the Global Harmonization Standard

PART I *What is the material and what do I need to know in an emergency?*

1. SECTION 1 – IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

TRADE NAME/MATERIAL NAME: Triple Antibiotic Ointment

DESCRIPTION: Bacitracin Zinc, Neomycin Sulfate, and Polymyxin B Sulfate Ointment
NDC #: 0168-0012-09; 0168-0012-31; 0168-0012-35
CHEMICAL NAME (for active ingredients):

Bacitracin Zinc: (2R,3S,4R,5R,6R)-5-amino-2-(aminomethyl)-6-{[(1R,2R,3S,4R,6S)-4,6-diamino-2-{[(2S,3R,4S,5R)-4-{[(2R,3R,4R,5S,6S)-3-amino-6-(aminomethyl)-4,5-dihydroxyoxan-2-yl]oxy}-3- amino-6-(aminomethyl)-4,5-dihydroxyoxan-2-yl]oxy}-3-hydroxy-5-(hydroxymethyl)oxolan-2-yl]oxy}-3-hydroxycyclohexyl]oxy}oxane-3-hydroxycyclohexyl]oxy}oxane-3,4-diol;

Neomycin Sulfate: 2-deoxy-4-*O*-(2,6-diamino-2,6-dideoxy-α-D-glucopyranosyl)-5-O-[3-*O*-(2,6-diamino-2,6-dideoxy-B-L-idopyranosyl)-β-D-ribofuranosyl]-D-streptamine;

Polymixin B Sulfate: (4*R*)-4-[(2*S*)-2-({2-[(1*S*)-1-amino-2-methylbutyl]- 4,5-dihydro-1,3-thiazol-5-yl}formamido)-4-methylpentanamido]-4-{[(1*S*)- 1-{[(3*S*,6*R*,9*S*,12*R*, 15*S*,18*R*,21*S*)- 18-(3-aminopropyl)-12-benzyl-15-(butan-2-yl)-3-(carbamoylmethyl)- 6-(carboxymethyl)-9-(1*H*-imidazol)

CHEMICAL FAMILY: Bacitracin Zinc: Cyclic Polypeptide; Neomycin Sulfate and Polymixin B Sulfate: Aminoglycosides
HOW SUPPLIED: Bacitracin Zinc, Neomycin Sulfate, and Polymyxin B Sulfate Topical Ointment
FORMULA (for active ingredient): Bacitracin Zinc: $C_{66}H_{103}N_{17}O_{16}SZn$; Neomycin Sulfate: $C_{23}H_{46}N_6O_{13}\bullet 3H_2O_4S$; Polymyxin B Sulfate: $C_{43}H_{82}N_{16}O_{12}\bullet H_2O_4S$
RELEVANT USE of the SUBSTANCE: Pharmaceutical for Human Use
USES ADVISED AGAINST Other than Relevant Use
SUPPLIER/MANUFACTURER'S NAME: **FOUGERA PHARMACEUTICALS INC.**
ADDRESS: 60 Baylis Road
Melville, NY 11747
BUSINESS PHONE/GENERAL SDS INFORMATION: 1-631-454-7677
EMERGENCY PHONE (U.S./Canada/Puerto Rico): CHEMTEL: (U.S, Canada, Int'l) 1(813) 676-1670 (24 hrs)

ALL WHMIS required information is included in appropriate sections based on the ANSI Z400.1-2010 format. This material has been classified in accordance with the hazard criteria of the CPR and the SDS contains all the information required by the CPR. The material is also classified per all applicable EU Directives through EC 1907: 2006, the European Union CLP EC 1272/2008 and the Global Harmonization Standard.

2. HAZARD IDENTIFICATION

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

EU LABELING/CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

EMERGENCY OVERVIEW: ***Product Description:*** This product is a pale yellow ointment with a petroleum jelly odor. ***Health Hazards:*** May be harmful if swallowed. Prolonged skin contact may be irritating. Individuals who have had allergic reactions to aminoglycosides may experience allergic reactions to this product, including skin and respiratory sensitization and allergic reactions. Therapeutic use of this product may cause adverse symptoms on the neurological system, ears, liver and kidneys. Due to the Neomycin Sulfate component, this product may cause harm to the fetus during pregnancy. ***Flammability Hazards:*** If heated to high temperatures for a prolonged period, this product may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon, nitrogen, zinc and sulfur oxides). ***Reactivity Hazards:*** This product is not reactive. ***Environmental Hazards:*** This product has not been tested for environmental effects, however, all release to the environment should be avoided. One active ingredient may cause acute and chronic toxicity to aquatic organisms. ***Emergency Considerations:*** Emergency responders should wear appropriate protection for situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/w	**LABEL ELEMENTS** **EU Classification (67/548/EEC)** **GHS & EU Classification (1272/2008 EC)** **Risk Phrases/Hazard Statements**
ACTIVE INGREDIENTS				
Bacitracin Zinc L-isoleucinamide, N-[[2-(1-amino-2-methylbutyl)-4,5-dihydro-4-thiazolyl]carbonyl]-L-leucyl-D-α-glutamyl-N-[(3S,6R,9S,12R,15S,18R,21S)-3-(2-amino-2-oxoethyl)-18-(3-aminopropyl)-6-(carboxymethyl)-9-(1H-imidazol-5-ylmethyl)-15-(1-methylpropyl)-2,5,8,11,14,17,20-heptaoxo-12-(phenylmethyl)-1,4,7,10,13,16,19-heptaazacyclopentacos-21-yl]-, zinc salt (1:1)	1405-89-6	215-787-8	500 Units	SELF-CLASSIFICATION EU 67/548 Classification: Irritant, Dangerous for the Environment Risk Phrase Codes: R43, R53/53 Hazard Symbols: Xn GHS and EU 1272/2008 Classification: Skin Sensitization Cat. 1B, Aquatic Acute Toxicity Cat. 3, Aquatic Chronic Toxicity Cat. 3 Hazard Codes: H317, H402, H412 Hazard Symbol/Pictogram: GHS08

See Section 16 for full classification information of product and components.

3. COMPOSITION and INFORMATION ON INGREDIENTS (Continued)

CHEMICAL NAME	CAS #	EINECS #	% w/w	**LABEL ELEMENTS** **EU Classification (67/548/EEC)** **GHS & EU Classification (1272/2008 EC)** **Risk Phrases/Hazard Statements**
ACTIVE INGREDIENTS (continued)				
Neomycin Sulfate 2-deoxy-4-*O*-(2,6-diamino-2,6-dideoxy-α-D-glucopyranosyl)-5-O-[3-*O*-(2,6-diamino-2,6-dideoxy-B-L-idopyranosyl)-β-D-ribofuranosyl]-D-streptamine	1405-10-3	215-773-1	0.4%	SELF-CLASSIFICATION EU 67/548 Classification: Reproductive Toxicity Cat. 3, Harmful, Irritant Risk Phrase Codes: R63, R42/43, R36/38, R33 Hazard Symbols: Xn GHS and EU 1272/2008 Classification: Reproductive Toxicity Cat. 2, Skin Sensitization Cat. 1A, Respiratory Sensitization Cat. 1B, Skin Irritation Cat. 2, Eye Irritation Cat. 2A, STOT RE Cat. 2 Hazard Codes: H361d, H317, H334, H315, H319, H373 Hazard Symbol/Pictogram: GHS07, GHS08
Polymixin B Sulfate (4*R*)-4-[(2*S*)-2-({2-[(1*S*)-1-amino-2-methylbutyl]-4,5-dihydro-1,3-thiazol-5-yl}formamido)-4-methylpentanamido]-4-{[(1*S*)- 1-{[(3*S*,6*R*,9*S*,12*R*,15*S*,18*R*,21*S*)- 18-(3-aminopropyl)-12-benzyl-15-(butan-2-yl)-3-(carbamoylmethyl)- 6-(carboxymethyl)-9-(1*H*-imidazol)	1405-20-5	215-774-7	10,000 Units	SELF-CLASSIFICATION EU 67/548 Classification: Harmful, Irritant Risk Phrase Codes: R22, H36/38 Hazard Symbols: Xn/Xi GHS and EU 1272/2008 Classification: Acute Oral Toxicity Cat. 4, Skin Irritation Cat. 2, Eye Irritation Cat. 2A Hazard Codes: H302, H315, H319 Hazard Symbol/Pictogram: GHS07
EXCIPIENTS				
White Petrolatum	8009-03-8	232-373-2	Proprietary	EU 67/548 Classification: Carcinogenic Cat. 2 Risk Phrase Codes: R45 Hazard Symbols: Xn GHS and EU 1272/2008 Classification: Carcinogenic Cat. 1B Hazard Codes: H350 Hazard Symbol/Pictogram: GHS08

See Section 16 for full classification information of product and components.

PART II *What should I do if a hazardous situation occurs?*

4 FIRST-AID MEASURES

PROTECTION OF FIRST AID RESPONDERS: rescuers should wear adequate personal protective equipment. Rescuers should be taken for medical attention, if necessary.

DESCRIPTION OF FIRST AID MEASURES: Contaminated individuals must be taken for medical attention if any adverse effects occur. Persons developing hypersensitivity reactions should receive medical attention. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Only trained personnel should administer supplemental oxygen and/or cardio-pulmonary resuscitation, if necessary. Remove victim(s) to fresh air, as quickly as possible. Take copy of product label and SDS to physician or other health professional with victim(s).

Skin Exposure: If adverse skin effects occur, discontinue use. Seek medical attention.

Eye Exposure: If this product contaminates the eyes, rinse eyes under gently running water. Use sufficient force to open eyelids and then "roll" eyes while flushing. Minimum flushing is for 20 minutes. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

Inhalation: If vapors of this product are inhaled, causing irritation, remove victim to fresh air. If necessary, use artificial respiration to support vital functions.

Ingestion: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain immediate medical attention.

IMPORTANT SYMPTOMS AND EFFECTS: See Sections 2 (Hazard Identification) and 11 (Toxicological Information).

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing liver and kidney conditions and hearing problems and may be aggravated by exposure to this product. Dehydration increases the toxicity of Neomycin Sulfate. Workplace exposure may also aggravate these conditions. Persons who may have hypersensitivity reactions to aminoglycosides or the components, and other disorders described in Section 11 (Toxicological Information) may experience aggravation upon exposure.

INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED: Treat symptoms and eliminate exposure. Persons developing hypersensitivity reactions should receive medical attention. No specific antidote is known. Treatment should be symptomatic and supportive.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not available. ***AUTOIGNITION TEMPERATURE:*** Not available.

FLAMMABLE LIMITS (in air by volume, %): Not applicable.

FIRE EXTINGUISHING MEDIA: Use extinguishing media appropriate for surrounding fire.

5. FIRE-FIGHTING MEASURES (Continued)

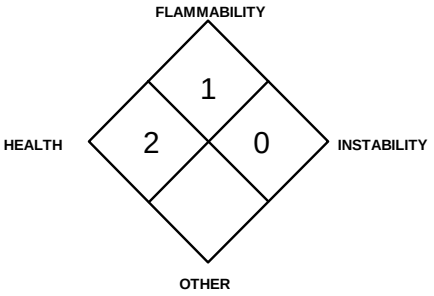
UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.

SPECIAL HAZARDS ARISING FROM THE PRODUCT: If heated to high temperatures for a prolonged period this product can ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon, nitrogen, zinc and sulfur oxides).

Explosion Sensitivity to Mechanical Impact or Static Discharge: Not sensitive.

SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

NFPA RATING



Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate **3** = Serious **4** = Severe

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES: Spill kits, clearly labeled, should be kept in or near preparation and administrative areas. It is suggested that kits include a respirator, chemical splash goggles, two pairs of gloves, two sheets (12" x 12") of absorbent material, 250-mL and 1-liter spill control pillows and a small scoop to collect glass fragments (if applicable). Absorbents should be incinerable. Finally, the kit should contain two large waste-disposal bags. Avoid generating aerosols from this product. Spills may be slippery.

PROTECTIVE EQUIPMENT:

Small Spills: Wear goggles and gloves while wiping up small spills of this product with polypad or sponge.

Large Spills: Use proper protective equipment, including double nitrile or appropriate gloves, full body gown, and full-face respirator equipped with a High Efficiency Particulate (HEPA) filter. Self-Contained Breathing Apparatus (SCBA) can be used instead of an air-purifying respirator.

METHODS FOR CLEAN-UP AND CONTAINMENT:

Small Spills: The product should be gently covered with absorbent pads. Clean spill with pad and dispose of properly. Decontaminate the spill area (three times) using a bleach and detergent solution and then rinse with clean water.

Large Spills: Review Sections 2, 8, 11 and 12 before proceeding with cleanup. Restrict access to the spill areas. For spills of amounts larger than 5 mL limit spread by gently covering with absorbent sheets, or spill-control pads or pillows. Be sure not to generate aerosols. The dispersion of aerosols into surrounding air and the possibility of inhalation is a serious matter and should be treated as such. Do not apply chemical in-activators as they may produce hazardous by-products. Thoroughly clean all contaminated surfaces three times using a bleach and detergent solution and then rinse with clean water.

All Spills: Use procedures described above and then place all spill residues in an appropriate, labeled container and seal. Move to a secure area. Dispose of in accordance with Federal, State, and local hazardous waste disposal regulations (see Section 13, Disposal Considerations). For spills on water, contain, minimize dispersion and collect. Dispose of recovered product and report spill per regulatory requirements.

ENVIRONMENTAL PRECAUTIONS: Prevent product from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

REFERENCE TO OTHER SECTIONS: Review Sections 2, 8, 11 and 12 before proceeding with cleanup. See Section 13, Disposal Considerations for more information.

PART III *How can I prevent hazardous situations from occurring?*

7. HANDLING and USE

PRECAUTIONS FOR SAFE HANDLING: All employees who handle this product should be thoroughly trained to handle it safely. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat or drink while handling this product. Appropriate personal protective equipment must be worn (see Section 8, Engineering Controls and Personal Protection). Avoid generation of aerosols.

PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL: Handle this material following standard medical practices and following the recommendations presented on the Package Insert.

CONDITIONS FOR SAFE STORAGE: Containers of this product must be properly labeled. Store containers in a cool, dry location, away from direct sunlight and sources of intense heat. Recommended Storage Temperature: 20-25°C (68-77°F) [USP Controlled Room Temperature]. Protect from freezing. Store away from incompatible materials (see Section 10, Stability and Reactivity). Product should be stored in secondary containers. Keep containers tightly closed when not in use. Inspect all incoming containers before storage, to ensure containers are properly labeled and not damaged. Have appropriate extinguishing equipment in the storage area (e.g., sprinkler system, portable fire extinguishers). Empty containers may contain residual product; therefore, empty containers should be handled with care and disposed of properly.

SPECIFIC END USE(S): This product is a human pharmaceutical.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear nitrile or other appropriate gloves (double gloving is recommended), goggles, and lab coat.

7. HANDLING and USE (Continued)

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT (continued): Wipe equipment down with damp sponge or polypad. If applicable, wash equipment using a bleach and detergent solution and then rinse with clean water. Collect all rinsates and dispose of according to applicable waste disposal regulations or waste disposal regulations of Canada. All disposable items contaminated with this product should be disposed of properly.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

Ventilation and Engineering Controls*:* Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this SDS.

Workplace Exposure Limits/Control Parameters:

CHEMICAL NAME	*CAS #*	*EXPOSURE LIMITS IN AIR*							
		ACGIH-TLVs		*OSHA-PELs*		*NIOSH-RELs*		*NIOSH*	*OTHER*
		TWA mg/m³	*STEL mg/m³*	*TWA mg/m³*	*STEL mg/m³*	*TWA mg/m³*	*STEL mg/m³*	*IDLH mg/m³*	*mg/m³*
Bacitracin Zinc	1405-89-6	NE	NE	NE	NE	NE	NE	NE	NE
Neomycin Sulfate	1405-10-3	NE	NE	NE	NE	NE	NE	NE	NE
Polymixin B Sulfate	1405-20-5	NE	NE	NE	NE	NE	NE	NE	NE
White Petrolatum	8009-03-8	NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established See Section 16 for Definitions of Terms Used.

International Occupational Exposure Limits: No additional international exposure limits are available for components. Exposure limits are added or changed and should be check periodically.

PROTECTIVE EQUIPMENT: *The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132, including* U.S. Federal OSHA Respiratory Protection (29 CFR 1910.134), OSHA Eye Protection 29 CFR 1910.133, OSHA Hand Protection 29 CFR 1910.138, OSHA Foot Protection 29 CFR 1910.136 and OSHA Body Protection 29 CFR1910.132)*, equivalent standards of Canada (including CSA Respiratory Standard Z94.4-02,* Z94.3-M1982, *Industrial Eye and Face Protectors and* CSA Standard Z195-02, *Protective Footwear), or standards of EU member states (including EN 529:2005 for respiratory PPE, CEN/TR 15419:2006 for hand protection, and CR 13464:1999 for face/eye protection). Please reference applicable regulations and standards for relevant details.*

Respiratory Protection: Maintain airborne contaminant concentrations below exposure limits listed above, if applicable. For materials without listed exposure limits, minimize respiratory exposure. If necessary, use only respiratory protection authorized under appropriate regulations. Oxygen levels below 19.5% are considered IDLH by U.S. OSHA. In such atmospheres, use of a full-facepiece pressure/demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under U.S. OSHA's Respiratory Protection Standard (1910.134-1998).

Eye Protection: Wear splash goggles or safety glasses as appropriate for the task. If necessary, refer to appropriate regulations.

Skin Protection: Use appropriate protective clothing for the task (e.g., lab coat, etc.). If necessary, refer to the U.S. OSHA Technical Manual (Section VII: Personal Protective Equipment) or other appropriate regulations.

Hand Protection: Wash hands and wrists before putting on and after removing gloves. During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. When used in medical administration of the product, double glove with nitrile or other appropriate gloves to avoid contact and/or absorption of the product. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS. Because all gloves are to some extent permeable and their permeability increases with time, they should be changed regularly (hourly is preferable) or immediately if torn or punctured. If necessary refer to appropriate regulations.

9. PHYSICAL and CHEMICAL PROPERTIES

FORM: Ointment.
COLOR: Pale yellow.
MOLECULAR WEIGHT: Mixture.
MOLECULAR FORMULA: Mixture.
ODOR: Petroleum jelly odor.
ODOR THRESHOLD: Not established.
BOILING POINT: 200°C (392°F)
MELTING POINT: 58°C (136°F)
EVAPORATION RATE (nBuAc = 1): Not established.
pH: Not established.
VAPOR PRESSURE (air = 1): < 1 mmHg
SPECIFIC GRAVITY @ 60°C (water = 1): 0.85
SOLUBILITY IN WATER: Insoluble.
OTHER SOLUBILITIES: Not known.
COEFFICIENT WATER/OIL DISTRIBUTION: Not established.
HOW TO DETECT THIS SUBSTANCE (warning properties): The appearance of this product can be a distinguishing characteristic to identify it in event of accidental release.

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: This product is stable.
DECOMPOSITION PRODUCTS: Combustion: If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon, nitrogen, zinc and sulfur oxides). ***Hydrolysis:*** None known.
MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility. Acids, caustics, and other chemicals that could affect its performance should be avoided.

10. STABILITY and REACTIVITY (Continued)

POSSIBILITY OF HAZARDOUS REACTIONS/POLYMERIZATION: Will not occur.
CONDITIONS TO AVOID: Avoid heat, light, and contact with incompatible chemicals.

PART IV *Is there any other useful information about this material?*

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to medical employees handling this product in an occupational setting. This product is designed for application on the skin. The following paragraphs describe the symptoms of exposure by route of exposure.

Inhalation: Although unlikely, due to high viscosity of the product, inhalation of mists or sprays of this product, especially in a poorly ventilated space, may cause irritation, coughing, and sneezing.

Contact with Skin or Eyes: Skin contact may cause burning sensation, stinging, prickling, itching, and tingling. Aminoglycosides have a low order of toxicity when applied topically; however, rashes and allergic anaphylactoid reactions have occurred in some patients. Anaphylactoid reactions have ranged from generalized itching, swelling of the lips and face, sweating, and tightness of the chest, to hypotension, unconsciousness, apnea, and cardiac arrest. Reaction may be life-threatening in certain individuals. Eye contact can cause temporary blurred vision and irritation.

Skin Absorption: Neomycin and Polymyxin B Sulfates can be absorbed through open wounds, burns, and granulating surfaces. Absorption can be significant and can adversely affect the kidneys and destroy fibers of the acoustic nerve and cause permanent bilateral deafness. When absorbed, Neomycin and Polymyxin B are nephrotoxic antibiotics (can cause damage to the liver), and the nephrotoxic potentials are additive.

Ingestion: Ingestion is not a significant route of occupational exposure. Ingestion is not a significant route of occupational exposure. Acute ingestion of large quantities of this product or chronic ingestion caused by poor hygiene practices may cause nausea, vomiting, diarrhea and inflammation of the small intestine and the colon. Although ingestion may cause severe allergic reactions, reactions are rare. Neuromuscular blockage and respiratory paralysis have been reported following the oral use of Neomycin. Chronic ingestion caused by poor hygiene practices may cause weight loss, diarrhea, excess fat in the stools, excessive discharge of nitrogenous substances in the feces or urine, difficulty digesting dairy products, intestinal crypt-cell necrosis, kidney damage, hearing loss, and hair loss.

Injection: Though not anticipated to be a significant route of exposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection. Symptoms of intramuscular injection of Bacitracin Zinc may include loss of appetite, nausea, vomiting, diarrhea, rectal itching and burning, skin rashes, pain, hives, fever, bone marrow toxicities, blood dyscrasias, eosinophilia, kidney damage, and anaphylactoid reactions. Reaction may be life-threatening in certain individuals.

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	2*
FLAMMABILITY HAZARD	(RED)	1
PHYSICAL HAZARD	(YELLOW)	0

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate
3 = Serious **4** = Severe * = Chronic hazard

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses: In therapeutic use, damage to the kidneys, liver or renal damage, ototoxicity (damage to hearing) and neuromuscular blockage have been reported. Hypersensitivity to aminoglycosides may cause rash. Ingestion can cause serious allergic reactions in susceptible individuals. Allergic reaction by inhalation may be possible. Increased liver toxicity has been reported following concurrent administration of aminoglycosides and cephalosporins. Acute muscular paralysis and breathing disorders due to this can occur with aminoglycoside drugs. Can cause fetal harm. These effects may be possible as a result of workplace exposure. The actual risk in the workplace is not known.

IRRITANCY OF PRODUCT: This product may irritate contaminated tissue if contact is prolonged.

SENSITIZATION OF PRODUCT: Aminoglycosides have a low order of toxicity when applied topically; however, rashes and allergic anaphylactoid reactions have occurred in some patients. Anaphylactoid reactions have ranged from generalized itching, swelling of the lips and face, sweating, and tightness of the chest, to hypotension, unconsciousness, apnea, and cardiac arrest. Bacitracin is considered to be one of the most prevalent allergens. Rashes and allergic anaphylactoid reactions have occurred in some patients. Anaphylactoid reactions have ranged from generalized itching, swelling of the lips and face, sweating, and tightness of the chest, to hypotension, unconsciousness, apnea, and cardiac arrest. Reaction may be life-threatening in certain individuals.

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms. Exposure to this product may cause the following health effects:

Acute: Ingestion may be harmful. Eye contact may cause irritation.

Chronic: Dermatitis (inflammation and redness of the skin) may occur after chronic, low-level skin contact. May cause fetal harm. Chronic exposure to this material may cause adverse effects as described under 'General Toxicity Information'.

TARGET ORGANS:

Acute: *Occupational Exposure:* Skin, eyes. *Therapeutic Doses:* Skin.

Chronic: *Occupational Exposure:* Skin. *Therapeutic Doses:* Skin, other effects described under 'Other Potential Health Effects'.

11. TOXICOLOGICAL INFORMATION (Continued)

TOXICITY DATA: Only toxicity data available for the active component of this product are presented in this SDS. Additional data are available for the excipient components of this product, but are not presented; Contact Fougera for more information.

NEOMYCIN SULFATE:

Standard Draize Test (Skin-Human) 6 mg/3 days-intermittent: Mild
Standard Draize Test (Skin-Human) 0.2%: Severe
TDLo (Oral-Human) 12,600 mg/kg/7 days: Behavioral: somnolence (general depressed activity), hallucinations, distorted perceptions, anorexia (human)
LD_{50} (Oral-Mouse) > 8 gm(base)/kg
LD_{50} (Subcutaneous-Rat) 200 mg/kg
LD_{50} (Subcutaneous-Mouse) 190 mg/kg
LD_{50} (Intraperitoneal-Mouse) 305 mg/kg
LD_{50} (Intravenous-Mouse) 17,400 µg/kg
LD_{50} (Intramuscular-Mouse) 142 mg/kg
LD_{50} (Intramuscular-Guinea Pig) > 250 mg/kg: Sense Organs and Special Senses (Ear): change in acuity
LD_{50} (Intracerebral-Mouse) 32 mg/kg
TDLo (Subcutaneous-Rat) 280 mg/kg/7 days-intermittent: Kidney/Ureter/Bladder: changes in bladder weight; Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol); Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: phosphatases
TDLo (Subcutaneous-Mouse) 560 mg/kg/7 days-intermittent: Gastrointestinal: other changes; Kidney/Ureter/Bladder: other changes in urine composition; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: other Enzymes
TDLo (Intravenous-Rat) 15 mg/kg: Behavioral: alteration of classical conditioning
TDLo (Intraspinal-Rat) 36.88 µg/kg: Behavioral: analgesia
TDLo (Intracerebral-Rat) 714.3 µg/kg: Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol); Biochemical: Neurotransmitters or modulators (putative): catecholamine levels in CNS

NEOMYCIN SULFATE (continued):

TDLo (Intramuscular-Monkey) 500 mg/kg/5 days-intermittent: Sense Organs and Special Senses (Ear): change in acuity, changes in cochlear structure or function; Kidney/Ureter/Bladder: other changes in urine composition
TDLo (Intramuscular-Cat) 5050 mg/kg/14 weeks-intermittent: Kidney/Ureter/Bladder: changes in tubules (including acute renal failure, acute tubular necrosis), interstitial nephritis; Related to Chronic Data: death
TDLo (Intramuscular-Guinea Pig) 2 gm/kg/8 days-intermittent: Sense Organs and Special Senses (Ear): change in acuity, changes in cochlear structure or function; Related to Chronic Data: death

POLYMIXIN B SULFATE:

Standard Draize Test (Skin-Child) 5%: Moderate
LD_{50} (Oral-Mouse) 790 mg(base)/kg
LD_{50} (Intraperitoneal-Mouse) 20,500 µg(base)/kg
LD_{50} (Subcutaneous-Mouse) 59,500 µg(base)/kg
LD_{50} (Subcutaneous-Guinea Pig) 58 mg/kg
LD_{50} (Intravenous-Mouse) 5400 µg(base)/kg
LDLo (Intravenous-Dog) 8 mg/kg
LDLo (Intracerebral-Dog) 320 µg/kg: Behavioral: coma
TDLo (Subcutaneous-Mouse) 284 mg/kg/9 days-intermittent: Behavioral: muscle weakness; Skin and Appendages: dermatitis, other (after systemic exposure); Skin and Appendages: hair
DNA Adduct (Bacteria-*Escherichia coli*) 50 mg/L
Mutation Test Systems-Not Otherwise Specified (Microorganism-Not Otherwise Specified) 25 mg/L
Mutation Test Systems-Not Otherwise Specified (Yeast-*Saccharomyces cerevisiae*) 5 mg/L

CARCINOGENIC INFORMATION: The following information is available for one of the active ingredients.

The effect of oral administration of Neomycin (100 and 200 µg/mL in drinking water) on colon tumors induced by azoxymethane (AOM) was studied in female F344 rats. 5-week-old rats were fed NIH-07 diet and given daily in drinking water 0, 100, and 200 µg neomycin/ml (0, 100, and 200 ppm). At 7 weeks of age, all animals except vehicle-treated groups received weekly sc injections of 8 mg AOM/kg bw for 8 weeks. The AOM- or vehicle-treated groups were necropsied 30 weeks after the last injection of AOM. The combined incidence of adenomas and adenocarcinomas of the colon did not differ significantly among the 3 groups. The animals in the groups given 100 and 200 µg neomycin had a higher incidence of colon adenocarcinomas than did those in the control group. Colonic and cecal bacterial beta-glucuronidase activity was significantly lower in the group given 200 µg Neomycin than it was in the control group. The excretion of fecal cholesterol, total bile acids, and deoxycholic acid was increased significantly in animals given 100 and 200 µg Neomycin as compared to animals given no Neomycin. These results suggest that long-term oral administration of neomycin increases the incidence of colon adenocarcinomas.

The remaining components of this product are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

REPRODUCTIVE TOXICITY INFORMATION: There are no adequate and well-controlled studies of in pregnant women. This product has not been rated by the U.S. FDA for Pregnancy Risk Category. The following information is available for the Neomycin Sulfate active ingredient.

Mutagenicity: Studies in humans have not been performed with the aminoglycosides, including Neomycin Sulfate to determine potential mutagenic effect. Treatment of cultured human lymphocytes *in vitro* with Neomycin increased the frequency of chromosome aberrations at the highest concentrations (80 µg/mL) tested; however, the effects of Neomycin on mutagenesis in humans are unknown. Long- term studies in animals to evaluate or mutagenic potential have not been conducted with Polymyxin B Sulfate.

Embryotoxicity/Teratogenicity: Aminoglycosides can cause fetal harm when administered to a pregnant woman. Aminoglycosides cross the placenta and there have been several reports of total irreversible, bilateral congenital deafness in children whose mothers received streptomycin (a related aminoglycoside) during pregnancy. Although serious side effects to the fetus or newborns have not been reported in the treatment of pregnant women with other aminoglycosides, the potential for harm exists.

Reproductive Toxicity: No long-term animal studies have been performed with Neomycin Sulfate to evaluate impairment of fertility. It is not known whether neomycin is excreted in human milk, but it has been shown to be excreted in cow milk following a single intramuscular injection. Other aminoglycosides have been shown to be excreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently, there are no ACGIH Biological Exposure Indices (BEIs) determined for components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY: This product has not been tested for soil absorption or mobility.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability.

BIOACCUMULATION: This product has not been tested for bioconcentration.

ECOTOXICITY: No specific information is currently available on the effect of this product on plants or animals in the environment.

12. ECOLOGICAL INFORMATION (Continued)

ECOTOXICITY (continued): This product may be harmful to contaminated terrestrial and aquatic plant and animal life, especially in large quantities. The following data are available for one active component.

BACITRACIN ZINC:

LC_{50} (Trout) 96 hours = 74 mg/L

EC_{50} (Artemia sp. Brine shrimp) 48 hours = 18,500-25,700 µg/L (21.82 mg/L)

RESULTS OF PBT AND vPvB ASSESSMENT: No Data Available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.

ENVIRONMENTAL EXPOSURE CONTROLS: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

OTHER ADVERSE EFFECTS: No component of this product is known to have ozone depletion potential.

13. DISPOSAL CONSIDERATIONS

DISPOSAL METHODS: It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Shipment of wastes must be done with appropriately permitted and registered transporters.

DISPOSAL CONTAINERS: Waste materials must be placed in and shipped in appropriate 5-gallon or 55-gallon poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers be done to all applicable regulations.

PRECAUTIONS TO BE FOLLOWED DURING WASTE HANDLING: Wear proper protective equipment when handling waste materials.

PREPARING WASTES FOR DISPOSAL: Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of Canada. This product, if unaltered by handling, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All gowns, gloves, and disposable materials used in the preparation or handling of this product should be disposed of in accordance with established hazardous waste disposal procedures. Handle as if capable of transmitting infectious agents. Incineration is recommended. Reusable equipment should be cleaned with soap and water.

U.S. EPA WASTE NUMBER: Not applicable to wastes consisting only of this product.

EWC WASTE CODE: Wastes from Human or Animal Health Care or Related Research: 18 01 08: Medicines Other Than Those Mentioned in 18 01 07.

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION SHIPPING REGULATIONS: This product is not classified as hazardous under regulations of U.S. DOT 49 CFR 172.101.

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is not classified as Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product does not meet the criteria as Dangerous Goods, per rules of IATA.

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is NOT classified as Dangerous Goods by the International Maritime Organization.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product does not meet the criteria as Dangerous Goods of the United Nations Economic Commission for Europe.

TRANSPORT IN BULK ACCORDING TO THE IBC CODE: Not applicable.

ENVIRONMENTAL HAZARDS: This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) and is not specifically listed in Annex III under MARPOL 73/78.

15. REGULATORY INFORMATION

UNITED STATES REGULATIONS:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity (TPQ): There are no specific Threshold Planning Quantities for any component of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. CERCLA Reportable Quantities (RQ): Not applicable.

U.S. TSCA Inventory Status: This product is regulated by the Food and Drug Administration; it is not subject to requirements under TSCA.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): The Neomycin component is listed on the California Proposition 65 lists, when used in oral therapeutic use. Since this is a topical preparation, this listing does not apply to this product.

Other U.S. Federal Regulations: Regulations of the FDA under the Federal Food, Drug and Cosmetic Act are applicable when this material is used in pharmaceutical preparations.

15. REGULATORY INFORMATION (Continued)

UNITED STATES REGULATIONS (continued):

Other U.S. Federal Regulations (continued): Under the Hazard Communication Standard (HCS), Section (b)(5)(ii) drugs are subject to labeling requirements by the FDA under the Federal Food, Drug and Cosmetic Act and are exempt from labeling provisions of the HCS; this section of the HCS exempts only labeling requirements and not requirements for a Safety Data Sheet for drugs.

CANADIAN REGULATIONS:

Canadian DSL/NDSL Inventory Status: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it is exempt from requirements of the DSL/NDSL Inventory.

Canadian Environmental Protection Act (CEPA) Priorities Substances Lists: No component is on the CEPA Priorities Substances List.

Other Canadian Regulations: Not applicable.

Canadian WHMIS Classification and Symbols: The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act.

EUROPEAN REGULATIONS:

Safety, Health, and Environmental Regulations/Legislation Specific for the Product: Formulated, finished medicinal products for human use are subject to Directive 2001/83/EC and subsequent amendments to the directive.

Chemical Safety Assessment: No Data Available. The chemical safety assessment is required for some substances according to European Union Regulation (EC) 1907/2006, Article 14.

16. OTHER INFORMATION

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): **WARNING!** MAY HARMFUL IF ACCIDENTALLY INGESTED. PROLONGED THERAPEUTIC USE MAY CAUSE SYSTEMIC EFFECTS. MAY CAUSE ALLERGIC SKIN AND RESPIRATORY REACTIONS. LIMITED EVIDENCE OF HARM TO FETUS DURING PREGNANCY. CONTAINS TRACE COMPOUND THAT MAY CAUSE ACUTE AND CHRONIC HARM TO AQUATIC ORGANISMS. Do not taste or swallow. Avoid contact with skin or clothing. Avoid breathing mists or sprays. Keep container tightly closed. Use only with adequate ventilation. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. FIRST-AID: In case of contact, flush eyes with plenty of water. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. If swallowed, call a physician immediately. Do NOT induce vomiting unless directed by a physician. Never give anything by mouth to an unconscious person. IN CASE OF FIRE: Use water fog, dry chemical, CO_2, or "alcohol" foam. IN CASE OF SPILL: Wipe up spilled product. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Safety Data Sheet for additional information.

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

67/548/EEC EU LABELING/CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

CLASSIFICATION FOR COMPONENTS:

Full Text Global Harmonization AND EU CLP Regulation (EC) 1272/2008:

Bacitracin Zinc: This is a self-classification.
Classification: Skin Sensitization Category 1B, Aquatic Acute Toxicity Category 3, Aquatic Chronic Toxicity Category 3
Hazard Statements: H317: May cause an allergic skin reaction. H402: Harmful to aquatic life. H412: Harmful to aquatic life with long-lasting effects.

Neomycin Sulfate: This is a self-classification.
Classification: Reproductive Toxicity Category 2, Skin Sensitization Category 1A, Respiratory Sensitization Category 1B, Skin Irritation Category 2, Eye Irritation Category 2A, Specific Target Organ Toxicity Repeated Exposure Category 2
Hazard Statements: H361: Suspected of damaging fertility or the unborn child. H317: May cause an allergic skin reaction. H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. H315: Causes skin irritation. H319: Causes serious eye irritation. H373: May cause damage to the liver through prolonged or repeated exposure.

Polymixin B Sulfate: This is a self-classification.
Classification: Acute Oral Toxicity Category 4, Skin Irritation Category 2, Eye Irritation Category 2A
Hazard Statements: H302: May be harmful if swallowed. H315: Causes skin irritation. H319: Causes serious eye irritation.

White Petrolatum: The following is a Self-Classification.
Classification: Carcinogenic Category 1B
Hazard Statements: H350: May cause cancer.

All Other Components: No classification has been published or is applicable.

Full Text EU 67/548/EEC:

Bacitracin Zinc: This is a self-classification.
Classification: Irritant, Dangerous for the Environment
Risk Phrases: R43: May cause sensitisation by skin contact. R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Neomycin Sulfate: This is a self-classification.
Classification: Reproductive Toxicity Category 3, Harmful, Irritant
Risk Phrases: R63: Possible risk of harm to the unborn child. R42/43: May cause sensitisation by inhalation and skin contact. R36/38: Irritating to eyes and skin. R33: Danger of cumulative effects.

16. OTHER INFORMATION (Continued)

CLASSIFICATION FOR COMPONENTS (continued):

Full Text EU 67/548/EEC (continued):

Polymixin B Sulfate: This is a self-classification.

Classification: Harmful, Irritant

Risk Phrases: R22: May be harmful if swallowed. R36/38: Irritating to eyes and skin.

White Petrolatum: The following is a Self-Classification.

Classification: Carcinogenic Category 2

Risk Phrases: R45: May cause cancer.

All Other Components: No classification has been published or is applicable.

REVISION DETAILS: May 2015: Review and up-date SDS to comply with EU CLP and the Global Harmonization Standard. Correction of CAS# for Bacitracin Zinc in Sections 3 and 8.

REFERENCES AND DATA SOURCES: Contact the supplier for information.

METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.

***PREPARED BY*:** CHEMICAL SAFETY ASSOCIATES, Inc. • PO Box 1961, Hilo, HI 96721 • 800/441-3365 • 808/969-4846

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DEFINITION OF TERMS

A large number of abbreviations and acronyms appear on a SDS. Some of these, which are commonly used, include the following:

CAS #: This is the Chemical Abstract Service Number that uniquely identifies each constituent.

EXPOSURE LIMITS IN AIR:

CEILING LEVEL: The concentration that shall not be exceeded during any part of the working exposure.

DFG MAK Germ Cell Mutagen Categories: 1: Germ cell mutagens that have been shown to increase the mutant frequency in the progeny of exposed humans. **2:** Germ cell mutagens that have been shown to increase the mutant frequency in the progeny of exposed mammals. **3A:** Substances that have been shown to induce genetic damage in germ cells of human of animals, or which produce mutagenic effects in somatic cells of mammals *in vivo* and have been shown to reach the germ cells in an active form. **3B:** Substances that are suspected of being germ cell mutagens because of their genotoxic effects in mammalian somatic cell *in vivo*; in exceptional cases, substances for which there are no *in vivo* data, but that are clearly mutagenic in vitro and structurally related to known in vivo mutagens. **4:** Not applicable (Category 4 carcinogenic substances are those with non-genotoxic mechanisms of action. By definition, germ cell mutagens are genotoxic. Therefore, a Category 4 for germ cell mutagens cannot apply. At some time in the future, it is conceivable that a Category 4 could be established for genotoxic substances with primary targets other than DNA [e.g. purely aneugenic substances] if research results make this seem sensible.) **5:** Germ cell mutagens, the potency of which is considered to be so low that, provided the MAK value is observed, their contribution to genetic risk for humans is expected not to be significant.

DFG MAK Pregnancy Risk Group Classification: Group A: A risk of damage to the developing embryo or fetus has been unequivocally demonstrated. Exposure of pregnant women can lead to damage of the developing organism, even when MAK and BAT (Biological Tolerance Value for Working Materials) values are observed. **Group B:** Currently available information indicates a risk of damage to the developing embryo or fetus must be considered to be probable. Damage to the developing organism cannot be excluded when pregnant women are exposed, even when MAK and BAT values are observed. **Group C:** There is no reason to fear a risk of damage to the developing embryo or fetus when MAK and BAT values are observed. **Group D:** Classification in one of the groups A–C is not yet possible because, although the data available may indicate a trend, they are not sufficient for final evaluation.

IDLH: Immediately Dangerous to Life and Health. This level represents a concentration from which one can escape within 30-minutes without suffering escape-preventing or permanent injury.

LOQ: Limit of Quantitation.

MAK: Federal Republic of Germany Maximum Concentration Values in the workplace.

NE: Not Established. When no exposure guidelines are established, an entry of NE is made for reference.

NIC: Notice of Intended Change.

NIOSH CEILING: The exposure that shall not be exceeded during any part of the workday. If instantaneous monitoring is not feasible, the ceiling shall be assumed as a 15-minute TWA exposure (unless otherwise specified) that shall not be exceeded at any time during a workday.

NIOSH RELs: NIOSH's Recommended Exposure Limits.

PEL: OSHA's Permissible Exposure Limits. This exposure value means exactly the same as a TLV, except that it is enforceable by OSHA. The OSHA Permissible Exposure Limits are based in the 1989 PELs and the June, 1993 Air Contaminants Rule (Federal Register: 58: 35338-35351 and 58: 40191). Both the current PELs and the vacated PELs are indicated. The phrase, "Vacated 1989 PEL" is placed next to the PEL that was vacated by Court Order.

SKIN: Used when a there is a danger of cutaneous absorption.

STEL: Short Term Exposure Limit, usually a 15-minute time-weighted average (TWA) exposure that should not be exceeded at any time during a workday, even if the 8-hr TWA is within the TLV-TWA, PEL-TWA or REL-TWA.

TLV: Threshold Limit Value. An airborne concentration of a substance that represents conditions under which it is generally believed that nearly all workers may be repeatedly exposed without adverse effect. The duration must be considered, including the 8-hour.

TWA: Time Weighted Average exposure concentration for a conventional 8-hr (TLV, PEL) or up to a 10-hr (REL) workday and a 40-hr workweek.

WEEL: Workplace Environmental Exposure Limits from the AIHA.

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS:

This rating system was developed by the National Paint and Coating Association and has been adopted by industry to identify the degree of chemical hazards.

HEALTH HAZARD: **0** Minimal Hazard: No significant health risk, irritation of skin or eyes not anticipated. *Skin Irritation*: Essentially non-irritating. Mechanical irritation may occur. PII or Draize = 0. *Eye Irritation*: Essentially non-irritating, minimal effects clearing in < 24 hours. Mechanical irritation may occur. Draize = 0. *Oral Toxicity LD_{50} Rat*: > 5000 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 2000 mg/kg. *Inhalation Toxicity 4-hrs LC_{50} Rat*: > 20 mg/L. **1:** Slight Hazard: Minor reversible injury may occur; may irritate the stomach if swallowed; may defat the skin and exacerbate existing dermatitis. *Skin Irritation*: Slightly or mildly irritating. PII or Draize > 0 < 5. *Eye Irritation*: Slightly to mildly irritating, but reversible within 7 days. Draize > 0 ≤ 25. *Oral Toxicity LD_{50} Rat*: > 500–5000 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 1000–2000 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: > 2–20 mg/L. **2** *Moderate Hazard*: Temporary or transitory injury may occur; prolonged exposure may affect the CNS.

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

HEALTH HAZARD (continued): **2 (continued):** *Skin Irritation*: Moderately irritating; primary irritant; sensitizer. PII or Draize ≥ 5, with no destruction of dermal tissue. *Eye Irritation*: Moderately to severely irritating; reversible corneal opacity; corneal involvement or irritation clearing in 8–21 days. Draize = 26–100, with reversible effects. *Oral Toxicity LD_{50} Rat*: > 50–500 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 200–1000 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: > 0.5–2 mg/L. **3** Serious Hazard: Major injury likely unless prompt action is taken and medical treatment is given; high level of toxicity; corrosive. *Skin Irritation*: Severely irritating and/or corrosive; may cause destruction of dermal tissue, skin burns, and dermal necrosis. PII or Draize > 5–8, with destruction of tissue. *Eye Irritation*: Corrosive, irreversible destruction of ocular tissue; corneal involvement or irritation persisting for more than 21 days. Draize > 80 with effects irreversible in 21 days. *Oral Toxicity LD_{50} Rat*: > 1–50 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 20–200 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: > 0.05–0.5 mg/L. **4** Severe Hazard: Life-threatening; major or permanent damage may result from single or repeated exposure; extremely toxic; irreversible injury may result from brief contact. *Skin Irritation*: Not appropriate. Do not rate as a 4, based on skin irritation alone. *Eye Irritation*: Not appropriate. Do not rate as a 4, based on eye irritation alone. *Oral Toxicity LD_{50} Rat*: ≤ 1 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: ≤ 20 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: ≤ 0.05 mg/L.

FLAMMABILITY HAZARD: **0** Minimal Hazard: Materials that will not burn in air when exposure to a temperature of 815.5°C (1500°F) for a period of 5 minutes. **1** Slight Hazard: Materials that must be pre-heated before ignition can occur. Material requires considerable pre-heating, under all ambient temperature conditions before ignition and combustion can occur. This usually includes the following: Materials that will burn in air when exposed to a temperature of 815.5°C (1500°F) for a period of 5 minutes or less; Liquids, solids and semisolids having a flash point at or above 93.3°C (200°F) (i.e. OSHA Class IIIB); and Most ordinary combustible materials (e.g. wood, paper, etc.). **2** Moderate Hazard: Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not, under normal conditions, form hazardous atmospheres in air, but under high ambient temperatures or moderate heating may release vapor in sufficient quantities to produce hazardous atmospheres with air. This usually includes the following: Liquids having a flash-point at or above 37.8°C (100°F); Solid materials in the form of course dusts that may burn rapidly but that generally do not form explosive atmospheres; Solid materials in a fibrous or shredded form that may burn rapidly and create flash fire hazards (e.g. cotton, sisal, hemp); and Solids and semisolids (e.g. viscous and slow flowing as asphalt) that readily give off flammable vapors. **3** Serious Hazard: Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures, or, unaffected by ambient temperature, are readily ignited under almost all conditions. This usually includes the following: Liquids having a flash point below 22.8°C (73°F) and having a boiling point at or above 38°C (100°□F) and those liquids having a flash point at or above 22.8°C (73°F) and below 37.8°C (100°F) (i.e. OSHA Class IB and IC); Materials that on account of their physical form or environmental conditions can form explosive mixtures with air and are readily dispersed in air (e.g., dusts of combustible solids, mists or droplets of flammable liquids); and Materials that burn extremely rapidly, usually by reason of self-contained oxygen (e.g. dry nitrocellulose and many organic peroxides). **4** Severe Hazard: Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air, and that will burn readily. This usually includes the following: Flammable gases; Flammable cryogenic materials; Any liquid or gaseous material that is liquid while under pressure and has a flash point below 22.8°C (73°F) and a boiling point below 37.8°C (100°F) (i.e. OSHA Class IA); and Materials that ignite spontaneously when exposed to air at a temperature of 54.4°C (130°F) or below (pyrophoric).

PHYSICAL HAZARD: **0** *Water Reactivity*: Materials that do not react with water. *Organic Peroxides*: Materials that are normally stable, even under fire conditions and will not react with water. *Explosives*: Substances that are Non-Explosive. *Compressed Gases*: No Rating. *Pyrophorics*: No Rating. *Oxidizers*: No 0 rating. *Unstable Reactives*: Substances that will not polymerize, decompose, condense, or self-react.) **1** *Water Reactivity*: Materials that change or decompose upon exposure to moisture. *Organic Peroxides*: Materials that are normally stable, but can become unstable at high temperatures and pressures. These materials may react with water, but will not release energy violently. *Explosives*: Division 1.5 & 1.6 explosives. Substances that are very insensitive explosives or that do not have a mass explosion hazard. *Compressed Gases*: Pressure below OSHA definition. *Pyrophorics*: No Rating. *Oxidizers*: Packaging Group III oxidizers; Solids: any material that in either concentration tested, exhibits a mean burning time less than or equal to the mean burning time of a 3:7 potassium bromate/cellulose mixture and the criteria for Packing Group I and II are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise time of a 1:1 nitric acid (65%)/cellulose mixture and the criteria for Packing Group I and II are not met. *Unstable Reactives*: Substances that may decompose condense, or self-react, but only under conditions of high temperature and/or pressure and have little or no potential to cause significant heat generation or explosion hazard. Substances that readily undergo hazardous polymerization in the absence of inhibitors. Substances that readily undergo hazardous polymerization in the absence of inhibitors.

DEFINITION OF TERMS (Continued)

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

PHYSICAL HAZARD (continued): **2** *Water Reactivity*: Materials that may react violently with water. *Organic Peroxides*: Materials that, in themselves, are normally unstable and will readily undergo violent chemical change, but will not detonate. These materials may also react violently with water. *Explosives*: Division 1.4 explosives. Explosive substances where the explosive effects are largely confined to the package and no projection of fragments of appreciable size or range are expected. An external fire must not cause virtually instantaneous explosion of almost the entire contents of the package. *Compressed Gases*: Pressurized and meet OSHA definition but < 514.7 psi absolute at 21.1°C (70°F) [500 psig]. *Pyrophorics*: No Rating. *Oxidizers*: Packing Group II oxidizers. Solids: any material that, either in concentration tested, exhibits a mean burning time of less than or equal to the mean burning time of a 2:3 potassium bromate/cellulose mixture and the criteria for Packing Group I are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise of a 1:1 aqueous sodium chlorate solution (40%)/cellulose mixture and the criteria for Packing Group I are not met. *Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure, but have a low potential (or low risk) for significant heat generation or explosion. Substances that readily form peroxides upon exposure to air or oxygen at room temperature. **3** *Water Reactivity*: Materials that may form explosive reactions with water. *Organic Peroxides*: Materials that are capable of detonation or explosive reaction, but require a strong initiating source or must be heated under confinement before initiation; or materials that react explosively with water. *Explosives*: Division 1.3 explosives. Explosive substances that have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but do not have a mass explosion hazard. *Compressed Gases*: Pressure ≥ 514.7 psi absolute at 21.1°C (70°F) [500 psig]. *Pyrophorics*: No Rating. *Oxidizers*: Packing Group I oxidizers. Solids: any material that, in either concentration tested, exhibits a mean burning time less than the mean burning time of a 3:2 potassium bromate/cellulose mixture. Liquids: any material that spontaneously ignites when mixed with cellulose in a 1:1 ratio, or which exhibits a mean pressure rise time less than the pressure rise time of a 1:1 perchloric acid (50%)/cellulose mixture. *Unstable Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure and have a moderate potential (or moderate risk) to cause significant heat generation or explosion. **4** *Water Reactivity*: Materials that react explosively with water without requiring heat or confinement. *Organic Peroxides*: Materials that are readily capable of detonation or explosive decomposition at normal temperature and pressures. *Explosives*: Division 1.1 & 1.2 explosives. Explosive substances that have a mass explosion hazard or have a projection hazard. A mass explosion is one that affects almost the entire load instantaneously. *Compressed Gases*: No Rating. *Pyrophorics*: Add to the definition of Flammability 4. *Oxidizers*: No 4 rating. *Unstable Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure and have a high potential (or high risk) to cause significant heat generation or explosion.

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS:

HEALTH HAZARD: **0** Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials. Gases and vapors with an LC_{50} for acute inhalation toxicity greater than 10,000 ppm. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 200 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 2000 mg/kg. Materials with an LD_{50} for acute oral toxicity greater than 2000 mg/kg. Materials essentially non-irritating to the respiratory tract, eyes, and skin. **1** Materials that, under emergency conditions, can cause significant irritation. Gases and vapors with an LC_{50} for acute inhalation toxicity greater than 5,000 ppm but less than or equal to 10,000 ppm. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 10 mg/L but less than or equal to 200 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 1000 mg/kg but less than or equal to 2000 mg/kg. Materials that slightly to moderately irritate the respiratory tract, eyes and skin. Materials with an LD_{50} for acute oral toxicity greater than 500 mg/kg but less than or equal to 2000 mg/kg. **2** Materials that, under emergency conditions, can cause temporary incapacitation or residual injury. Gases with an LC_{50} for acute inhalation toxicity greater than 3,000 ppm but less than or equal to 5,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC_{50} for acute inhalation toxicity, if its LC_{50} is less than or equal to 5000 ppm and that does not meet the criteria for either degree of hazard 3 or degree of hazard 4. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 2 mg/L but less than or equal to 10 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 200 mg/kg but less than or equal to 1000 mg/kg. Compressed liquefied gases with boiling points between -30°C (-22°F) and -55°C (-66.5°F) that cause severe tissue damage, depending on duration of exposure. Materials that are respiratory irritants. Materials that cause severe, but reversible irritation to the eyes or are lachrymators. Materials that are primary skin irritants or sensitizers. Materials whose LD_{50} for acute oral toxicity is greater than 50 mg/kg but less than or equal to 500 mg/kg. **3** Materials that, under emergency conditions, can cause serious or permanent injury. Gases with an LC_{50} for acute inhalation toxicity greater than 1,000 ppm but less than or equal to 3,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater its LC_{50} for acute inhalation toxicity, if its LC_{50} is less than or equal to 3000 ppm and that does not meet the criteria for degree of hazard 4. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 0.5 mg/L but less than or equal to 2 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 40 mg/kg but less than or equal to 200 mg/kg. Materials that are corrosive to the respiratory tract. Materials that are corrosive to the eyes or cause irreversible corneal opacity. Materials corrosive to the skin. Cryogenic gases that cause frostbite and irreversible tissue damage. Compressed liquefied gases with boiling points below -55°C (-66.5°F) that cause frostbite and irreversible tissue damage. Materials with an LD_{50} for acute oral toxicity greater than 5 mg/kg but less than or equal to 50 mg/kg. **4** Materials that, under emergency conditions, can be lethal. Gases with an LC_{50} for acute inhalation toxicity less than or equal to 1,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than ten times its LC_{50} for acute inhalation toxicity, if its LC_{50} is less than or equal to 1000 ppm. Dusts and mists whose LC_{50} for acute inhalation toxicity is less than or equal to 0.5 mg/L. Materials whose LD_{50} for acute dermal toxicity is less than or equal to 40 mg/kg. Materials whose LD_{50} for acute oral toxicity is less than or equal to 5 mg/kg.

FLAMMABILITY HAZARD: **0** Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand. Materials that will not burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in according with Annex D of NFPA 704. **1** Materials that must be preheated before ignition can occur. Materials in this degree require considerable preheating, under all ambient temperature conditions, before ignition and combustion can occur: Materials that will burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in according with Annex D of NFPA 704. Liquids, solids, and semisolids having a flash point at or above 93.4°C (200°F) (i.e. Class IIIB liquids). Liquids with a flash point greater than 35°C (95°F) that do not sustain combustion when tested using the *Method of Testing for Sustained Combustibility*, per 49 CFR 173, Appendix H or the UN *Recommendations on the Transport of Dangerous Goods, Model Regulations* (current edition) and the related *Manual of Tests and Criteria* (current edition). Liquids with a flash point greater than 35°C (95°F) in a water-miscible solution or dispersion with a water non-combustible liquid/solid content of more than 85% by weight. Liquids that have no fire point when tested by ASTM D 92, *Standard Test Method for Flash and Fire Points by Cleveland Open Cup*, up to the boiling point of the liquid or up to a temperature at which the sample being tested shows an obvious physical change. Combustible pellets with a representative diameter of greater than 2 mm (10 mesh). Most ordinary combustible materials. Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent.

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

FLAMMABILITY HAZARD (continued):**2** Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not under normal conditions form hazardous atmospheres with air, but under high ambient temperatures or under moderate heating could release vapor in sufficient quantities to produce hazardous atmospheres with air. Liquids having a flash point at or above 37.8°C (100°F) and below 93.4°C (200°F) (i.e. Class II and Class IIIA liquids.) Solid materials in the form of powders or coarse dusts of representative diameter between 420 microns (40 mesh) and 2 mm (10 mesh) that burn rapidly but that generally do not form explosive mixtures with air. Solid materials in fibrous or shredded form that burn rapidly and create flash fire hazards, such as cotton, sisal, and hemp. Solids and semisolids that readily give off flammable vapors. Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. **3** Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures or, though unaffected by ambient temperatures, are readily ignited under almost all conditions. Liquids having a flash point below 22.8°C (73°F) and having a boiling point at or above 37.8°C (100°F) and those liquids having a flash point at or above 22.8°C (73°F) and below 37.8°C (100°F) (i.e. Class IB and IC liquids). Materials that on account of their physical form or environmental conditions can form explosive mixtures with air and are readily dispersed in air. Flammable or combustible dusts with representative diameter less than 420 microns (40 mesh). Materials that burn with extreme rapidity, usually by reason of self-contained oxygen (e.g. dry nitrocellulose and many organic peroxides). Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. **4** Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air and will burn readily. Flammable gases. Flammable cryogenic materials. Any liquid or gaseous materials that is liquid while under pressure and has a flash point below 22.8°C (73°F) and a boiling point below 37.8°C (100°F) (i.e. Class IA liquids). Materials that ignite when exposed to air, Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent.

INSTABILITY HAZARD: **0** Materials that in themselves are normally stable, even under fire conditions. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) below 0.01 W/mL. Materials that do not exhibit an exotherm at temperatures less than or equal to 500°C (932°F) when tested by differential scanning calorimetry. **1** Materials that in themselves are normally stable, but that can become unstable at elevated temperatures and pressures. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 0.01 W/mL and below 10 W/mL. **2** Materials that readily undergo violent chemical change at elevated temperatures and pressures. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 10 W/mL and below 100W/mL. **3** Materials that in themselves are capable of detonation or explosive decomposition or explosive reaction, but that require a strong initiating source or that must be heated under confinement before initiation. Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 100 W/mL and below 1000 W/mL. Materials that are sensitive to thermal or mechanical shock at elevated temperatures and pressures. **4** Materials that in themselves are readily capable of detonation or explosive decomposition or explosive reaction at normal temperatures and pressures. Materials that are sensitive to localized thermal or mechanical shock at normal temperatures and pressures. Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) of 1000 W/mL or greater.

FLAMMABILITY LIMITS IN AIR:

Much of the information related to fire and explosion is derived from the National Fire Protection Association (**NFPA**). Flash Point: Minimum temperature at which a liquid gives off sufficient vapor to form an ignitable mixture with air near the surface of the liquid or within the test vessel used. Autoignition Temperature: Minimum temperature of a solid, liquid, or gas required to initiate or cause self-sustained combustion in air with no other source of ignition. LEL: Lowest concentration of a flammable vapor or gas/air mixture that will ignite and burn with a flame. UEL: Highest concentration of a flammable vapor or gas/air mixture that will ignite and burn with a flame.

TOXICOLOGICAL INFORMATION:

Human and Animal Toxicology: Possible health hazards as derived from human data, animal studies, or from the results of studies with similar compounds are presented. LD_{50}: Lethal Dose (solids & liquids) that kills 50% of the exposed animals. LC_{50}: Lethal Concentration (gases) that kills 50% of the exposed animals. ppm: Concentration expressed in parts of material per million parts of air or water. mg/m^3: Concentration expressed in weight of substance per volume of air. mg/kg: Quantity of material, by weight, administered to a test subject, based on their body weight in kg. TDLo: Lowest dose to cause a symptom. TCLo: Lowest concentration to cause a symptom. TDo, LDLo, and LDo, or TC, TCo, LCLo, and LCo: Lowest dose (or concentration) to cause lethal or toxic effects. **Cancer Information:** IARC: International Agency for Research on Cancer. NTP: National Toxicology Program. RTECS: Registry of Toxic Effects of Chemical Substances. IARC and NTP rate chemicals on a scale of decreasing potential to cause human cancer with rankings from 1 to 4. Subrankings (2A, 2B, etc.) are also used. **Other Information:** BEI: ACGIH Biological Exposure Indices, represent the levels of determinants which are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV.

REPRODUCTIVE TOXICITY INFORMATION:

A mutagen is a chemical that causes permanent changes to genetic material (DNA) such that the changes will propagate through generation lines. An embryo toxin is a chemical that causes damage to a developing embryo (i.e. within the first eight weeks of pregnancy in humans), but the damage does not propagate across generational lines. A teratogen is a chemical that causes damage to a developing fetus, but the damage does not propagate across generational lines. A reproductive toxin is any substance that interferes in any way with the reproductive process.

ECOLOGICAL INFORMATION:

EC: Effect concentration in water. BCF: Bioconcentration Factor, which is used to determine if a substance will concentrate in life forms that consume contaminated plant or animal matter. TLm: Median threshold limit. $\log K_{OW}$ or $\log K_{OC}$: Coefficient of Oil/Water Distribution is used to assess a substance's behavior in the environment.

REGULATORY INFORMATION:

U.S. and CANADA:

This section explains the impact of various laws and regulations on the material. EPA: U.S. Environmental Protection Agency. ACGIH: American Conference of Governmental Industrial Hygienists, a professional association that establishes exposure limits. OSHA: U.S. Occupational Safety and Health Administration. NIOSH: National Institute of Occupational Safety and Health, which is the research arm of OSHA. WHMIS: Canadian Workplace Hazardous Materials Information System. DOT: U.S. Department of Transportation. TC: Transport Canada. SARA: Superfund Amendments and Reauthorization Act. DSL/NDSL: Canadian Domestic/Non-Domestic Substances List. TSCA: U.S. Toxic Substance Control Act. CERCLA: Comprehensive Environmental Response, Compensation, and Liability Act. Marine Pollutant status according to the DOT; CERCLA or Superfund; and various state regulations. This section also includes information on the precautionary warnings that appear on the material's package label.

REVISION HISTORY

Date	**Changes**
November 16, 2015	Update CHEMTEL emergency phone number.
May 30, 2015	Change emergency telephone number to ChemTel.
May 23, 2015	Review and up-date SDS to comply with EU CLP and the Global Harmonization Standard. Correction of CAS# for Bacitracin Zinc in Sections 3 and 8.
September 30, 2014	New

HEALTHCARE BEYOND BURN CARE™

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: US OSHA Hazard Communication Standard (29 CFR 1910.1200) and Canada WHMIS 2015 which includes the amended Hazardous Products Act (HPA) and the Hazardous Products Regulation (HPR)

Issuing Date 04-Dec-2019 **Revision Date** 04-Dec-2019 **Revision Number** 1

1. Identification

Product identifier

Product Name First Aid/ Burn Cream

Other means of identification

Product Code(s) FAC.00.121

Synonyms First Aid Cream; First Aid /Burn Cream Antiseptic Pain Relief with Aloe

Recommended use of the chemical and restrictions on use

Recommended use First aid to help prevent infection and for the temporary relief of pain and itching associated with minor cuts, scrapes and burns

Restrictions on use For external use only.

Details of the supplier of the safety data sheet

Manufacturer Address
WaterJel ® Technologies
50 Broad Street
Carlstadt, NJ 07072
P: 201-507-8300

Emergency telephone number

Emergency Telephone 800-275-3433 (8:00 am-5:00 pm EST Weekdays)

2. Hazard(s) identification

Classification

Label elements

Hazard statements
Not classified.

Other information
No information available.

3. Composition/information on ingredients

Substance

Not applicable.

Mixture

Synonyms First Aid Cream; First Aid /Burn Cream Antiseptic Pain Relief with Aloe

Chemical name	CAS No	Weight-%	Hazardous Material Information Review Act registry number (HMIRA registry #)	Date HMIRA filed and date exemption granted (if applicable)
Stearic acid	57-11-4	5-10	-	-
Glycerin	56-81-5	1-5	-	-
Propylene glycol	57-55-6	0.5-1.5	-	-

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures

Description of first aid measures

Inhalation Remove to fresh air.

Eye contact Rinse thoroughly with plenty of water, also under the eyelids.

Skin contact Wash skin with soap and water.

Ingestion Clean mouth with water and drink afterwards plenty of water.

Most important symptoms and effects, both acute and delayed

Symptoms May cause temporary eye irritation.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. Fire-fighting measures

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media No information available.

Specific hazards arising from the chemical No information available.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place.

8. Exposure controls/personal protection

Control parameters

Exposure Limits .

Chemical name	ACGIH TLV	OSHA PEL	NIOSH
Stearic acid 57-11-4	TWA: 10 mg/m³ inhalable particulate matter TWA: 3 mg/m³ respirable particulate matter	-	-
Glycerin 56-81-5	-	TWA: 15 mg/m³ mist, total particulate TWA: 5 mg/m³ mist, respirable fraction (vacated) TWA: 10 mg/m³ mist, total particulate (vacated) TWA: 5 mg/m³ mist, respirable fraction	-

Chemical name	Alberta	British Columbia	Ontario	Quebec
Glycerin 56-81-5	TWA: 10 mg/m³	TWA: 10 mg/m³ TWA: 3 mg/m³		TWA: 10 mg/m³
Propylene glycol 57-55-6			TWA: 10 mg/m³ TWA: 50 ppm TWA: 155 mg/m³	

Appropriate engineering controls

Engineering controls Showers

Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection No special protective equipment required.

Hand protection No special protective equipment required.

Skin and body protection No special protective equipment required.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance	White cream
Physical state	Solid
Color	White
Odor	Odorless
Odor threshold	No information available

Property	**Values**	**Remarks • Method**
pH	6.4 - 7.6	
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Relative density	No data available	None known
Water solubility	Miscible in water	
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	10,000 - 75,000 cP	Spindle #4 (64), 6 RPM, 15 seconds

Other information

Explosive properties	No information available.
Oxidizing properties	No information available.
Softening point	No information available
Molecular weight	No information available
VOC Content (%)	No information available
Liquid Density	No information available
Bulk density	No information available

10. Stability and reactivity

Reactivity None under normal use conditions.

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid None known based on information supplied.

Incompatible materials None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms May cause temporary eye irritation.

Acute toxicity

Numerical measures of toxicity

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral) 29,131.40 mg/kg

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Stearic acid	= 4600 mg/kg (Rat)		
Glycerin	= 12600 mg/kg (Rat)	> 10 g/kg (Rabbit)	> 570 mg/m³ (Rat) 1 h
Propylene glycol	= 20 g/kg (Rat)	= 20800 mg/kg (Rabbit)	

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

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Legend

IARC (International Agency for Research on Cancer)
Group 3 - Not Classifiable as to Carcinogenicity in Humans

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

12. Ecological information

Ecotoxicity .

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Glycerin 56-81-5	-	LC50: 51 - 57mL/L (96h, Oncorhynchus mykiss)	-	-
Propylene glycol 57-55-6	EC50: =19000mg/L (96h, Pseudokirchneriella subcapitata)	LC50: =51400mg/L (96h, Pimephales promelas) LC50: 41 - 47mL/L (96h, Oncorhynchus mykiss) LC50: =51600mg/L (96h, Oncorhynchus mykiss) LC50: =710mg/L (96h, Pimephales promelas)	-	EC50: >1000mg/L (48h, Daphnia magna)

Persistence and degradability No information available.

Bioaccumulation No information available.

Component Information

Chemical name	Partition coefficient
Glycerin 56-81-5	-1.76

Mobility in soil No information available.

Other adverse effects No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

14. Transport information

DOT	Not regulated
TDG	Not regulated
MEX	Not regulated
IATA	Not regulated
IMDG	Not regulated

15. Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

International Inventories

TSCA	Contact supplier for inventory compliance status.
DSL/NDSL	Contact supplier for inventory compliance status.

Legend:
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

US Federal Regulations

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories
Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

US State Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Glycerin 56-81-5	X	X	X
Propylene glycol 57-55-6	X	-	X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA	**Health hazards** 0	**Flammability** 0	**Instability** 0	**Physical and chemical properties** -
HMIS	**Health hazards** 0	**Flammability** 0	**Physical hazards** 0	**Personal protection** X

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

Key literature references and sources for data used to compile the SDS

U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AEGL(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
World Health Organization

Issuing Date 04-Dec-2019

Revision Date 04-Dec-2019

Revision Note Initial Release.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet

SAFETY DATA SHEET

Issuing Date 05-June-2015 **Revision Date** 08-Jun-2018 **Revision Number** 4

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name EYEWASH

Other means of identification

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended Use Medicinal products

Uses advised against No information available

Details of the supplier of the safety data sheet

Supplier Name NIAGARA PHARMACEUTICALS INC.

Supplier Address 60 INNOVATION DRIVE
FLAMBOROUGH
ON
L9H7P3
CA

Supplier Phone Number Phone:905-690-6277
Fax:905-690-6281

Supplier Email rjames@niagarapharmaceuticals.com

Emergency telephone number

Company Emergency Phone Number 905-708-7962

2. HAZARDS IDENTIFICATION

Classification

The Eyewash is an approved drug by the FDA used for cleansing the eye to help irritation or burning by removing loose foreign material. **This drug product is considered exempt from SDS as it does not fall under the definition of "Hazardous product" as per regulations - 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).**

GHS Label elements, including precautionary statements

Precautionary Statements - Prevention
For single use only

Precautionary Statements - Response
If concerned: Get medical advice/attention

Precautionary Statements - Storage
None

Precautionary Statements - Disposal
Dispose of contents/container in accordance with local regulations

Hazards not otherwise classified (HNOC)

Not applicable

Unknown Toxicity
0% of the mixture consists of ingredient(s) of unknown toxicity

Other information

No information available

Interactions with Other Chemicals
No information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No	Weight-%	Trade Secret
Boric acid (H3BO3)	10043-35-3	1 - 5	*
Sodium borate	1330-43-4	0.1 - 1	*

*The exact percentage (concentration) of composition has been withheld as a trade secret

4. FIRST AID MEASURES

First aid measures

Eye contact This product is a first aid measure for cleansing the eye to help relieve irritation or burning by removing loose foreign material.

Skin contact None

Inhalation None

Ingestion Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

Most Important Symptoms and Effects No information available.

Indication of any immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media
None.

Unsuitable extinguishing media
No information available

Specific hazards arising from the chemical
None

Hazardous Combustion Products
None

Explosion Data
Sensitivity to Mechanical Impact No.

Sensitivity to Static Discharge No.

Protective equipment and precautions 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 None

Environmental precautions

Environmental precautions Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Soak up with inert absorbent material.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Store as sealed bottle.Do not use if seal is missing or broken. For single use only.

Incompatible Products None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Boric acid (H3BO3) 10043-35-3	TWA: 2 mg/m^3 inhalable fraction STEL: 6 mg/m^3 inhalable fraction	-	
Sodium borate 1330-43-4	STEL: 6 mg/m^3 inhalable fraction TWA: 2 mg/m^3 inhalable fraction	(vacated) TWA: 10 mg/m^3	TWA: 1 mg/m^3

ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value OSHA PEL: Occupational Safety and Health Administration - Permissible Exposure Limits Immediately Dangerous to Life or Health

Other Exposure Guidelines Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992)

Appropriate engineering controls

Engineering Measures Showers
Eyewash stations
Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/face protection No special protective equipment required.

Skin and body protection No special protective equipment required

Respiratory protection No protective equipment is needed under normal use conditions.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice. .

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical and Chemical Properties

Physical state	Liquid		
Appearance	Clear, colorless. No visual impurities	**Odor**	Odorless
Color	No information available	**Odor Threshold**	No information available

Property	Values	Remarks Method
pH	7.4	None known
Melting / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash Point	No data available	None known
Evaporation Rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		
Upper flammability limit	No data available	
Lower flammability limit	No data available	
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Specific Gravity	1	None known
Water Solubility	Completely soluble	None known
Solubility in other solvents	No data available	None known
Partition coefficient: n-octanol/water	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive properties	No data available	
Oxidizing properties	No data available	

Other Information

Softening Point	No data available
VOC Content (%)	No data available
Particle Size	No data available
Particle Size Distribution	

10. STABILITY AND REACTIVITY

Reactivity

No data available.

Chemical stability
Stable under recommended storage conditions.

Possibility of Hazardous Reactions
None under normal processing.

Hazardous Polymerization
Hazardous polymerization does not occur.

Conditions to avoid
None known based on information supplied.

Incompatible materials
None known based on information supplied.

Hazardous Decomposition Products
None known

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Boric acid (H3BO3) 10043-35-3	= 2660 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	> 2.03 mg/L (Rat) 4 h
Sodium borate 1330-43-4	= 2403 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	-

Information on toxicological effects

Symptoms No information available.

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

Sensitization No information available.

Mutagenic Effects No information available.

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen.

Reproductive toxicity No information available

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Chronic Toxicity No known effect based on information supplied.

Target Organ Effects No information available

Aspiration Hazard No information available.

Numerical measures of toxicity Product Information

The following values are calculated based on chapter 3.1 of the GHS document
Not applicable

12. ECOLOGICAL INFORMATION

Ecotoxicity

The environmental impact of this product has not been fully investigated.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Boric acid (H3BO3) 10043-35-3		72h LC50: = 1020 mg/L (Carassius auratus)		48h EC50: 115 - 153 mg/L
Sodium borate 1330-43-4	96h EC50: = 158 mg/L (Desmodesmus subspicatus) 96h EC50: 2.6 - 21.8 mg/L (Pseudokirchneriella subcapitata)	96h LC50: = 340 mg/L (Limanda limanda)		48h LC50: 1085 - 1402 mg/L

Persistence and Degradability

No information available.

Bioaccumulation

Chemical Name	Log Pow
Boric acid (H3BO3) 10043-35-3	-0.757

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal methods

This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

Contaminated Packaging

Dispose of contents/containers in accordance with local regulations.

California Hazardous Waste Codes 561

This product contains one substance that is listed with the State of California as a hazardous waste. However the amounts used in this product is negligible and is of below the prescribed limits for toxicity.

Chemical Name	California Hazardous Waste
Boric acid (H3BO3) 10043-35-3	Toxic

14. TRANSPORT INFORMATION

DOT	NOT REGULATED
Proper Shipping Name	NON REGULATED
Hazard Class	N/A
TDG	Not regulated
MEX	Not regulated
ICAO	Not regulated
IATA	Not regulated
Proper Shipping Name	NON REGULATED
Hazard Class	N/A
IMDG/IMO	Not regulated
Hazard Class	N/A
RID	Not regulated
ADR	Not regulated
ADN	Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA	Complies
DSL	All components are listed either on the DSL or NDSL.

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

US Federal Regulations

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Rhode Island	Illinois
Sodium borate 1330-43-4		X	X		

International Regulations

Component	Carcinogen Status	Exposure Limits
Sodium borate 1330-43-4 (0.1 - 1)		Mexico: TWA 1 mg/m^3

Canada
WHMIS Hazard Class
Not applicable

16. OTHER INFORMATION

NFPA	**Health Hazards**	0	**Flammability**	0	**Instability** 0	**Physical and Chemical Hazards**	-
HMIS	**Health Hazards**	**0**	**Flammability**	0	**Physical Hazard** 0	**Personal Protection**	X

Prepared By
Product Stewardship
23 British American Blvd.
Latham, NY 12110
1-800-572-6501

Revision Date 08-Jun-2018
Revision Note No information available

Disclaimer
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End of Safety Data Sheet