Safety Data Sheet

Folic Acid Injection, USP

Section 1: Chemical Product and Company Identification

Product Name: Folic Acid Injection USP
Chemical Name(s): (2S)-2-[(4-{[(2-amino-4-hydroxypteridin-6-yl)methyl]amino}phenyl)formamido]pentanedioic acid
Synonym: Acidum Folicum; Folacin; PGA; Pteroylglutamic Acid; Pteroylmonoglutamic Acid; Wills' factor; Vitamin M; liver Lactobacillus casei factor; Folsaure.

HMIS

Health Hazard	1
Fire Hazard	1
Reactivity	1
Personal Protection	X

CAS Number: 59-30-3
RTECS #: LP5425000
Trade Name: Folvite
Chemical Formula: $C_{19}H_{19}N_7O_6$

Contact Information:
X-GEN Pharmaceuticals DJB, Inc.
PO Box 445, Big Flats, NY 14814
Technical Assistance: 607-562-2700
Online Assistance: www.xgenpharmadjb.com

Emergency phone number:
National Poison Control
1-800-222-1222

**For information regarding recommended uses and restrictions on usage refer to the product package insert.

Section 2: Hazard Identification

GHS Pictograms

Signal Word DANGER

GHS Class
Respiratory sensitization. Category 1.
Skin Sensitization. Category 1.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.
May cause harm to breast-fed children.

Precautionary Statements	Obtain special instructions before use. Do not breathe dust/fume/gas/mist/vapors/spray. Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact during pregnancy and while nursing. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection. In case of inadequate ventilation wear respiratory protection. IF ON SKIN: Wash with plenty of water. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. IF exposed or concerned: Get medical advice/attention. Specific treatment (see ... on this label). If skin irritation or rash occurs: Get medical advice/attention. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. Take off contaminated clothing and wash it before reuse. Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.
Emergency Overview	This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.
Route of Exposure	Inhalation Ingestion Eye contact skin absorption. Injection.
Potential Health Effects	Eye: Contact with eyes may cause irritation Skin: May cause skin irritation Inhalation: May cause irritation of respiratory tract Ingestion: May cause irritation
Signs/Symptoms	Adverse reactions from therapeutic doses include: allergic sensitization. Occupational exposure has not been fully investigated.
Aggravation of Pre-Existing Conditions	Pre-Existing skin and respiratory conditions

Section 3: Composition/Information on Ingredients

Chemical Name	CAS#	Ingredient Percent	EC Num.
Folic Acid	59-30-3	5 mg/mL	
Edetate Disodium	139-33-3	2 mg/mL	
Benzyl Alcohol	100-51-6	15 mg/mL	

Section 4: First Aid Measures

Eye Contact	Immediately flush eyes with plenty of water for at least 15 – 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact	Immediately wash skin with plenty of soap and water for 15 – 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation	If inhaled remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid	For Adverse Event information, please call **NEEDED**.

Section 5: Fire Fighting Measures

Flash Point	Not Established
Flash Point Method	Not Established
Auto Ignition Temperature	Not Established
Lower Flammable/Explosive Limit	Not Established
Upper Flammable/Explosive Limit	Not Established
Fire Fighting Instructions	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular

weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

Section 6: Accidental Release Measures

Personnel Precautions	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapor or mists. Use proper personal protective equipment as listed in section 8.
Environmental Precautions	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup	Absorb spill with inert material (e,g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

Section 7: Handling and Storage

Handling	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage	Store at controlled room temperature 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature]. Protect from Light.
Work Practices	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

Section 8: Exposure Controls, Personal Protection

Engineering Controls	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye / Face Protections	Chemical splash goggles. Wear a face shield also when splash hazard exists.

Skin Protection Description	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e . an end-user such as a clinician / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

Section 9: Physical and Chemical Properties

Physical State	Liquid Solution
Color	Yellow – Orange
Odor	Odorless
Boiling Point	Not Established
Melting Point	Not Established
Solubility	Water Soluble with NaOH
Vapor Density	Not Established
Vapor Pressure	Not Established
Percent Volatile	Not Established
pH	8.0 – 11.0
Molecular Formula	Mixture
Molecular Weight	441.40
Flash Point	Not Established
Flash Point Method	Not Established

Auto Ignition Temperature Not Established

Section 10: Stability and Reactivity

Chemical Stability	Stable under normal temperatures and pressures
Hazardous Polymerization	Not reported
Conditions to Avoid	Exposure to light may cause decomposition

Section 11: Toxicological Information

FOLIC ACID

Acute Effects	Eye, Skin, and respiratory irritation may occur
Acute Toxicity	LD50: IV Mouse 282 mg/kg
RTECS Number	LP5425000
Ingestion	Oral - Mouse LD50: 10 gm/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information	Intravenous. - Rat LD50: 500 m g/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50: 282 m g/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rabbit LD50: 410 m g/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Guinea pig LD50: 120 m g/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse LDLo: 200 m g/kg [Kidney/Ureter/Bladder - other changes Blood - changes in spleen] Subcutaneous - Rat TDLo: 1500 m g/kg/5W (intermittent) [Kidney/Ureter/Bladder – interstitial nephritis Kidney/Ureter/Bladder - other changes Kidney/Ureter/Bladder - changes in kidney weight] Subcutaneous - Rat TDLo: 1500 m g/kg/5W (intermittent) [Biochemical - Metabolism (Intermediary) - other] Subcutaneous - Mouse Unscheduled DNA synthesis: 150 m g/kg Intraperitoneal. - Mouse LD50: 85 m g/kg [Behavioral - convulsions or effect on seizure threshold Behavioral - muscle weakness Behavioral - coma] Intraperitoneal. - Rat Unscheduled DNA synthesis: 150 m g/kg Intraperitoneal. - Mouse Unscheduled DNA synthesis: 250 m g/kg

EDETATE SODIUM

RTECS Number	AH4375000
Eye	Rabbit, not irritating
Skin	Rabbit, not irritating
Inhalation	Inhalation – Rat LOAEC 30 mg/m^3/6 h (aerosol) (OECD Guideline) (ECHA)
Other Toxicological Information	Intravenous – Mouse LD50 : 56 mg/kg (RTEC)

BENZYL ALCOHOL

RTECS Number	DN3150000
Skin	Administration onto the skin - Rabbit LD50: 2000 m g/kg [Details of toxic effects not reported other than lethal dose value] Administration onto the skin - Rabbit Standard Draize test.: 100 m g/24H
Inhalation	Inhalation - Mouse LC 50: >500 m g/m 3 [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax , or Respiration - Respiratory depression] Inhalation - R at LC 50: >500 m g/m 3 [Behavioral - Somnolence Behavioral
Ingestion	Oral - Rat LD50: 1230 m g/k g [Behavioral - Somnolence (general depressed activity) Behavioral - Excitement Behavioral - Coma] Oral - Mouse LD50: 1360 m g/k g [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50: 1360 mg/k g [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax , or Respiration - Respiratory depression] Oral - Rat LD50: 1660 m g/k g [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax , or Respiration - Respiratory de pression] O ra l - Rat LD50: 1.5 mL/kg [Details of toxic effects not reported other than lethal dose value]

Other Toxicological Information	Intravenous. - Rat LD50: 53 m g/k g [Lungs, Thorax , or Respiration - dyspnea] Intravenous. - Mouse LD50: 324 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rat LDLo: 1700 m g/k g [Sense Organs and Special Senses (Eye) - miosis (pupillary constriction) Behavioral - coma Kidney/Urete r/Bladder - other changes] Intraperitoneal. - Rat LD50: 400 m g/k g [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse LD50: 650 m g/k g [Behavioral - altered sleep time (including change in righting reflex) Behavioral - somnolence (general depressed activity) Lungs, Thorax , or Respiration - dyspnea] Intraperitoneal. - Rat LDLo: 650 m g/k g [Behavioral - somnolence (general depressed activity)

Section 12: Ecological Information

Ecotoxicity	No ecotoxicity data was found for the product.
Environmental Stability	No environmental information was found for this product.
Edetate Disodium Ecotoxicity	Guppy (Poecilia reticulata) LC 50 (96hr) 320 m g/L (O EC D SIDS) Ze bra fish (Danio re rio) NO EC (35d) >= 25.7 m g/L (O EC D Guide Ethylenediamintetraacetic acid, calcium disodium complex) Water flea (Daphnia magna) EC 50 (48hr) 140 m g/L, NO EC (21d) 25 m g/L (EEC Guide line XI/681/86, GLP) (TS : Ethylenediaminetetraacetic acid, disodium salt) Green algae (Scenedesmus quadricauda) NO EC (24 d) 200 m g/L (EC HA)

Section 13: Disposal Considerations

Waste Disposal	Dispose of in accordance with Local, State, Federal and provincial regulations.

Section 14: Transport Information

DOT Shipping Name	Not Regulated
DOT UN Number	Not Regulated

Section 15: Regulatory Information

Folic Acid:

TSCA Inventory Status:	Listed
EINECS Number:	200-419-0

Canada DSL: Listed

Edetate Disodium:

TSCA Inventory Status: Listed

EINECS Number: 205-358-3

Canada DSL: Listed

Benzyl Alcohol:

TSCA Inventory Status: Listed

EINECS Number: 202-859-9

Canada DSL: Listed

Canada IDL: Identified under the Canadian Hazardous Products Act Ingredient Disclosure List

Water for Injection:

TSCA Inventory Status: Listed

Canada DSL: Listed

Section 16: Additional Information

References: Not Available
Created: 25 September 2019
Last Updated: 3/5/20
Prepared & Approved by: X-Gen Pharmaceuticals DJB, Inc., Safety Committee

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