Penicillin G procaine

sc-205797





The Power to Question

Hazard Alert Code Key:

EXTREME

HIGH

MODERATE

LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

Penicillin G procaine

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA FLAMM BILLITY HEALTH AZARD INST BLITY

SUPPLIER

Santa Cruz Biotechnology, Inc. 2145 Delaware Avenue Santa Cruz, California 95060 800.457.3801 or 831.457.3800

EMERGENCY: ChemWatch

Within the US & Canada: 877-715-9305 Outside the US & Canada: +800 2436 2255 (1-800-CHEMCALL) or call +613 9573 3112

SYNONYMS

C29-H38-N4-O6-S, (2-phenylacetamido)-, "4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, procaine", "penicillin G compd. with 2-(diethylamino)ethyl p-aminobenzoate", "(2S-(2alpha, (2alpha, 5alpha, 6beta))-3, 3-dimethyl-7-oxo-6-", "((phenylacetyl)amino)-compd. with 2-(diethlamino)ethyl 4-aminobenzoate", "benzopenicillin procaine", "benzyl-6-aminopenicillinic acid procaine", "benzylpenicillin procaine", "procaine benzylpenicillinate", "benzylpenicillin novocaine salt", Depocilljn, Duphapen, Hostacillin, Hydracillin, "Jenacillin O", Micro-Pen, Nopcaine, "Penzal N-300", Retardillin, Vetspen, Vitablend, "for hydrate:", "Abocillin DC", Afsillin, Ampin-Penicillin, Aquacillin, aquasuspen, Avloprocil, Cilicaine, Crysticillan, Depo-Penicillin, Despacilina, Distaquaine, Diurnal-Penicillin, "Dorsallin A.R.", Duracillin, Eskacillin, Flo-Cillin, Hpercillin, "Ilcocillin P", Kabipenin, Ledercillin, Lenticillin, Lentopen, Megapen, Mylipen, Neoproc, "Novocaine Penicillin", Parencillin, "Penaquacaine G", Pen-Fifty, Penlator, Pfizerpen-AS, Premocillin, Sharcillin, Wycillin, antibiotic

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

		Min	Max
Flammability:	1		
Toxicity:	2		Min/Nil=0
Body Contact:	0		Low=1 Moderate=2
Reactivity:	activity: 1		High=3 Extreme=4

Chronic:

CANADIAN WHMIS SYMBOLS





EMERGENCY OVERVIEW

risk

May cause SENSITISATION by inhalation and skin contact.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

- Accidental ingestion of the material may be damaging to the health of the individual.
- Penicillins can cause temporary diarrhea, nausea, heartburn and itchiness of the anus. They are fairly safe in the non-allergic.

FYF

■ Although the material is not thought to be an irritant, direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result.

SKIN

- The material is not thought to produce adverse health effects or skin irritation following contact (as classified using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.
- Open cuts, abraded or irritated skin should not be exposed to this material.
- Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED

- The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified using animal models). Nevertheless, adverse effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
- Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

CHRONIC HEALTH EFFECTS

■ Inhaling this product is more likely to cause a sensitization reaction in some persons compared to the general population.

Skin contact with the material is more likely to cause a sensitization reaction in some persons compared to the general population.

Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

Allergic contact dermatitis is relatively common amongst those handling the penicillins or following repeated topical application of penicillin containing ointments.

Repeated ingestion of penicillins can cause nausea and/or vomiting, stomach upset, diarrhea, sore or dry throat, and a sore or black hairy tongue. Resistance may develop for some bacteria, and there may be overgrowth of non-susceptible organisms (superinfection). Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung.

Exposure to small quantities may induce hypersensitivity reactions characterized by acute bronchospasm, hives (urticaria), deep dermal wheals (angioneurotic edema), running nose (rhinitis) and blurred vision. Anaphylactic shock and skin rash (non-thrombocytopenic purpura) may occur.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME CAS RN % penicillin G procaine 54-35-3 >98

Section 4 - FIRST AID MEASURES

SWALLOWED

· If swallowed do NOT induce vomiting. · If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

EYE

■ If this product comes in contact with the eyes: · Wash out immediately with fresh running water. · Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.

SKIN

■ If skin contact occurs: · Immediately remove all contaminated clothing, including footwear · Flush skin and hair with running water (and soap if available).

INHALED

· If fumes or combustion products are inhaled remove from contaminated area. · Other measures are usually unnecessary.

NOTES TO PHYSICIAN

■ Treat symptomatically.

Penicillins are widely distributed in body fluids and tissues. They appear in pleural, pericardial, peritoneal and synovial fluids and diffuse across the placenta into fetal circulation.

Section 5 - FIRE FIGHTING MEASURES				
Vapour Pressure (mmHG):	Negligible			
Upper Explosive Limit (%):	20.0			
Specific Gravity (water=1):	1.255256			
Lower Explosive Limit (%):	8.5			

EXTINGUISHING MEDIA

- · Foam.
- · Dry chemical powder.

FIRE FIGHTING

- · Alert Emergency Responders and tell them location and nature of hazard.
- · Wear breathing apparatus plus protective gloves.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

- · Combustible solid which burns but propagates flame with difficulty.
- · Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.

Combustion products include: carbon monoxide (CO), carbon dioxide (CO2), nitrogen oxides (NOx), sulfur oxides (SOx), other pyrolysis products typical of burning organic material.

May emit poisonous fumes.

May emit corrosive fumes.

FIRE INCOMPATIBILITY

■ Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids,chlorine bleaches, pool chlorine etc. as ignition may result.

PERSONAL PROTECTION

Glasses:

Chemical goggles.

Gloves:

Respirator:

Particulate

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- · Clean up waste regularly and abnormal spills immediately.
- · Avoid breathing dust and contact with skin and eyes.
- Wear protective clothing, gloves, safety glasses and dust respirator.
- · Use dry clean up procedures and avoid generating dust.
- · Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).
- · Dampen with water to prevent dusting before sweeping.
- · Place in suitable containers for disposal.

MAJOR SPILLS

- Moderate hazard.
- · CAUTION: Advise personnel in area.
- · Alert Emergency Responders and tell them location and nature of hazard.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- · Avoid all personal contact, including inhalation.
- · Wear protective clothing when risk of exposure occurs.

Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.

- · Do NOT cut, drill, grind or weld such containers.
- · In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

RECOMMENDED STORAGE METHODS

- Glass container.
- · Polyethylene or polypropylene container.
- · Check all containers are clearly labelled and free from leaks.

STORAGE REQUIREMENTS

- · Store in original containers.
- Keep containers securely sealed.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

Source	Material	TWA ppm	TWA mg/m³	STEL ppm	STEL mg/m³	Peak ppm	Peak mg/m³	TWA F/CC	Notes
US - California Permissible Exposure Limits for Chemical Contaminants	penicillin G procaine (Particulates not otherwise regulated Respirable fraction)		5						(n)
US - Tennessee Occupational Exposure Limits - Limits For Air Contaminants	penicillin G procaine (Particulates not otherwise regulated Respirable fraction)		5						
US - Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants	penicillin G procaine (Particulates not otherwise regulated (PNOR)(f)- Respirable fraction)		5						
US - Michigan Exposure Limits for Air Contaminants	penicillin G procaine (Particulates not otherwise regulated, Respirable dust)		5						
Canada - Prince Edward Island Occupational Exposure Limits	penicillin G procaine (Particles (Insoluble or Poorly Soluble) [NOS] Inhalable particles)		10						See Appendix B current TLV/BEI Book

ENDOELTABLE

PERSONAL PROTECTION



RESPIRATOR

Particulate

Consult your EHS staff for recommendations

FYF

■ When handling very small quantities of the material eye protection may not be required.

For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:

- · Chemical goggles
- · Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

HANDS/FEET

■ NOTE: The material may produce skin sensitization in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:

- · frequency and duration of contact,
- · chemical resistance of glove material,
- · glove thickness and
- · dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).

- · When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.
- · When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.
- · Contaminated gloves should be replaced.

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

- · Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
- Double gloving should be considered.
- · PVC gloves.
- · Protective shoe covers.
- Head covering.

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

- polychloroprene
- nitrile rubber
- · butyl rubber
- fluorocaoutchouc
- · polyvinyl chloride

Gloves should be examined for wear and/ or degradation constantly.

OTHER

- · For quantities up to 500 grams a laboratory coat may be suitable.
- · For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
- · For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
- · Eye wash unit.
- · Ensure there is ready access to an emergency shower.
- · For Emergencies: Vinyl suit.

ENGINEERING CONTROLS

■ Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation.

HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid.

Does not mix with water.

Sinks in water.

State	Divided solid	Molecular Weight	588.72
Melting Range (°F)	222.8- 230 (decomp)	Viscosity	Not Applicable
Boiling Range (°F)	Not available	Solubility in water (g/L)	Partly miscible
Flash Point (°F)	Not available	pH (1% solution)	5-7.5 (satd)
Decomposition Temp (°F)	Not available	pH (as supplied)	Not applicable
Autoignition Temp (°F)	1607	Vapour Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	20.0	Specific Gravity (water=1)	1.255256
Lower Explosive Limit (%)	8.5	Relative Vapor Density (air=1)	Not Applicable
Volatile Component (%vol)	Negligible	Evaporation Rate	Not applicable

APPEARANCE

White, monoclinic, hemimorphic crystalline powder; does not mix well with water (1:250). Soluble in alcohol (1:30), chloroform (1:60)

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

- · Presence of incompatible materials.
- · Product is considered stable.

STORAGE INCOMPATIBILITY

■ Avoid reaction with oxidizing agents.

Incompatible with metal ions, especially copper, zinc, mercury.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

PENICILLIN G PROCAINE

TOXICITY AND IRRITATION

PENICILLIN G PROCAINE:

■ unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY	IRRITATION
Oral (rat) LD50: >2000 mg/kg	Nil Reported
Intraperitoneal (rat) LD50: 420 mg/kg	Nil Reported
Intramuscular (rat) LD50: >2000 mg/kg	
Oral (mouse) LD50: >2000 mg/kg	
Intraperitoneal (mouse) LD50: 371 mg/kg	
Intramuscular (mouse) LD50: >2000 mg/kg	
Intraperitoneal (g.pig) LD50: 518 mg/kg	
Intramuscular (g.pig) LD50: 1194 mg/kg	
Subcutaneous (rat) LD50: >6000 mg/kg	
Intravenous (rat) LD50: 97 mg/kg	
Oral (mouse) LD50: >2000 mg/kg	
Intraperitoneal (mouse) LD50: 146 mg/kg	
Subcutaneous (mouse) LD50: 2300 mg/kg	
Intravenous (mouse) LD50: 119 mg/kg	
Intramuscular (mouse) LD50: 1600 mg/kg	
Intravenous (rabbit) LD50: 70 mg/kg	

■ Allergic reactions involving the respiratory tract are usually due to interactions between IgE antibodies and allergens and occur rapidly. Allergic potential of the allergen and period of exposure often determine the severity of symptoms.

Attention should be paid to atopic diathesis, characterized by increased susceptibility to nasal inflammation, asthma and eczema.

Exogenous allergic alveolitis is induced essentially by allergen specific immune-complexes of the IgG type; cell-mediated reactions (T lymphocytes) may be involved. Such allergy is of the delayed type with onset up to four hours following exposure.

Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's edema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type.

for p-aminobenzoates (PABA and its derivatives):

PABA (p-aminobenzoic acid; syn: 4-aminobenzoic acid) is a chemical found in the folic acid vitamin and also in several foods including grains, eggs, milk, and meat.

PABA is taken by mouth for skin conditions including vitiligo, pemphigus, dermatomyositis, morphea, lymphoblastoma cutis, Peyronie's disease, and scleroderma. PABA is also used to treat infertility in women, arthritis, anaemia), rheumatic fever, constipation, systemic lupus erythematosus (SLE), and headache. It is also used to darken gray hair, prevent hair loss, make skin look younger, and prevent sunburn. PABA and its derivatives is best known as a sunscreen that is applied to the skin. Local anesthetics used in temporary pain relief are often derivatives of PABA (e.g. benzocaine).

PABA reportedly enhances the effects of cortisone, oestrogen, and other hormones It prevents accumulation of abnormal fibrous tissue. PABA enables intestinal bacteria to produce folic acid. It functions in the breakdown and utilisation of proteins and in the formation of blood cells

Human overdose data on PABA or its esters are rare. Most toxicology data are derived from animal experimentation or chronic, large dose therapeutic use. Nausea, vomiting, and abdominal cramps as well as metallic taste are often seen with oral therapy. Ingestions of more than 10 grams per day for days have been necessary to induce symptoms other than local gastrointestinal irritation. Clinical use of PABA at doses of 10 grams per day or more have produced nausea, vomiting, acidosis, pruritus, rash, fever, methaemoglobinaemia and, possibly, hepatitis.

This regime tended to produce a decrease in white cell count (leucopenia) while higher doses produced delirium.

Chronic feeding studies indicate rats are resistant to p-aminobenzoic acid with acute gastroenteritis and haemorrhage of the small intestine capillaries being involved in any toxic effect. Acute necrosis of the liver occurred in some dogs during feeding trials.

PABA is an essential nutrient for some bacteria and is sometimes called Vitamin B x . However, PABA is not essential for humans and it varies in its activity from other B vitamins. Although humans lack the ability to synthesise folate from PABA, it is often sold, misleadingly, as an essential nutrient. PABA is sometimes included in multi-vitamin preparations; adverse effects from oral doses have not been reported at lower doses.

Derivatives of PABA, have been associated with acute allergic reactions. As sunscreens PABA derivatives have reportedly produced allergic contact dermatitis; although transient this effect may be severe compounding the phototoxicity for which it is applied. PABA or other related substances are also capable of inducing photoallergic reactions or systemic lupus erythematous. In the past, PABA has been widely used as UV filter in sunscreen formulations. However, it has been determined that it increases the risk of DNA damage and risk of skin cancer. Other derivatives of PABA, such as octyl dimethyl PABA (padimate(s) A and O) are more commonly used so their safety has been brought into question as well.

In bioassays designed to examine the potential for PABA contact sensitisation there have been mixed results. One researcher was not able to produce delayed contact hypersensitivities in guinea pigs in the Magnussen Kligman maximisation test, in a modified Draize test or in a single injection adjuvant test. Another, however, produced sensitisation responses in 33% of animals in the maximisation test (5 responders in 15 test animals).

Mixed results have been produced in bioassays for photoallergic potential. One study with guinea pigs could not produce evidence supporting this proposition whilst another showed photoallergic and persistent light reactions

Aminobenzoic acid is chemically similar to other drugs that cause photosensitivity reactions in susceptible individuals including thiazides, sulfonamides, sulfonylureas, furosemide, and carbonic anhydrase inhibitors. Cross-reactivity may also occur with benzocaine and p-phenylenediamine. Individuals who have had photosensitivity reactions while taking any of these drugs should not use a sunscreen containing aminobenzoic acid or one of its derivatives (aminobenzoate, menthyl anthranilate, or padimate A or O).

A nitrosamine known as NPABAO (2-ethylhexyl-4-(N-methyl-N-nitrosoamino)benzoate has been found in certain sunscreens containing padimate-O as the active ingredient. Nitrosamines themselves can be carcinogenic; however, at this time it is uncertain whether this nitrosamine is present in sufficient quantities in sunscreens to be of concern.

Padimate O absorbs ultraviolet rays, thereby preventing direct DNA damage by UV-B. However, the thus excited padimate O molecule can then react with DNA and produce indirect DNA damage, similar to the effects of ionizing radiation. A study in 1993 demonstrated the sunlight-induced mutagenicity of Padimate O The photobiological properties of padimate O resemble those of Michler's ketone which is considered photocarcinogenic in rats and mice. These findings suggest that padimate O might also be photocarcinogenic

Sulfonamides (sulfa drugs) are chemically similar to PABA, and their antibacterial activity is due to their ability to interfere with PABA utilization by bacteria. The chemically related 4-aminosalicylic acid, used as as an antibacterial has produced, allergic reactions are recorded in over 5% of adults treated with the sodium salt. Fever, athralgia, lymphadenopathy, and more rarely a syndrome resembling mononucleosis may also occur. Other (apparently) allergic reactions to aminosalicylate include jaundice, liver necrosis, pancreatitis, pulmonary infiltration, encephalitis, nephritis, and renal failure. Skin rashes often occurs after treatment Exfoliative dermatitis is common. The p-aminophenyl group formed during metabolism of aminosalicylate may provoke reaction in hypersensitive individuals (cross-sensitive) to sulfonamides, phenacetin, sulfones and to certain hair-dyes containing related compounds. Somnolence, convulsions, repiratory tract changes recorded.

for hydrate:

Convulsions, excitement, dyspnea, interstitial nephritis, allergic dermatitis after systemic exposure recorded.

Section 12 - ECOLOGICAL INFORMATION

No data

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.

! Puncture containers to prevent re-use and bury at an authorized landfill.

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- · Reduction
- · Reuse
- Recycling
- · Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.

DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.

- · Recycle wherever possible.
- · Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified.

Section 14 - TRANSPORTATION INFORMATION

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: DOT, IATA, IMDG

Section 15 - REGULATORY INFORMATION

penicillin G procaine (CAS: 54-35-3,6130-64-9) is found on the following regulatory lists;

"Canada Non-Domestic Substances List (NDSL)", "US Toxic Substances Control Act (TSCA) - Inventory"

Section 16 - OTHER INFORMATION

ND

Substance CAS Suggested codes penicillin G procaine 54-35-3 penicillin G procaine 6130-64-9

Ingredients with multiple CAS Nos

Ingredient Name CAS penicillin G procaine 54-35-3, 6130-64-9

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- Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

 A list of reference resources used to assist the committee may be found at:

 www.chemwatch.net/references.
- The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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