Material Safety Data Sheet

Procarbazine Hydrochloride
sc-204862

Hazard Alert Code Key:

EXTREME
HIGH
MODERATE
LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
Procarbazine Hydrochloride

STATEMENT OF HAZARDOUS NATURE

NFPA

SYNONYMS

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

<table>
<thead>
<tr>
<th></th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability:</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Toxicity:</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Body Contact:</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Reactivity:</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Chronic:</td>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

CANADIAN WHMIS SYMBOLS

Min/Nil=0
Low=1
Moderate=2
High=3
Extreme=4
EMERGENCY OVERVIEW
RISK
Harmful if swallowed.
May cause CANCER.
May cause heritable genetic damage.
May impair fertility.
May cause harm to the unborn child.
Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

■ Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.
■ The killing action of antineoplastic drugs used for cancer chemotherapy is not selective for cancerous cells alone but affect all dividing cells. Acute side effects include loss of appetite, nausea and vomiting, allergic reaction (skin rash, itch, redness, low blood pressure, unwellness and anaphylactic shock) and local irritation.

EYE

■ 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

■ Skin contact is not thought to produce harmful health effects (as classified using animal models). Systemic harm, however, has been identified following exposure of animals by at least one other route and the material may still produce health damage following entry through wounds, lesions or abrasions.
■ 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

■ There is ample evidence that this material can be regarded as being able to cause cancer in humans based on experiments and other information.
Based on experiments and other information, there is ample evidence to presume that exposure to this material can cause genetic defects that can be inherited.
Ample evidence exists from experimentation that reduced human fertility is directly caused by exposure to the material.
Ample evidence exists, from results in experimentation, that developmental disorders are directly caused by human exposure to the material.
Exposure to the material may result in a possible risk of irreversible effects. The material may produce mutagenic effects in man. This concern is raised, generally, on the basis of appropriate studies with similar materials using mammalian somatic cells in vivo. Such findings are often supported by positive results from in vitro mutagenicity studies.
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.

Anti-cancer drugs used for chemotherapy can depress the bone marrow with reduction in the number of white blood cells and platelets and bleeding. Susceptibility to infections and bleeding is increased, which can be life-threatening.

- CAUTION: May produce immunosuppression in individuals occupationally exposed to the material.
Exposure to immunosuppressives may aggravate infectious diseases.
Chronic exposure to therapeutic doses of compounds which produce immunosuppression has been associated with development of lymphomas (occasionally malignant) and mammary tumours. These may be secondary effects induced by activation of endogenous retroviruses.
Patients on immunosuppressive medications have a 10- to 100-fold increased risk of cancer compared to the general population. Furthermore, people who currently have or have already been treated for cancer have a higher rate of tumor progression and recurrence than patients with an intact immune system.
Patients receiving immunosuppressive regimens involving combinations of drugs, as part of an immunosuppressive regimen are at increased risk of developing lymphomas and other malignancies, particularly of the skin. The risk appears to be related to the intensity and duration of immunosuppression rather than to the use of any specific agent.
Increased incidences of neoplasms, in mice and humans, have been reported after long-term immunosuppression by azathioprine and cyclosporin. Cyclosporin has been classified as a human carcinogen, by IARC, based on development of lymphomas after repeated and prolonged exposures to therapeutic doses. Administration during the first trimester of pregnancy caused congenital malformation of the foetus in 4 of 5 patients. Other pregnancies were terminated. Oral doses of 5-10 mg/kg administered in rats on days 8-14 gestation produced malformations, primarily of the eyes and limbs. Repeated oral administration of promethazine chloride induced pulmonary tumours and leukaemias in mice and mammary tumours in rats. Repeated intraperitoneal injections produced malignant tumours of the nervous and haematopoietic systems in mice and rats and adenocarcinomas of the mammary glands in rats. Intravenous injection produced malignant tumours in several organs in rats. Leukaemias, haemangioendothelial sarcomas and osteogenic sarcomas were induced in monkeys following intraperitoneal, subcutaneous, intravenous or oral administration. Acute nonlymphocytic leukaemia has been produced in humans in combination with other chemotherapeutic agents.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>NAME</th>
<th>CAS RN</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>procarbazine hydrochloride</td>
<td>366-70-1</td>
<td>&gt;98</td>
</tr>
</tbody>
</table>

Section 4 - FIRST AID MEASURES

SWALLOWED
· IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY. · Where Medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:

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 or hair contact occurs: · Flush skin and hair with running water (and soap if available). · Seek medical attention in event of irritation.

INHALED
· If dust is inhaled, remove from contaminated area. · Encourage patient to blow nose to ensure clear passage of breathing. · If irritation or discomfort persists seek medical attention.

NOTES TO PHYSICIAN
■ Treat symptomatically.

For employees potentially exposed to antineoplastic and/ or cytotoxic agents on a regular basis, a preplacement physical examination and history (noting risk factors) is recommended. Periodic follow-up examinations should also be undertaken and should be overseen by a physician familiar with the toxic effects of the substance and full details of the nature of work undertaken by the employee.

Readily absorbed form the gastrointestinal tract; crosses the blood-brain barrier and diffuses to the cerebrospinal fluid. Plasma half-life is reportedly 10 minutes. Rapidly metabolised with only about 5% excreted unchanged in the urine. The remainder is oxidised to N-isopropyl-terephthalamic acid and excreted in the urine; 24-42% of the dose is excreted in 24 hours. Some is excreted as carbon dioxide as methane from the lungs. During oxidative degradation in the body, hydrogen peroxide and free radicals are formed and may account for several of the drugs actions.

Section 5 - FIRE FIGHTING MEASURES

Vapour Pressure (mmHG): Negligible
Upper Explosive Limit (%): Not available.
Specific Gravity (water=1): Not available
Lower Explosive Limit (%): Not available

EXTINGUISHING MEDIA
· Water spray or fog.
· Foam.

FIRE FIGHTING
· Alert Emergency Responders and tell them location and nature of hazard.
· Wear breathing apparatus plus protective gloves.
When any large container (including road and rail tankers) is involved in a fire, consider evacuation by 100 metres in all directions.

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), hydrogen chloride, phosgene, nitrogen oxides (NOx), other pyrolysis products typical of burning organic material.

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

Glasses:
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.

Environmental hazard - contain spillage.

It is recommended that areas handling final finished product have cytotoxic spill kits available.

Spill kits should include:
- impermeable body covering,
- shoe covers,
- latex and utility latex gloves,
- goggles,
- approved HEPA respirator,
- disposable dust pan and scoop,
- absorbent towels,
- spill control pillows,
- disposable sponges,
- sharps container,
- disposable garbage bag and
- hazardous waste label.

To avoid accidental exposure due to waste handling of cytotoxics:
- Place waste residue in a segregated sealed plastic container.
- Used syringes, needles and sharps should not be crushed, clipped, recapped, but placed directly into an approved sharps container.

All personnel likely to involved in a antineoplastic (cytotoxic) spill must receive practical training in:
- the correct procedures for handling cytotoxic drugs or waste in order to prevent and minimize the risk of spills
- the location of the skill kit in the area.

MAJOR SPILLS
- Clear area of personnel and move upwind.
- Alert Emergency Responders and tell them location and nature of hazard.

Environmental hazard - contain spillage.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING
- The National Institute of Health (USA) recommends that the preparation of injectable antineoplastic drugs should be performed in a Class II laminar flow biological safety cabinet and that personnel preparing drugs of this class should wear appropriate personal protective gear.
- Emphasise controls on containment.
- 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.
- 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
- Antineoplastics (cytotoxics):
  - should be clearly identifiable to all personnel involved in their handling
  - should be stored in impervious break-resistant containers.

Observe manufacturer's storing and handling recommendations.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION
**EXPOSURE CONTROLS**

The following materials had no OELs on our records

- procarbazine hydrochloride: CAS:366-70-1

**PERSONAL PROTECTION**

**RESPIRATOR**
Particulate
Consult your EHS staff for recommendations

**EYE**
- Chemical protective goggles with full seal
- Shielded mask (gas-type)
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses 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**

- 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.

**OTHER**

- When handling antineoplastic materials, it is recommended that a disposal work-uniform (such as Tyvek or closed front surgical-type gown with knit cuffs) is worn.
- 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.
- For emergencies: Vinyl suit.

**ENGINEERING CONTROLS**

- Employees exposed to confirmed human carcinogens should be authorized to do so by the employer, and work in a regulated area.
- Work should be undertaken in an isolated system such as a “glove-box”. Employees should wash their hands and arms upon completion of the assigned task and before engaging in other activities not associated with the isolated system.
- Within regulated areas, the carcinogen should be stored in sealed containers, or enclosed in a closed system, including piping systems, with any sample ports or openings closed while the carcinogens are contained within.
- Open-vessel systems are prohibited.
- Each operation should be provided with continuous local exhaust ventilation so that air movement is always from ordinary work areas to the operation.
- Exhaust air should not be discharged to regulated areas, non-regulated areas or the external environment unless decontaminated. Clean make-up air should be introduced in sufficient volume to maintain correct operation of the local exhaust system.
- For maintenance and decontamination activities, authorized employees entering the area should be provided with and required to wear clean, impervious garments, including gloves, boots and continuous-air supplied hood. Prior to removing protective garments the employee should undergo decontamination and be required to shower upon removal of the garments and hood.
- Except for outdoor systems, regulated areas should be maintained under negative pressure (with respect to non-regulated areas).
Local exhaust ventilation requires make-up air be supplied in equal volumes to replaced air.
Laboratory hoods must be designed and maintained so as to draw air inward at an average linear face velocity of 150 feet/ min. with a minimum of 125 feet/ min. Design and construction of the fume hood requires that insertion of any portion of the employees body, other than hands and arms, be disallowed.

**Section 9 - PHYSICAL AND CHEMICAL PROPERTIES**

**PHYSICAL PROPERTIES**

Solid.
Mixes with water.

<table>
<thead>
<tr>
<th>State</th>
<th>Divided solid</th>
<th>Molecular Weight</th>
<th>257.76</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting Range (°F)</td>
<td>Not available</td>
<td>Viscosity</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Boiling Range (°F)</td>
<td>Not available</td>
<td>Solubility in water (g/L)</td>
<td>Miscible</td>
</tr>
<tr>
<td>Flash Point (°F)</td>
<td>Not available</td>
<td>pH (1% solution)</td>
<td>Not available</td>
</tr>
<tr>
<td>Decomposition Temp (°F)</td>
<td>433.4- 438.8</td>
<td>pH (as supplied)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition Temp (°F)</td>
<td>Not available</td>
<td>Vapour Pressure (mmHG)</td>
<td>Negligible</td>
</tr>
<tr>
<td>Upper Explosive Limit (%)</td>
<td>Not available</td>
<td>Specific Gravity (water=1)</td>
<td>Not available</td>
</tr>
<tr>
<td>Lower Explosive Limit (%)</td>
<td>Not available</td>
<td>Relative Vapor Density (air=1)</td>
<td>&gt;1</td>
</tr>
<tr>
<td>Volatile Component (%vol)</td>
<td>Negligible</td>
<td>Evaporation Rate</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

**APPEARANCE**

White to pale-yellow crystalline powder; mixes with water (14%), methanol. Aqueous solutions are unstable and acid to litmus.

**Section 10 - CHEMICAL STABILITY**

**CONDITIONS CONTRIBUTING TO INSTABILITY**

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

**STORAGE INCOMPATIBILITY**

- Avoid reaction with oxidizing agents.

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

**Section 11 - TOXICOLOGICAL INFORMATION**

**PROCARBAZINE HYDROCHLORIDE**

**TOXICITY AND IRRITATION**

PROCARBAZINE HYDROCHLORIDE:

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

<table>
<thead>
<tr>
<th>TOXICITY</th>
<th>IRRITATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral (rat) LD50: 570 mg/kg</td>
<td>Nil Reported</td>
</tr>
<tr>
<td>Subcutaneous (rat) LD50: 490 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Intravenous (rat) LD50: 350 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Oral (mouse) LD50: 660 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Intraperitoneal (mouse) LD50: 699 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Subcutaneous (mouse) LD50: 710 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Intravenous (mouse) LD50: 540 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

- WARNING: This substance has been classified by the IARC as Group 2A: Probably Carcinogenic to Humans.

NOTE: Substance has been shown to be mutagenic in at least one assay, or belongs to a family of chemicals producing damage or change to cellular DNA.

Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).

**CARCINOGEN**

<table>
<thead>
<tr>
<th>PROCARBAZINE HYDROCHLORIDE</th>
<th>US Environmental Defense Scorecard Recognized Carcinogens</th>
<th>Reference(s)</th>
<th>P65</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROCARBAZINE HYDROCHLORIDE</td>
<td>US Environmental Defense Scorecard Suspected Carcinogens</td>
<td>Reference(s)</td>
<td>P65</td>
</tr>
</tbody>
</table>
Section 12 - ECOLOGICAL INFORMATION

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
This material and its container must be disposed of as hazardous waste.
Avoid release to the environment.
Refer to special instructions/safety data sheets.

Ecotoxicity

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Persistence: Water/Soil</th>
<th>Persistence: Air</th>
<th>Bioaccumulation</th>
<th>Mobility</th>
</tr>
</thead>
<tbody>
<tr>
<td>procarbazine hydrochloride</td>
<td>HIGH</td>
<td>LOW</td>
<td>MED</td>
<td></td>
</tr>
</tbody>
</table>

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions
All waste must be handled in accordance with local, state and federal regulations.
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.
· Antineoplastic (cytotoxic) wastes must be packed directly, ready for incineration, into color-coded, secure, labelled, leak-proof containers sufficiently robust to withstand handling without breaking, bursting or leaking.
· Containers of special design are available for particular needs (such as disposal of sharps) and should be used.

Section 14 - TRANSPORTATION INFORMATION

DOT:
Symbols: G Hazard class or Division: 9
Identification Numbers: UN3077 PG: III
Label Codes: 9 Special provisions: 8, 146, 335, BS4, IB8, IP3, N20, T1, TP33
Packaging: Exceptions: 155 Packaging: Non-bulk: 213
Packaging: Exceptions: 155 Quantity limitations: No limit
Passenger aircraft/rail:
Quantity Limitations: Cargo No limit Vessel stowage: Location: A aircraft only:
Vessel stowage: Other: None
Hazardous materials descriptions and proper shipping names:
Environmentally hazardous substance, solid, n.o.s

Air Transport IATA:
ICAO/IATA Class: 9 ICAO/IATA Subrisk: None
UN/ID Number: 3077 Packing Group: III
Special provisions: A97
Cargo Only
Packing Instructions: 911 Maximum Qty/Pack: 400 kg
Passenger and Cargo Passenger and Cargo
Packing Instructions: 911 Maximum Qty/Pack: 400 kg
Passenger and Cargo Limited Quantity Passenger and Cargo Limited Quantity
Packing Instructions: Y911 Maximum Qty/Pack: 30 kg G
Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. *(CONTAINS PROCARBAZINE HYDROCHLORIDE)
Maritime Transport IMDG:
IMDG Class: 9 IMDG Subrisk: None
UN Number: 3077 Packing Group: III
EMS Number: F-A, S-F Special provisions: 179 274 335 909
Limited Quantities: 5 kg Marine Pollutant: Yes
Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

Section 15 - REGULATORY INFORMATION

procarbazine hydrochloride (CAS: 366-70-1) is found on the following regulatory lists:

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

■ Exposure may produce irreversible effects*.  
* (limited evidence).

ND
Substance CAS Suggested codes procarbazine hydrochloride 366-70-1

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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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