

1) WHITE GYPSUM - CALCIUM SULFATE HEMIHYDRATE (CASO4•½H2O)

i) INTRODUCTION

Health risks caused by the naturally occurring mineral, gypsum, are minimal when it is properly used. Since the purer forms of this mineral are used in foods and other products that are ingested by humans, the chance for negative chemical or allergic reactions with the user of the products is extremely low.

Finely ground forms of this mineral have an affinity for water, so prolonged handling of the powder without gloves will cause dry skin. The powder will also dry out your nasal passages and throat from prolonged exposure.

When using the bare hands in frequent contact, precautions should be taken to prevent drying of the skin, or rubber gloves should be worn during handling.

Under no circumstances should an excessive bulk of the rehydrated material outside of the instructions for use be allowed to set up on the skin or the resulting heat may cause severe burns. If proper instructions are followed, mineral gypsum products are easy and safe to use.

ii) MATERIAL SAFETY DATA

(a) Food and Drug Administration [CFR Title 21, v.3, sec 184.1230] – Calcium Sulfate is Generally Recognized as Safe (GRAS).

(b) All ingredients of this product are included in the U.S. Environmental Protection Agency's Toxic Substances Control Act Chemical Substance Inventory.

(c) All components of this product are included in the Canadian Domestic Substances List (DSL)

iii) POTENTIAL HEALTH EFFECTS

(a) ACUTE:

1. **Eyes:** Direct contact can cause mechanical irritation of eyes. If burning, redness, itching, pain or other symptoms persist or develop, consult physician.
2. **Skin:** Direct, prolonged or repeated contact with the skin may cause irritation. Rinse with water until skin is free of material to avoid irritation, then wash skin thoroughly with mild soap and water. Repeated exposure may dry skin.
3. **Inhalation:** Dust exposures generated during the handling of the product may irritate eyes, skin, nose, throat, and upper respiratory tract. If respiratory symptoms persist, consult physician.
4. **Ingestion:** Unlikely, but gastric disturbances may result if swallowed. Plaster of Paris is non-toxic, however, ingestion of a sufficient quantity could lead to mechanical obstruction of the gut, especially the pyloric region.

(b) CHRONIC:

1. **Inhalation:** Testing of dust from plaster of Paris has not detected respirable crystalline silica. Exposures to respirable crystalline silica are not expected during the normal use of this product; however, actual levels must be determined by workplace hygiene testing. The weight percent of respirable crystalline silica has not been measured in this product.
2. **Skin:** Repeated contact may dry the skin, causing cracking or dermatitis. Sensitive individuals may develop an allergic dermatitis.

(c) MEDICAL CONDITIONS THAT MAY BE AGGRAVATED:

1. Pre-existing upper respiratory and lung diseases such as, but not limited to, bronchitis, emphysema and asthma.
2. Pre-existing skin diseases such as, but not limited to, rashes and dermatitis.

iv) TOXICOLOGICAL INFORMATION**(a) ACUTE:**

1. The sulfate ion has caused gastro-intestinal disturbance in humans following large oral doses.
2. Limited studies involving the repeated inhalation of an (unspecified) amount of calcium sulfate failed to identify any particular target organs in monkeys, rats and hamsters.
3. No evidence of mutagenicity was found in Ames bacterial tests.

(b) TOXICITY:

1. Oral LD50 rat > 5000 mg/kg
2. Dermal LD50 – None Determined
3. Skin Irritation LD50 – None Determined
4. Eye Irritation LD50– None Determined

2) HYDROXYETHYLATED DENT CORN STARCH, SOLUBLE, A.C.S. REAGENT and PREGELATINIZED MODIFIED WAXY MAIZE INSTANT STARCH**i) INTRODUCTION**

- (a) These constituents impart viscosity to the slurry mix on preparation in cold water. They are direct food product starches characterized by a stable viscosity in acid and neutral food systems possessing the properties of stability and texture typical of modified waxy maize starches, best utilized in high shear systems.

ii) POTENTIAL HEALTH EFFECTS**(a) ACUTE:**

1. May cause eye irritation.
2. May cause skin irritation.
3. Material may be irritating to mucous membranes and upper respiratory tract.

iii) TOXICOLOGICAL INFORMATION**(a) IRRITATION:**

1. Skn-hmn 300 ug/3d-i mld 85dka8 -,127,1977

(b) TOXICITY:

1. lpr-mus ld50:6600 mg/kg pcjoau 15,139,1981

3) POLYETHER POYLCARBOXYLATE, SODIUM SALT**i) INTRODUCTION**

This constituent may be used as a surfactant to control slurry surface tension.

ii) MATERIAL SAFETY DATA

This material is NOT HAZARDOUS by OSHA Hazard Communication definition.

iii) **TOXICOLOGICAL INFORMATION**

(a) **ACUTE:**

1. Eyes: Slight irritant.

4) **STATE REPORTING:**

i) **California:**

These materials are not known to contain any chemicals currently listed as carcinogens or reproductive toxins under California Proposition 65 at levels which would be subject to the proposition.

ii) **Massachusetts:**

(a) Massachusetts Substances List (MSL) - Extraordinarily hazardous substances must be identified when present in materials at levels greater than state specified criterion. The criterion is $\geq 0.0001\%$.

(b) Hazardous Substances (MSL-HS) on the MSL must be identified when present in materials at greater than the state specified criterion. The criterion is $\geq 1\%$.

Components present in this material are at levels less than specified and do not require reporting under the statute.

iii) **Pennsylvania:**

(a) Special Hazardous Substances (PA-SHS) must be identified when present in materials at levels greater than the state specified criterion. The criterion is $\geq 0.01\%$.

(b) Hazardous Substances (PA-HS) must be identified when present in materials at levels greater than the state specified criterion. The criterion is $\geq 1\%$.

(c) Environmental Hazards (PA-EH) must be identified when present in materials at levels greater than the state specified criterion. The criterion is $\geq 0.01\%$.

Components present in this material are at levels less than specified and do not require reporting under the statute.

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Manufacturer: BSN medical Inc.