



Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 10/29/2021

Version US-EN-Rev 1

Reviewed on 10/29/2021

1 Identification

- **Product identifier**
- **Trade name:** Cytrans® Granules
- **Relevant identified uses of the substance or mixture and uses advised against**
Dental material
The product is intended for professional use.
To avoid risks for humans and environment obtain instructions.
- **Application of the substance / the mixture** Bone grafting material
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
GC America Inc.
3737 W. 127th Street
Alsip, IL 60803
USA

SDS.gcamerica@gc.dental
- **Information department:** Regulatory Affairs
- **Emergency telephone number:**
During normal opening times (Monday–Friday 8:00 AM–5:00 PM Central Time): +1 (708) 597-0900
Transportation (CHEMTREC®) Emergency Telephone No. +1 (800) 424-9300

2 Hazard(s) identification

- **Classification of the substance or mixture**
The substance is not classified, according to the Globally Harmonized System (GHS).
- **Additional information:**
The information provided is in regards to the toxicity and hazard rating(s) of the individual component(s) in the formulation. The associated risk(s) depends on the route(s) of exposure. The hazard rating system is based entirely on the existence of the risk(s) and does not take into account the likelihood of reduced risk(s) through proper usage and handling.
- **Label elements**
- **GHS label elements**
Exempt from labeling – medical devices and drugs do not require labeling according to HCS 2012.
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Hazard(s) not otherwise classified (HNOC):** None known.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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3 Composition/information on ingredients

- **Chemical characterization: Substances**
- **CAS No. Description**
carbonate apatite

4 First-aid measures

- **Description of first aid measures**
- **General information:**
No special measures required.
If symptoms persist consult doctor.
- **After inhalation:**
Supply fresh air; consult doctor in case of complaints.
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**
Rinse with warm water.
If symptoms persist consult doctor.
- **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire fighting measures that suit the environment.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards arising from the substance or mixture**
In case of fire, the following can be released:
Carbon monoxide (CO)
Carbon dioxide
- **Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.
- **Additional information**
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Remove persons from danger area.

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- **Environmental precautions:**

Do not allow product to reach sewage system or any water course.
Do not allow to penetrate the ground/soil.

- **Methods and material for containment and cleaning up:**

Pick up mechanically.
Dispose of the collected material according to regulations.

- **Reference to other sections**

See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

- **Protective Action Criteria for Chemicals**

Protective Action Criterion (PAC); Protective Action Criteria (PACs); Lower Explosive Limit (LEL)
* indicates the PAC value is between 10% and up to 50% of the LEL (10% LEL ≤ PAC < 50% LEL).
** indicates the PAC value is between 50% and up to 100% of the LEL (50% LEL ≤ PAC < 100% LEL).
*** indicates the PAC value is at 100% or more of the LEL (PAC ≥ LEL).
excerpt from Introduction to PAC Table 2 – PAC Rev. 29 – May 2016

- **PAC-1:**

Substance is not listed.

- **PAC-2:**

Substance is not listed.

- **PAC-3:**

Substance is not listed.

7 Handling and storage

- **Handling:**

- **Precautions for safe handling**

Observe instructions for use.
Prevent formation of dust.
Any deposit of dust which cannot be avoided must be regularly removed.

- **Information about protection against explosions and fires:**

No further relevant information available.

- **Conditions for safe storage, including any incompatibilities**

- **Storage:**

- **Requirements to be met by storerooms and receptacles:**

Store only in unopened original receptacles.

- **Information about storage in one common storage facility:** Store away from foodstuffs.

- **Further information about storage conditions:** Observe instructions for use / storage.

- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.

- **Control parameters**

- **Components with limit values that require monitoring at the workplace:** Not required.

- **Additional information:** The lists that were valid during the creation were used as basis.

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- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
Do not inhale dust / smoke / mist.
Wash hands before breaks and at the end of work.
- **Breathing equipment:**



Suitable respiratory protective device recommended.

- **Protection of hands:**



Protective gloves

- **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a substance, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:**



Safety glasses

9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form: Granules

Color: White

- **Odor:** Odorless

- **Odor threshold:** Not determined.

- **pH-value:** 7.8

- **Change in condition**

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined.

- **Flash point:** Not applicable.

- **Flammability (solid, gaseous):** Product is not flammable.

- **Ignition temperature:** Undetermined.

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· Decomposition temperature:	Not determined.
· Auto igniting:	Not determined.
· Danger of explosion:	Not determined.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not applicable.
· Density:	Not determined.
· Relative density	Not determined.
· Vapor density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with Water:	Insoluble.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
Organic solvents:	0 %
VOC content:	0.00 %
Solids content:	100.0 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** Stable at ambient temperature.
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:**
Carbon dioxide
Carbon monoxide

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **LD/LC50 values that are relevant for classification:** No further relevant information available.
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.

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- **Symptoms related to the physical, chemical and toxicological characteristics:**
No further relevant information available.
- **Subacute to chronic toxicity:** No further relevant information available.
- **Numerical measures of toxicity:** No further relevant information available.
- **Additional toxicological information:** The substance is not subject to classification.
- **Carcinogenic categories**

· IARC (International Agency for Research on Cancer)

Substance is not listed.

· NTP (National Toxicology Program)
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Substance is not listed.

· OSHA-Ca (Occupational Safety & Health Administration)
--

Substance is not listed.

- **Carcinogenic categories' legend:**

- IARC Group 1: The agent is carcinogenic to humans.

- IARC Group 2A: The agent is probably carcinogenic to humans.

- IARC Group 2B: The agent is possibly carcinogenic to humans.

- IARC Group 3: The agent is not classifiable as to its carcinogenicity to humans.

- IARC Group 4: The agent is probably not carcinogenic to humans.

- NTP K: Known to be human carcinogen.

- NTP R: Reasonably anticipated to be human carcinogen.

- **Additional carcinogenic information:** No further relevant information available.
- **Repeated dose toxicity.** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
No further relevant information available.
No further relevant information available.
- **Germ cell mutagenicity** No further relevant information available.
- **Carcinogenicity** No further relevant information available.
- **Reproductive toxicity** No further relevant information available.
- **Specific target organ toxicity - single exposure** No further relevant information available.
- **Specific target organ toxicity - repeated exposure** No further relevant information available.
- **Aspiration hazard** No further relevant information available.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German regulation, AwSV) (Self-assessment): slightly hazardous to water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Dispose of contents / container in accordance with local / regional / national / international regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number | |
| · DOT, ADR, IMDG, IATA | Not regulated. |
| · UN proper shipping name | |
| · DOT, ADR, IMDG, IATA | Not regulated. |
| · Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | |
| · Class | Not regulated. |
| · Packing group | |
| · DOT, ADR, IMDG, IATA | Not regulated. |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Not regulated. |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **SARA (Superfund Amendments and Reauthorization Act)**

- **Section 355 (extremely hazardous substances):**

Substance is not listed.

- **Section 313 (Specific toxic chemical listings):**

Substance is not listed.

- **TSCA (Toxic Substances Control Act):**

Substance is not listed.

- **Additional information:**

If a substance is marked with **, then substance is a trade secret. This is allowed under OSHA's Hazard Communication Standard (HCS) as a trade secret and under GHS as Confidential Business Information (CBI).

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<ul style="list-style-type: none"> · Hazardous Air Pollutants
Substance is not listed.

<ul style="list-style-type: none"> · Proposition 65
<ul style="list-style-type: none"> · Chemicals known to cause cancer:
Substance is not listed.

<ul style="list-style-type: none"> · Chemicals known to cause reproductive toxicity for females:
Substance is not listed.

<ul style="list-style-type: none"> · Chemicals known to cause reproductive toxicity for males:
Substance is not listed.

<ul style="list-style-type: none"> · Chemicals known to cause developmental toxicity:
Substance is not listed.

- **Carcinogenic categories**

<ul style="list-style-type: none"> · EPA (Environmental Protection Agency)
Substance is not listed.

- **EPA carcinogenic categories' legend:**

EPA weight-of-evidence (WoE): official codes and categories from EPA's 1986 guidelines and unofficial, derived codes from EPA's standard hazard descriptors from 1996, 1999, and 2005 guidelines

A: human carcinogen (1986)

B1: probable human carcinogen – based on limited evidence of carcinogenicity in humans (1986)

B2: probable human carcinogen – based on sufficient evidence of carcinogenicity in animals (1986)

C: possible human carcinogen (1986)

D: not classifiable as to human carcinogenicity (1986)

E: evidence of non-carcinogenicity for humans (1986)

CaH: carcinogenic to humans

CBD: carcinogenic potential cannot be determined

I: data are inadequate for an assessment of human carcinogenic potential

II: inadequate information to assess carcinogenic potential

K/L: known/likely human carcinogen

L: likely to be carcinogenic to humans

NL: not likely to be carcinogenic to humans

S: suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential

SC: suggestive evidence of carcinogenic potential

<ul style="list-style-type: none"> · TLV (Threshold Limit Value)
Substance is not listed.

- **ACGIH carcinogenic categories' legend:**

A1: confirmed human carcinogen

A2: suspected human carcinogen

A3: confirmed animal carcinogen with unknown relevance to humans

A4: not classifiable as a human carcinogen

A5: not suspected as a human carcinogen

<ul style="list-style-type: none"> · NIOSH-Ca (National Institute for Occupational Safety and Health)
Substance is not listed.

- **GHS label elements**

Exempt from labeling – medical devices and drugs do not require labeling according to HCS 2012.

- **Hazard pictograms** Void

- **Signal word** Void

- **Hazard statements** Void

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- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

- **Department issuing SDS:** Regulatory Affairs
- **Contact:**
Regulatory Affairs
Telephone No. +1 (708) 597-0900
SDS.gcamerica@gc.dental
- **Date of preparation / last revision** 10/29/2021 / -
- **Abbreviations and acronyms:**
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
HCS: Hazard Communication Standard (USA)
MSDS: Material Safety Data Sheet
SDS: Safety Data Sheet
ADN: Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ECHA: European Chemicals Agency
OSHA: Occupational Safety and Health Administration (USA)
PAC: Protective Action Criterion (USA)
PACs: Protective Action Criteria (USA)
HNOC: Hazard Not Otherwise Classified (USA)
LEL: Lower Explosive Limit
UEL: Upper Explosive Limit
OSHA-Ca: Occupational Safety and Health Administration – Carcinogens or potential carcinogens regulated (USA)
NIOSH-Ca: National Institute for Occupational Safety and Health – Carcinogen List (USA)
NIOSH: National Institute for Occupational Safety and Health (USA)
TSCA: Toxic Substances Control Act (USA)
AwSV: Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (Ordinance on facilities for handling substances that are hazardous to water) (Germany)
NOEC: No Observed Effect Concentration
ADR: Accord européen relatif au transport international des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG Code: International Maritime Dangerous Goods Code
DOT: Department of Transportation (USA)
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
CAS: Chemical Abstracts Service (division of the American Chemical Society)
VOC: Volatile Organic Compounds (USA, EU)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
- **Sources**
 - Manufacturers' MSDSs/SDSs
 - OSHA (<https://www.osha.gov/dts/chemicalsampling/toc/chmcas.html>)
 - PubChem (<https://pubchem.ncbi.nlm.nih.gov/>)
 - ECHA (<http://echa.europa.eu/>)
 - EnviChem (www.echemportal.org)
- **Notes:**
CAS Registry Number® is a registered trademark of the American Chemical Society.
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