

Safety Data Sheet

according to HPR, Schedule 1

Printing date 08/11/2025

Version CA-EN-Rev 3

Reviewed on 08/11/2025

1 Identification

- **Product identifier**
- **Trade name:** OMNIFLEX (Catalyst, Set: Fast)
- **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** Dental impression material
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
GC America Inc.
3737 W. 127th Street
Alsip, IL 60803
USA

Telephone No. +1 (708) 597-0900
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 identification

- **Classification of the substance or mixture**

| | |
|---|--|
| Acute Toxicity (Inhalation) - Category 4 | H332 Harmful if inhaled. |
| Skin Irritation - Category 2 | H315 Causes skin irritation. |
| Serious Eye Damage - Category 1 | H318 Causes serious eye damage. |
| Specific Target Organ Toxicity - Single Exposure - Category 1 | H370 Causes damage to organs. |
| Specific Target Organ Toxicity - Single Exposure - Category 3 | H335 May cause respiratory irritation. |
| Specific Target Organ Toxicity - Repeated Exposure - Category 1 | H372 Causes damage to organs through prolonged or repeated exposure. |
- **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 classification and labeling – devices and drugs are not regulated according to WHMIS 2015.
The product is classified and labeled according to the Globally Harmonized System (GHS).

(Contd. on page 2)

CA

Safety Data Sheet

according to HPR, Schedule 1

Printing date 08/11/2025

Version CA-EN-Rev 3

Reviewed on 08/11/2025

Trade name: OMNIFLEX (Catalyst, Set: Fast)

(Contd. of page 1)

- **Hazard pictograms**



- **Signal word** Danger

- **Hazard-determining components of labeling:**

copper(II) hydroxide
titanium dioxide

- **Hazard statements**

H332 Harmful if inhaled.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H370 Causes damage to organs.
H335 May cause respiratory irritation.
H372 Causes damage to organs through prolonged or repeated exposure.

- **Precautionary statements**

P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a poison center/doctor.
P321 Specific treatment (see on this label).
P362+P364 Take off contaminated clothing and wash it before reuse.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

3 Composition/Information on ingredients

- **Chemical characterization: Mixtures**

- **Description:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**

| | | |
|------------------|--|----------------|
| | chlorinated fatty acid ester** | 30 – 60% w/w * |
| CAS: 20427-59-2 | copper(II) hydroxide | 10 – 30% w/w * |
| CAS: 13463-67-7 | titanium dioxide | 10 – 30% w/w * |
| CAS: 112926-00-8 | silicon dioxide, amorphous (gel or precipitated) | 1 – 5% w/w * |

* Actual concentration ranges are withheld as a trade secret.

- **Additional information:**

Concentrations of dangerous components are expressed in percent by weight (% w/w).

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).

CA

(Contd. on page 3)

Safety Data Sheet

according to HPR, Schedule 1

Printing date 08/11/2025

Version CA-EN-Rev 3

Reviewed on 08/11/2025

Trade name: OMNIFLEX (Catalyst, Set: Fast)

(Contd. of page 2)

4 First-aid measures

- **Description of first aid measures**

- **General information:**

Immediately remove any clothing soiled by the product.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

If symptoms persist consult doctor.

- **After inhalation:**

Supply fresh air or oxygen; call for doctor.

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

In case of unconsciousness place patient stably in side position for transportation.

Do not use mouth to mouth or mouth to nose resuscitation.

- **After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

Seek medical treatment.

- **After eye contact:**

Protect unharmed eye.

Rinse opened eye for several minutes under running water.

If symptoms persist consult doctor.

Call a doctor immediately.

- **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**

Formation of toxic gases is possible during heating or in case of fire.

No further relevant information available.

- **Advice for firefighters**

- **Protective equipment:**

Mouth respiratory protective device.

Wear self-contained respiratory protective device.

- **Additional information**

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

CA

(Contd. on page 4)

Safety Data Sheet

according to HPR, Schedule 1

Printing date 08/11/2025

Version CA-EN-Rev 3

Reviewed on 08/11/2025

Trade name: OMNIFLEX (Catalyst, Set: Fast)

(Contd. of page 3)

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Remove persons from danger area.
Avoid contact with the eyes and skin.
Wear protective clothing.
- **Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to penetrate the ground/soil.
In case of seepage into the ground inform responsible authorities.
- **Methods and material for containment and cleaning up:**
Absorb liquid components with liquid-binding material.
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.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Observe instructions for use.
Ensure good ventilation/exhaustion at the workplace.
Do not inhale dust / smoke / mist.
Prevent formation of aerosols.
Avoid contact with the eyes and skin.
- **Information about protection against explosions and fires:** No special measures required.
- **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.
Keep receptacle tightly sealed.
- **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 section 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.

(Contd. on page 5)

CA

Safety Data Sheet

according to HPR, Schedule 1

Printing date 08/11/2025

Version CA-EN-Rev 3

Reviewed on 08/11/2025

Trade name: OMNIFLEX (Catalyst, Set: Fast)

(Contd. of page 4)

- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
Avoid contact with the eyes and skin.
Wash hands before breaks and at the end of work.
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
- **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 preparation of several substances, 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: | Pasty |
| Color: | Light blue |
| Odor: | Characteristic |
| Odor threshold: | Not determined. |

- **pH-value:** Not determined.

- **Change in condition**

| | |
|-------------------------------------|---------------|
| Melting point/Melting range: | Undetermined. |
| Boiling point/Boiling range: | Undetermined. |

- **Flash point:** Not determined.

- **Flammability:** Not applicable.

(Contd. on page 6)

CA

Safety Data Sheet

according to HPR, Schedule 1

Printing date 08/11/2025

Version CA-EN-Rev 3

Reviewed on 08/11/2025

Trade name: OMNIFLEX (Catalyst, Set: Fast)

(Contd. of page 5)

| | |
|---|--|
| · Auto igniting: | Undetermined. |
| · Decomposition temperature: | Not determined. |
| · Ignition temperature: | Product is not self-igniting. |
| · Danger of explosion: | Not determined. |
| · Explosion limits: | |
| Lower: | Not determined. |
| Upper: | Not determined. |
| · Vapor pressure: | Not determined. |
| · Density: | Not determined. |
| · Relative density | Not determined. |
| · Vapor density | Not determined. |
| · Evaporation rate | Not determined. |
| · Solubility in / Miscibility with Water: | Insoluble. |
| · Partition coefficient (n-octanol/water): | Not determined. |
| · Viscosity: | |
| Dynamic: | Not determined. |
| Kinematic: | Not determined. |
| · Solvent content: | |
| Solids content: | 56.6 % |
| · 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:** Reacts with strong acids.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**

- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

CAS: 20427-59-2 copper(II) hydroxide

| | | |
|--------|------|---|
| Oral | LD50 | 500 mg/kg (ATE) 1000 mg/kg (rat (f+m)) |
| Dermal | LD50 | 2058 mg/kg (rabbit) |

(Contd. on page 7)

CA

Safety Data Sheet

according to HPR, Schedule 1

Printing date 08/11/2025

Version CA-EN-Rev 3

Reviewed on 08/11/2025

Trade name: OMNIFLEX (Catalyst, Set: Fast)

(Contd. of page 6)

| | | |
|------------|----------|----------------------|
| Inhalative | LC50/4 h | 0.47 mg/l (ATE) |
| | | 1.3 mg/l (rat (f+m)) |

- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Strong irritant with the danger of severe eye injury.
- **Sensitization:** No sensitizing effects known.
- **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.
- **Experience with humans:**
May cause damage to blood.
May cause damage to skin.
May cause damage to respiratory system.
May cause damage to brain.
May cause damage to digestive system.
May cause damage to eyes.
- **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Harmful
Corrosive
Irritant

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

| | |
|--|----|
| titanium dioxide | 2B |
| silicon dioxide, amorphous (gel or precipitated) | 3 |

- **NTP (National Toxicology Program)**

None of the ingredients is 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.

- **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.

CA

(Contd. on page 8)

Safety Data Sheet

according to HPR, Schedule 1

Printing date 08/11/2025

Version CA-EN-Rev 3

Reviewed on 08/11/2025

Trade name: OMNIFLEX (Catalyst, Set: Fast)

(Contd. of page 7)

12 Ecological information

- **Toxicity**

- **Aquatic toxicity:**

CAS: 20427-59-2 copper(II) hydroxide

| | |
|----------|-----------------------------|
| LC50/96h | 0.023 mg/L (fish) |
| EC50/48h | 0.0065 mg/l (daphnia magna) |

- **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.

- **Ecotoxicological effects:**

- **Remark:** Very toxic for fish

- **Additional ecological information:**

- **General notes:**

Water hazard class 3 (German regulation, AwSV) (Self-assessment): highly hazardous to water

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

Danger to drinking water if even extremely small quantities leak into the ground.

Also poisonous for fish and plankton in water bodies.

Very toxic for aquatic organisms

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

- **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/TDG, ADR, ADN, IMDG, IATA** Not regulated.

- **UN proper shipping name**

- **DOT/TDG, ADR, ADN, IMDG, IATA** Not regulated.

- **Transport hazard class(es)**

- **DOT/TDG, ADR, ADN, IMDG, IATA**

- **Class** Not regulated.

- **Packing group**

- **DOT/TDG, ADR, IMDG, IATA** Not regulated.

(Contd. on page 9)

CA

Safety Data Sheet

according to HPR, Schedule 1

Printing date 08/11/2025

Version CA-EN-Rev 3

Reviewed on 08/11/2025

Trade name: OMNIFLEX (Catalyst, Set: Fast)

(Contd. of page 8)

- | | |
|--|-----------------|
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · 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**
- **Canadian substance listings:**

- **Canadian Domestic Substances List (DSL)**

All ingredients are listed.

- **Canadian Non-Domestic Substances List (NDSL)**

None of the ingredients is 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).

- **Per- and polyfluoroalkyl substances (PFAS)**

None of the ingredients is listed.

- **GHS label elements**

Exempt from classification and labeling – devices and drugs are not regulated according to WHMIS 2015.

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



- **Signal word** Danger

- **Hazard-determining components of labeling:**

copper(II) hydroxide

titanium dioxide

- **Hazard statements**

H332 Harmful if inhaled.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H370 Causes damage to organs.

H335 May cause respiratory irritation.

H372 Causes damage to organs through prolonged or repeated exposure.

- **Precautionary statements**

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

(Contd. on page 10)

Safety Data Sheet

according to HPR, Schedule 1

Printing date 08/11/2025

Version CA-EN-Rev 3

Reviewed on 08/11/2025

Trade name: OMNIFLEX (Catalyst, Set: Fast)

(Contd. of page 9)

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a poison center/doctor.

P321 Specific treatment (see on this label).

P362+P364 Take off contaminated clothing and wash it before reuse.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **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 the latest revision of the safety data sheet** 08/11/2025 / 2

- **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)

TDG: Transportation of Dangerous Goods (Canada)

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)

HPR: Hazardous Products Regulations (Canada)

IMDG Code: International Maritime Dangerous Goods Code

DOT: Department of Transportation (USA)

IATA: International Air Transport Association

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

- **Sources**

- Manufacturers' MSDSs/SDSs
- OSHA (<https://www.osha.gov/chemicaldatabase>)
- 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.

CHEMTREC® is a registered service mark of the American Chemistry Council, Inc.

- *** Data compared to the previous version altered.** This version replaces all previous versions.

- **Disclaimer:**

The information contained herein is believed to be true and accurate. However, all statements, recommendations or suggestions are made without any guarantee, representation or warranty, express or implied, on our part. Therefore, no warranty is made or to be implied that the information set out in this document is accurate or complete, and we accordingly exclude all liability in connection with the

(Contd. on page 11)

Safety Data Sheet

according to HPR, Schedule 1

Printing date 08/11/2025

Version CA-EN-Rev 3

Reviewed on 08/11/2025

Trade name: OMNIFLEX (Catalyst, Set: Fast)

(Contd. of page 10)

use of this information or the products referred to herein. All such risks are assumed by the purchaser/user. The information contained herein is also subject to change without notice. For the avoidance of doubt, however, nothing in this document excludes or limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.

CA