

Safety Data Sheet
acc. to OSHA HCS

Printing date 03/28/2018

Reviewed on 02/28/2018

1 Identification

- **Product identifier**
- **Trade name:** Silanated Aluminum Oxide C
- **Article number:** 72174
- **Index number:** SDS 416-001.01
- **Application of the substance / the mixture** Component of medical device - For Company Internal Use Only
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ultradent Products
505 W Ultradent Drive (10200 South)
South Jordan, UT 84095
Email : customerservice@ultradent.com
Phone: 1-888-230-1420
- **Information department:** Customer Service
- **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazard(s) identification

- **Classification of the substance or mixture**



Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2A H319 Causes serious eye irritation.

- **Label elements**
- **GHS label elements** The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



- **Signal word** Warning
- **Hazard statements**
Causes skin irritation.
Causes serious eye irritation.
- **Precautionary statements**
Wash thoroughly after handling.
Wear protective gloves / eye protection / face protection.
If on skin: Wash with plenty of water.
Specific treatment (see on this label).
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
Continue rinsing.
If skin irritation occurs: Get medical advice/attention.
Take off contaminated clothing and wash it before reuse.
If eye irritation persists: Get medical advice/attention.

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· **Classification system:**· **NFPA ratings (scale 0 - 4)**· **HMIS-ratings (scale 0 - 4)**· **Other hazards**· **Results of PBT and vPvB assessment**· **PBT:** Not applicable.· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**· **Description:** Mixture of the substances listed below with nonhazardous additions.· **Dangerous components:**

1344-28-1	Aluminium Oxide	>50-≤100%
64-17-5	Ethyl Alcohol	≤2.5%
2344-80-1	Chloromethyltrimethylsilane	≤2.5%

4 First-aid measures

· **Description of first aid measures**· **General information:** Immediately remove any clothing soiled by the product.· **After inhalation:** In case of unconsciousness place patient stably in side position for transportation.· **After skin contact:** Immediately wash with water and soap and rinse thoroughly.· **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:** 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:** Use fire fighting measures that suit the environment.· **Special hazards arising from the substance or mixture** No further relevant information available.· **Advice for firefighters**· **Protective equipment:** No special measures required.

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6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **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**

· PAC-1:		
1344-28-1	Aluminium Oxide	15 mg/m ³
64-17-5	Ethyl Alcohol	1,800 ppm
· PAC-2:		
1344-28-1	Aluminium Oxide	170 mg/m ³
64-17-5	Ethyl Alcohol	3300* ppm
· PAC-3:		
1344-28-1	Aluminium Oxide	990 mg/m ³
64-17-5	Ethyl Alcohol	15000* ppm

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** No special precautions are necessary if used correctly.
- **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:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep receptacle tightly sealed.
- **Specific end use(s)** Component of medical device- For Company Internal Use Only

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:**
The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.
At this time, the remaining constituent has no known exposure limits.
At this time, the other constituents have no known exposure limits.

1344-28-1 Aluminium Oxide	
PEL	Long-term value: 15*; 15** mg/m ³ *Total dust; ** Respirable fraction

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REL	Long-term value: 10* 5** mg/m ³ as Al*Total dust**Respirable/pyro powd./welding f.
TLV	Long-term value: 1* mg/m ³ as Al; *as respirable fraction

64-17-5 Ethyl Alcohol

PEL	Long-term value: 1900 mg/m ³ , 1000 ppm
REL	Long-term value: 1900 mg/m ³ , 1000 ppm
STEL	Short-term value: 1000 mg/m ³
TLV	Short-term value: 1880 mg/m ³ , 1000 ppm
TWA	Short-term value: 1900 mg/m ³

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

· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

· **Breathing equipment:** Not required.

· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **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:**



Tightly sealed goggles

· **Body protection:** Protective work clothing

9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

Form: Crystalline powder

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· Color:	White
· Odor:	Odorless
· Odor threshold:	Not determined.
· pH-value:	Not applicable.
· Change in condition	
Melting point/Melting range:	2,000 °C
Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not determined.
· Decomposition temperature:	Not determined.
· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not applicable.
· Density at 20 °C:	3.90103 g/cm ³
· Bulk density:	920 kg/m ³
· 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.
· Solvent content:	
VOC content:	0.00 % 0.0 g/l / 0.00 lb/gl
· Solids content:	100.0 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **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:** No dangerous decomposition products known.

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11 Toxicological information

- **Information on toxicological effects**

- **Acute toxicity:**

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

ATE (Acute Toxicity Estimate)

Oral	LD50	309,091 mg/kg (mouse)
Inhalative	LC50/4 h	3,545 mg/l (mouse)

1344-28-1 Aluminium Oxide

Oral	LD50	>5,000 mg/kg (rat)
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64-17-5 Ethyl Alcohol

Oral	LD50	5,600 mg/kg (Guinea pig)
		3,400 mg/kg (mouse)
		7,060 mg/kg (rat)

Inhalative	LC50 Fish	>10,000 mg/l (Fish)

- **Primary irritant effect:**

- **on the skin:** Irritant to skin and mucous membranes.

- **on the eye:** Irritating effect.

- **Sensitization:** No sensitizing effects known.

- **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant

- **Carcinogenic categories**

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

64-17-5	Ethyl Alcohol	1
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- **NTP (National Toxicology Program)**

None of the ingredients is listed.

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

None of the ingredients is listed.

12 Ecological information

- **Toxicity**

- **Aquatic toxicity:**

64-17-5 Ethyl Alcohol

Algae Toxicity	1,000 mg/l (Algae)
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- **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 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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- **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:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| <ul style="list-style-type: none"> · UN-Number · DOT, ADN, IMDG, IATA | not regulated |
| <ul style="list-style-type: none"> · UN proper shipping name · DOT, ADN, IMDG, IATA | not regulated |
| <ul style="list-style-type: none"> · Transport hazard class(es) · DOT, ADN, IMDG, IATA · Class | not regulated |
| <ul style="list-style-type: none"> · Packing group · DOT, IMDG, IATA | not regulated |
| <ul style="list-style-type: none"> · Environmental hazards: | Not applicable. |
| <ul style="list-style-type: none"> · Special precautions for user | Not applicable. |
| <ul style="list-style-type: none"> · Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code | Not applicable. |
| <ul style="list-style-type: none"> · UN "Model Regulation": | not regulated |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

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

None of the ingredients is listed.

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

1344-28-1 | Aluminium Oxide

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

All ingredients are listed.

· **TSCA new (21st Century Act) (Substances not listed)**

2344-80-1 | Chloromethyltrimethylsilane

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· **Proposition 65**· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

64-17-5 Ethyl Alcohol

· **Carcinogenic categories**· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

1344-28-1 Aluminium Oxide

A4

64-17-5 Ethyl Alcohol

A3

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **GHS label elements** The product is classified and labeled according to the Globally Harmonized System (GHS).· **Hazard pictograms**

GHS07

· **Signal word** Warning· **Hazard statements**

Causes skin irritation.

Causes serious eye irritation.

· **Precautionary statements**

Wash thoroughly after handling.

Wear protective gloves / eye protection / face protection.

If on skin: Wash with plenty of water.

Specific treatment (see on this label).

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing.

If skin irritation occurs: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

If eye irritation persists: Get medical advice/attention.

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

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Regulatory Affairs· **Contact:** Customer Service· **Date of preparation / last revision** 03/28/2018 / -

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Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
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
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

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