

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.02.2024



Version number 3 (replaces version 2)

Revision: 07.02.2024

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name: COE-PAK Catalyst (AUTOMIX NDS)**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Auxillary for dental technology
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
GC EUROPE N.V.
Interleuvenlaan 33
B-3001 Leuven
Tel. +32/(0)16/74.10.00
Fax +32/(0)16/40.26.84
msds@gc.dental
- **Further information obtainable from:** Regulatory affairs
- **1.4 Emergency telephone number:**
National poison center for United Kingdom of Great Britain and Northern Ireland:
Belfast: +44 28 90 63 2032
Birmingham: +44 121 507 4123
Edinburgh: +44 131 242 1383
Newcastle Upon Tyne: +44 191 2606182/+44 191 2606180
Penarth: +44 292 071 55 54

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Eye Dam. 1 H318 Causes serious eye damage.
Aquatic Acute 1 H400 Very toxic to aquatic life.
Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB CLP regulation.
- **Exemptions**
The product, regulated as an invasive medical device by the Regulation (EC) 2017/745, is exempted from labelling requirements for substances and mixtures (according to the provision of the Art 1.5).
- **Hazard pictograms**
 
GHS05 GHS09
- **Signal word** Danger
- **Hazard-determining components of labelling:**
calcium dihydroxide

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 07.02.2024

Version number 3 (replaces version 2)

Revision: 07.02.2024

Trade name: COE-PAK_Catalyst_(AUTOMIX_NDS)

(Contd. of page 1)

- **Hazard statements**

H318 Causes serious eye damage.

H410 Very toxic to aquatic life with long lasting effects.

- **Precautionary statements**

P273 Avoid release to the environment.

P280 Wear 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.

P391 Collect spillage.

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

- **Additional information:**

Contains 4-chloro-3,5-dimethylphenol. May produce an allergic reaction.

- **2.3 Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**

- **Description:**

Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed. Information on the other substances that may be present can be obtained upon request.

- **Dangerous components:**

CAS: 1314-13-2 EINECS: 215-222-5 Index number: 030-013-00-7	zinc oxide ----- Aquatic Acute 1, H400; Aquatic Chronic 1, H410	25-<50%
CAS: 1305-62-0 EINECS: 215-137-3	calcium dihydroxide ----- Eye Dam. 1, H318; Skin Irrit. 2, H315; STOT SE 3, H335	5-<10%
CAS: 88-04-0 EINECS: 201-793-8 Index number: 604-038-00-4	4-chloro-3,5-dimethylphenol ----- Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	0.2-<0.5%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- **4.1 Description of first aid measures**

- **General information:**

Immediately remove any clothing soiled by the product.

If symptoms persist consult doctor.

- **After inhalation:**

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

Take affected persons into fresh air and keep quiet.

- **After skin contact:**

Seek medical treatment.

If skin irritation continues, consult a doctor.

(Contd. on page 3)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.02.2024

Version number 3 (replaces version 2)

Revision: 07.02.2024

Trade name: COE-PAK_Catalyst_(AUTOMIX_NDS)

(Contd. of page 2)

- **After eye contact:**
Protect unharmed eye.
Rinse opened eye for several minutes under running water.
Call a doctor immediately.
- **After swallowing:**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** Allergic reactions
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire extinguishing methods suitable to surrounding conditions.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **5.2 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.
- **5.3 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.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Remove persons from danger area.
Avoid contact with the eyes and skin.
Wear protective clothing.
- **6.2 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.
- **6.3 Methods and material for containment and cleaning up:**
Absorb liquid components with liquid-binding material.
Dispose of the material collected according to regulations.
- **6.4 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.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.

(Contd. on page 4)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.02.2024

Version number 3 (replaces version 2)

Revision: 07.02.2024

Trade name: COE-PAK_Catalyst_(AUTOMIX_NDS)

(Contd. of page 3)

Avoid contact with the eyes and skin.

- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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:** Keep container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients 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 valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
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
- **Respiratory protection:** Suitable respiratory protective device recommended.
- **Hand protection**



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/face protection**



Tightly sealed goggles

GB

(Contd. on page 5)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.02.2024

Version number 3 (replaces version 2)

Revision: 07.02.2024

Trade name: COE-PAK_Catalyst_(AUTOMIX_NDS)

(Contd. of page 4)

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Physical state	Fluid
· Colour:	According to product specification
· Odour:	Characteristic
· Odour threshold:	Not determined.
· Melting point/freezing point:	Undetermined.
· Boiling point or initial boiling point and boiling range	Undetermined.
· Flammability	Not applicable.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	Not applicable.
· Auto-ignition temperature:	Undetermined.
· Decomposition temperature:	Not determined.
· pH	Not determined.
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic at 20 °C:	730 mPas
· Solubility	
· water:	Insoluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density at 20 °C:	2.8 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.

· 9.2 Other information

· Appearance:	
· Form:	Pasty
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Solvent content:	
· VOC (EC)	0.0 g/l
· Change in condition	
· Evaporation rate	Not determined.

· Information with regard to physical hazard classes

· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void

(Contd. on page 6)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.02.2024

Version number 3 (replaces version 2)

Revision: 07.02.2024

Trade name: COE-PAK_Catalyst_(AUTOMIX_NDS)

(Contd. of page 5)

- | | |
|--|------|
| · Self-heating substances and mixtures | Void |
| · Substances and mixtures, which emit flammable gases in contact with water | Void |
| · Oxidising liquids | Void |
| · Oxidising solids | Void |
| · Organic peroxides | Void |
| · Corrosive to metals | Void |
| · Desensitised explosives | Void |

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

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

1305-62-0 calcium dihydroxide

Oral	LD50	7,340 mg/kg (rat (f+m))
------	------	-------------------------

88-04-0 4-chloro-3,5-dimethylphenol

Oral	LD50	3,830 mg/kg (rat (f+m))
------	------	-------------------------

- **Serious eye damage/irritation** Causes serious eye damage.
- **Additional toxicological information:**
- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
No further relevant information available.
- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

(Contd. on page 7)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.02.2024

Version number 3 (replaces version 2)

Revision: 07.02.2024

Trade name: COE-PAK_Catalyst_(AUTOMIX_NDS)

(Contd. of page 6)

· **12.6 Endocrine disrupting properties**

The product does not contain substances with endocrine disrupting properties.

· **12.7 Other adverse effects**· **Remark:** Very toxic for fish· **Additional ecological information:**· **General notes:**

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

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

Also poisonous for fish and plankton in water bodies.

Very toxic for aquatic organisms

SECTION 13: Disposal considerations· **13.1 Waste treatment methods**· **Recommendation**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packaging:**· **Recommendation:** Disposal must be made according to official regulations.**SECTION 14: Transport information**· **14.1 UN number or ID number**· **ADR, IMDG, IATA**

UN1760

· **14.2 UN proper shipping name**· **ADR**

1760 CORROSIVE LIQUID, N.O.S. (calcium dihydroxide), ENVIRONMENTALLY HAZARDOUS

· **IMDG**

CORROSIVE LIQUID, N.O.S. (calcium dihydroxide, zinc oxide), MARINE POLLUTANT

· **IATA**

CORROSIVE LIQUID, N.O.S. (calcium dihydroxide)

· **14.3 Transport hazard class(es)**· **ADR**· **Class**

8 (C9) Corrosive substances.

· **Label**

8

· **IMDG**· **Class**

8 Corrosive substances.

(Contd. on page 8)

Safety data sheet
according to 1907/2006/EC, Article 31


Printing date 07.02.2024

Version number 3 (replaces version 2)

Revision: 07.02.2024

Trade name: COE-PAK_Catalyst_(AUTOMIX_NDS)

(Contd. of page 7)

· Label	8
· IATA	
	
· Class	8 Corrosive substances.
· Label	8
· 14.4 Packing group · ADR, IMDG, IATA	II
· 14.5 Environmental hazards: · Marine pollutant:	No Symbol (fish and tree)
· Special marking (ADR):	Symbol (fish and tree)
· 14.6 Special precautions for user · Hazard identification number (Kemler code): · EMS Number: · Segregation groups · Stowage Category · Stowage Code	Warning: Corrosive substances. 80 F-A, S-B (SGG18) Alkalis B SW2 Clear of living quarters.
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· Transport category	2
· Tunnel restriction code	E
· IMDG	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1760 CORROSIVE LIQUID, N.O.S. (CALCIUM DIHYDROXIDE), 8, II, ENVIRONMENTALLY HAZARDOUS

SECTION 15: Regulatory information

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

- **Regulated explosives precursors**

None of the ingredients is listed.

(Contd. on page 9)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.02.2024

Version number 3 (replaces version 2)

Revision: 07.02.2024

Trade name: COE-PAK_Catalyst_(AUTOMIX_NDS)

(Contd. of page 8)

· **Regulated poisons**

None of the ingredients is listed.

· **Reportable explosives precursors**

None of the ingredients is listed.

· **Reportable poisons**

None of the ingredients is listed.

· **Directive 2012/18/EU**· **Named dangerous substances - ANNEX I** None of the ingredients is listed.· **Seveso category E1** Hazardous to the Aquatic Environment· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 100 t· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

· **Relevant phrases**

H302 Harmful if swallowed.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

· **Classification according to Regulation (EC) No 1272/2008** Calculation method· **Department issuing SDS:** Regulatory affairs· **Contact:** msds@gc.dental· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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)

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

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

· **Sources**· ECHA (<http://echa.europa.eu/>)· EnviChem (www.echemportal.org)

(Contd. on page 10)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.02.2024

Version number 3 (replaces version 2)

Revision: 07.02.2024

Trade name: COE-PAK_Catalyst_(AUTOMIX_NDS)

(Contd. of page 9)

*** 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 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.

GB