

Page 1/7

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

Printing date 03.08.2018

Version number 2

Revision: 20.01.2016

1.1 Product	identifier
1.2 Relevan	: <u>GC EXA'lence Regular, Putty-Base</u> t identified uses of the substance or mixture and uses advised against elevant information available.
	of the substance / the mixture Auxillary for dental technology
Manufactu GC EUROI Interleuven B-3001 Leu Tel. +32/(0	aan 33 Pen 16/74.10.00)16/40.26.84
1.4 Emerge National po Belfast: +4 Birminghan Edinburgh: Newcastle U	ormation obtainable from: Regulatory affairs ncy telephone number: ison center for United Kingdom of Great Britain and Northern Ireland: 28 90 63 2032 : +44 121 507 4123 +44 131 242 1383 ipon Tyne: +44 191 2606182/+44 191 2606180 4 292 071 55 54
2.1 Classifi Classificati Exempt froi	2: Hazards identification ation of the substance or mixture on according to Regulation (EC) No 1272/2008 a requirements - product regulated as a medical device or an in vitro diagnostic medical device. is not classified, according to the CLP regulation.

· 2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.
Hazard pictograms Void
Signal word Void
Hazard statements Void
Additional information:
Safety data sheet available on request.
2.3 Other hazards
Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

(Contd. on page 2)

GB

Printing date 03.08.2018

Version number 2

Revision: 20.01.2016

Trade name: GC EXA'lence Regular, Putty-Base

(Contd. of page 1)

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: 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:
-------------	-------------

Dungerous compon		
CAS: 8012-95-1	Paraffin oils	5-<10%
EINECS: 232-384-2	Asp. Tox. 1, H304; Aquatic Chronic 4, H413	
CAS: 68037-59-2	Methylhydrogen dimethylpolysiloxane	0.5-<1%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	

• 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:

No special measures required.

- If symptoms persist consult doctor.
- · After inhalation: Take affected persons into fresh air and keep quiet.
- · After skin contact: Immediately rinse with water.
- 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.

- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- 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.
- · 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.

(Contd. on page 3)

Printing date 03.08.2018

Version number 2

Revision: 20.01.2016

(Contd. of page 2)

Trade name: GC EXA'lence Regular, Putty-Base

· 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 No special precautions are necessary if used correctly.

- · 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: None.
- 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

• Additional information about design of technical facilities: No further data; see item 7.

· 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

- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals. Wash hands before breaks and at the end of work.

· Respiratory protection: 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.

(Contd. on page 4)

GB

Printing date 03.08.2018

Version number 2

Revision: 20.01.2016

(Contd. of page 3)

Trade name: GC EXA'lence Regular, Putty-Base

· Eye protection: Safety glasses

SECTION 9: Physical and chem	icai properties
9.1 Information on basic physical and c	hemical properties
General Information	
Appearance:	
Form:	Pasty
Colour:	According to product specification
Odour:	Odourless Not determined.
Odour threshold:	
pH-value:	Not determined.
Change in condition	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range	e: Undetermined.
Flash point:	Not applicable.
Flammability (solid, gas):	Not applicable.
Ignition temperature:	Undetermined.
Decomposition temperature:	Not determined.
Auto-ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapour pressure:	Not determined.
Density:	Not determined.
Relative density	Not determined.
Vapour 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:	
VOC (EC)	0.0 g/l
9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

(Contd. on page 5)

⁻ GB

Printing date 03.08.2018

Version number 2

Revision: 20.01.2016

Trade name: GC EXA'lence Regular, Putty-Base

(Contd. of page 4)

- · 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.
- \cdot 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 toxicological effects
- Acute toxicity Based on available data, the classification criteria are not met.
- · LD/LC50 values relevant for classification: No further relevant information available.
- Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Repeated dose toxicity No further relevant information available.
- CMR effects (carcinogenity, mutagenicity and toxicity for reproduction) No further relevant information available.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- Reproductive toxicity Based on available data, the classification criteria are not met.
- STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- Aspiration hazard Based on available data, the classification criteria are not met.

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.
- Additional ecological information:
- · General notes:
- Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for 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.
- · 12.5 Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · European waste catalogue

18 00 00 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care)

(Contd. on page 6)

GB

Printing date 03.08.2018

Version number 2

Revision: 20.01.2016

(Contd. of page 5)

Trade name: GC EXA'lence Regular, Putty-Base

18 01 00 wastes from natal care, diagnosis, treatment or prevention of disease in humans
 18 01 06* chemicals consisting of or containing dangerous substances

· Uncleaned packaging:

• **Recommendation:** Disposal must be made according to official regulations.

1 / 1 1121 21 1		
14.1 UN-Number ADR, ADN, IMDG, IATA	not regulated	
ADR, ADN, IMDO, IATA	ποι τεguiaiea	
14.2 UN proper shipping name ADR, ADN, IMDG, IATA	not regulated	
14.3 Transport hazard class(es)		
ADR, ADN, IMDG, IATA		
Class	not regulated	
14.4 Packing group		
ADR, IMDG, IATA	not regulated	
14.5 Environmental hazards:		
Marine pollutant:	No	
14.6 Special precautions for user	Not applicable.	
14.7 Transport in bulk according to Ann	ex II of	
Marpol and the IBC Code	Not applicable.	
UN "Model Regulation":	not regulated	

SECTION 15: Regulatory information

• 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

· Relevant phrases

H304 May be fatal if swallowed and enters airways.

- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H413 May cause long lasting harmful effects to aquatic life.
- · Classification according to Regulation (EC) No 1272/2008 Calculation method
- · Department issuing SDS: Regulatory affairs
- · Contact: msds@gc.dental
- · 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
- IATA: International Air Transport Association
- GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances

(Contd. on page 7)

GB

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

Printing date 03.08.2018

Version number 2

Revision: 20.01.2016

Trade name: GC EXA'lence Regular, Putty-Base

	(Contd. of page 6)
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	
Skin Irrit. 2: Skin corrosion/irritation – Category 2	
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3	
Asp. Tox. 1: Aspiration hazard – Category 1	
Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4	
· Sources	
• ECHA (http://echa.europa.eu/)	
• EnviChem (www.echemportal.org)	
• * Data compared to the previous version altered.	
This version replaces all previous versions.	
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or suggestions are made without any guarantee, representation or warranty, express or impli	
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complete, and we accordingly exclude all liability in connection with the use of this information	*
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limits our liability for death or personal injury caused by our negligence or for fraudulent misrepr	esentation.
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Page 1/7

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

Printing date 03.08.2018

Version number 2

Revision: 20.01.2016

SECTION 1: Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier · Trade name: GC EXA'lence Regular, Putty-Catalyst · 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 \cdot 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 *Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.* The product is not classified, according to the CLP regulation. · 2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008
Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.

Hazard pictograms Void
Signal word Void
Hazard statements Void
Additional information:
Safety data sheet available on request.

2.3 Other hazards
Results of PBT and vPvB assessment
PBT: Not applicable.

· **vPvB**: Not applicable.

(Contd. on page 2)

Printing date 03.08.2018

Version number 2

Revision: 20.01.2016

Trade name: GC EXA'lence Regular, Putty-Catalyst

(Contd. of page 1)

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: 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:

2 mger ous compone		
	Asp. Tox. 1, H304; Aquatic Chronic 4, H413	5-<10%
EINECS: 232-384-2		

• 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:

No special measures required.

If symptoms persist consult doctor.

- After inhalation: Take affected persons into fresh air and keep quiet.
- After skin contact: Immediately rinse with water.
- 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.

• 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

• 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.
- · 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. • 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.

(Contd. on page 3)

Printing date 03.08.2018

Version number 2

Revision: 20.01.2016

Trade name: GC EXA'lence Regular, Putty-Catalyst

(Contd. of page 2)

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 No special precautions are necessary if used correctly.
- · 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: None.
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- Additional information about design of technical facilities: No further data; see item 7.
- · 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
- · Personal protective equipment:
- General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals. Wash hands before breaks and at the end of work.

- · Respiratory protection: 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

(Contd. on page 4)

GR

Printing date 03.08.2018

Version number 2

Revision: 20.01.2016

Trade name: GC EXA'lence Regular, Putty-Catalyst

(Contd. of page 3)

0.1 Information on busic abusical and	
9.1 Information on basic physical and c General Information	chemical properties
Appearance:	
Form:	Pasty
Colour:	According to product specification
Odour:	Odourless
Odour threshold:	Not determined.
pH-value:	Not determined.
Change in condition	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range	e: Undetermined.
Flash point:	Not applicable.
Flammability (solid, gas):	Not applicable.
Ignition temperature:	Undetermined.
Decomposition temperature:	Not determined.
Auto-ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapour pressure:	Not determined.
Density:	Not determined.
Relative density	Not determined.
Vapour 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:	
Organic solvents:	0.0 %
VOC (EC)	0.0 g/l
9.2 Other information	No further relevant information available.

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.

(Contd. on page 5)

GB

Printing date 03.08.2018

Version number 2

Revision: 20.01.2016

(Contd. of page 4)

Trade name: GC EXA'lence Regular, Putty-Catalyst

- 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 toxicological effects
- Acute toxicity Based on available data, the classification criteria are not met.
- · LD/LC50 values relevant for classification: No further relevant information available.
- Primary irritant effect:
- Skin corrosion/irritation Based on available data, the classification criteria are not met.
- Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Repeated dose toxicity No further relevant information available.
- CMR effects (carcinogenity, mutagenicity and toxicity for reproduction) No further relevant information available.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- *Reproductive toxicity Based on available data, the classification criteria are not met.*
- STOT-single exposure Based on available data, the classification criteria are not met.
- STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

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.
- Additional ecological information:
- · General notes:

Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for 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.

- · 12.5 Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· European	waste catalogue
18 00 00	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except
	kitchen and restaurant wastes not arising from immediate health care)
18 01 00	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 06*	chemicals consisting of or containing dangerous substances

(Contd. on page 6)

GB

Printing date 03.08.2018

Version number 2

Revision: 20.01.2016

Trade name: GC EXA'lence Regular, Putty-Catalyst

(Contd. of page 5)

· Uncleaned packaging:

• *Recommendation: Disposal must be made according to official regulations.*

SECTION 14: Transport information		
14.1 UN-Number	not requilated	
ADR, ADN, IMDG, IATA	not regulated	
14.2 UN proper shipping name		
ADR, ADN, IMDG, IATA	not regulated	
14.3 Transport hazard class(es)		
ADR, ADN, IMDG, IATA		
Class	not regulated	
14.4 Packing group		
ADR, IMDG, IATA	not regulated	
14.5 Environmental hazards:		
Marine pollutant:	No	
14.6 Special precautions for user	Not applicable.	
14.7 Transport in bulk according to Ann	ex II of	
Marpol and the IBC Code	Not applicable.	
UN "Model Regulation":	not regulated	

SECTION 15: Regulatory information

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

SECTION 16: Other information

· Relevant phrases

H304 May be fatal if swallowed and enters airways. H413 May cause long lasting harmful effects to aquatic life.

- · Classification according to Regulation (EC) No 1272/2008 Calculation method
- · Department issuing SDS: Regulatory affairs

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 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

(Contd. on page 7)

[·] Contact: msds@gc.dental

[•] Abbreviations and acronyms:

GB

Printing date 03.08.2018

Version number 2

Revision: 20.01.2016

(Contd. of page 6)

GB

Trade name: GC EXA'lence Regular, Putty-Catalyst

Asp. Tox. 1: Aspiration hazard – Category 1

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard - Category 4

· Sources

• ECHA (http://echa.europa.eu/)

• EnviChem (www.echemportal.org)

• * Data compared to the previous version altered.

This version replaces all previous versions.

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