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

Printing date 21.09.2023

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Version number 3 (replaces version 2)

Revision: 21.09.2023

SECTION 1: Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier · Trade name: EXA'lence Regular/Fast, Heavy Body Rigid 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 • 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)16/40.26.84msds@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 The product is not classified, according to the GB CLP regulation. · 2.2 Label elements · Labelling according to Regulation (EC) No 1272/2008 Void · 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 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.

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Printing date 21.09.2023

Version number 3 (replaces version 2)

Revision: 21.09.2023

Trade name: EXA'lence_Regular/Fast,_Heavy_Body_Rigid_Catalyst

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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:

0 1			
CAS: 14808-60-7 EINECS: 238-878-4	Quartz	STOT RE 1, H372 substance with a Community workplace exposure limit	25-<50%
Additional the former of the East the second interaction of the line and a house a section of the section of the			

• 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: 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: If skin irritation continues, consult a 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.

• 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. 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. Wear protective clothing.

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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.

- · 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

· Ingredients with limit values that require monitoring at the workplace:

14808-60-7 Quartz

WEL Long-term value: 0.1 * mg/m³

respirable

• 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. Wash hands before breaks and at the end of work.

- Keep away from foodstuffs, beverages and feed.
- 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.

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^{· 8.1} Control parameters

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· 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 Safety glasses

SECTION 9: Physical and chemical properties

General Information Physical state	Fluid
Enysical state Colour:	According to product specification
Colour: Odour:	Odourless
Daour: Odour threshold:	Not determined.
	Undetermined.
Melting point/freezing point: Boiling point or initial boiling point and boiling ray	
Boiling point or initial boiling point and boiling ran Elammability	Not applicable.
Flammability Lower and unner explosion limit	Noi applicable.
Lower and upper explosion limit Lower:	Not determined.
	Not determined.
Upper: Elask a sint	
Flash point:	Not applicable.
Auto-ignition temperature:	Undetermined.
Decomposition temperature:	Not determined.
	Not determined.
Viscosity:	
Kinematic viscosity	Not determined.
Dynamic:	Not determined.
Solubility	T 1.1.
water:	Insoluble.
Partition coefficient n-octanol/water (log value)	Not determined.
Vapour pressure:	Not determined.
Density and/or relative density	
Density:	Not determined.
Relative density	Not determined.
Vapour density	Not determined.
9.2 Other information	
Appearance:	
Form:	Pasty
Important information on protection of health a	
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	···· 0· /
Evaporation rate	Not determined.
Information with regard to physical hazard classes	17 . 1
Explosives	Void
Flammable gases	Void
Aerosols	Void
Oxidising gases	Void

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Trade name: EXA'lence_Regular/Fast,_Heavy_Body_Rigid_Catalyst

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Gases under pressure	Void	
Flammable liquids	Void	
Flammable solids	Void	
Self-reactive substances and mixtures	Void	
Pyrophoric liquids	Void	
Pyrophoric solids	Void	
Self-heating substances and mixtures	Void	
Substances and mixtures, which emit flammal	ble 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: No further relevant information available.

• 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.
- 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.

 \cdot **STOT-single exposure** Based on available data, the classification criteria are not met.

 $\cdot \textit{STOT-repeated exposure Based on available data, the classification criteria are not met.}$

• Aspiration hazard Based on available data, the classification criteria are not met.

- Additional toxicological information:
- *Repeated dose toxicity No further relevant information available.*
- · CMR effects (carcinogenity, 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.

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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.
- · 12.6 Endocrine disrupting properties
- The product does not contain substances with endocrine disrupting properties.
- · 12.7 Other adverse effects
- 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.

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, 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 Maritime transport in bulk according instruments	g to IMO Not applicable.	
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· UN "Model Regulation":

not regulated

SECTION 15: Regulatory information

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

· Named dangerous substances - ANNEX I None of the ingredients is listed.

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

SECTION 16: Other information

Relevant phrases
H372 Causes damage to organs through prolonged or repeated exposure.
Classification according to Regulation (EC) No 1272/2008 Calculation method

- · Department issuing SDS: Regulatory affairs
- · Contact: msds@gc.dental

• Abbreviations and acronvms: 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 STOT RE 1: Specific target organ toxicity (repeated exposure) - Category 1 Sources • ECHA (http://echa.europa.eu/) • EnviChem (www.echemportal.org) • * Data compared to the previous version altered.

This version replaces all previous versions.

Disclaimer:

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[·] Directive 2012/18/EU



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Safety data sheet available on request.

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

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Trade name: EXA'lence_Regular/Fast,_Heavy_Body_Rigid_Base

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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:
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Dungerous compone		
	Quartz	10-<25%
EINECS: 238-878-4		
	substance with a Community workplace exposure limit	
CAS: 68037-59-2	Methylhydrogen dimethylpolysiloxane	5-<10%
	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: 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: If skin irritation continues, consult a 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.
- · 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. 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.

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SECTION 6: Accidental release measures

• 6.1 Personal precautions, protective equipment and emergency procedures Remove persons from danger area. 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.

· 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

· 8.1 Control parameters

· Ingredients with limit values that require monitoring at the workplace:

14808-60-7 Quartz

WEL Long-term value: 0.1* mg/m³ respirable

• 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. Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

· Respiratory protection: Suitable respiratory protective device recommended.

· Hand protection Protective gloves

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• Material of gloves

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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 Safety glasses

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SECTION 9: Physical and chemical properties

• 9.1 Information on basic physical and chemical prop	perties
· General Information	
· Physical state	Fluid
· Colour:	According to product specification
· Odour:	Odourless
• Odour threshold:	Not determined.
• Melting point/freezing point:	Undetermined.
• Boiling point or initial boiling point and boiling rang	
· 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:	Not determined.
· Solubility	
water:	Insoluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
Density and/or relative density	
Density:	Not determined.
Relative density	Not determined.
· Vapour density	Not determined.
• 9.2 Other information	
· Appearance:	
· Form:	Pasty
·Important information on protection of health ar	<i>nd</i>
environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
• Explosive properties:	Product does not present an explosion hazard.
· Solvent content:	
· <i>VOC (EC)</i>	0.0 g/l
· Change in condition	
· Evaporation rate	Not determined.
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Information with regard to physical hazard clo	ISSES	
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	
Self-heating substances and mixtures	Void	
Substances and mixtures, which emit flammal	ble 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: No further relevant information available.

• 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.

· 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.

• Additional toxicological information:

• *Repeated dose toxicity No further relevant information available.*

· CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

No further relevant information available.

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• 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.
- · 12.6 Endocrine disrupting properties
- The product does not contain substances with endocrine disrupting properties.
- 12.7 Other adverse effects
- 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.

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.

14.1 UN number or ID number	not normalistad	
· 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	

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Trade name: EXA'lence_Regular/Fast,_Heavy_Body_Rigid_Base

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· 14.6 Special precautions for user	Not applicable.			
· 14.7 Maritime transport in bulk according to IMO				
instruments	Not applicable.			
· UN "Model Regulation":	not regulated			

SECTION 15: Regulatory information

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

· Named dangerous substances - ANNEX I None of the ingredients is listed.

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

SECTION 16: Other information

· Relevant phrases

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H372 Causes damage to organs through prolonged or repeated exposure.

· 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

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

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2 STOT SE 2: Specific toget and toget togets (included)

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3 STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

· Sources

• ECHA (http://echa.europa.eu/)

• EnviChem (www.echemportal.org)

• * Data compared to the previous version altered.

This version replaces all previous versions.

Disclaimer:

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[·] Directive 2012/18/EU

⁽Contd. on page 8)

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Trade name: EXA'lence_Regular/Fast,_Heavy_Body_Rigid_Base

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