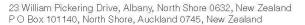


<u>Safety Data Sheet Cover-Sheet</u> – This page provides additional New Zealand specific information for this product, and must be read in conjunction with the Safety Data Sheet (SDS) attached.

Product Name:	Registrado Xtra
Manufacturer:	Voco
SDS Expiry:	16 December 2024
Supplier Details:	Henry Schein New Zealand 23 William Pickering Drive, Albany PO Box 101 140, North Shore, Auckland 0745 Ph. 0800 808 855 www.henryschein.co.nz
Emergency Contacts:	Poisons/Hazardous Chemical Info Centre – 0800POISON/0800764766 (24 Hours) Phone 111 for Fire, Ambulance or Police
HSNO Class/Category:	Non Hazardous
HSNO Group Standard:	Non Hazardous
Statements/Pictograms	: As per attached Safety Data Sheet (SDS)
Date Prepared:	This coversheet was prepared on 14 April 2020

This SDS coversheet has been produced by Henry Schein NZ and has been prepared in accordance with NZ EPA advice on making overseas SDS compliant to HSNO Act. The above information is based on the present state of our knowledge of the product at the time of publication. It is given in good faith, no warranty is implied with respect to the quality or the specifications of the product. Users must satisfy that the product is entirely suitable for their purpose. The SDS and this coversheet may be revised from time to time, please ensure you have a current copy.





Printing date 12/16/2019

Reviewed on 12/16/2019

# **1** Identification

- · Product identifier
- · Trade name: <u>Registrado x-tra/Clear Base</u>
- · Application of the substance / the mixture Bite registration
- Details of the supplier of the safety data sheet • Manufacturer/Supplier: VOCO GmbH Anton-Flettner-Str. 1-3

D-27472 Cuxhaven

- · Information department: Scientific department tel. +49 (0)4721-719-0
- Emergency telephone number: Scientific department tel. +49 (0)4721-719-0

## 2 Hazard(s) identification

Health effects are based on the unmixed/uncured material. Under FDA regulations this product is classified as a medical device. Medical devices are exempt from the labelling provisions of GHS according to the Hazard Communication Standard (HCS).

• *Classification of the substance or mixture The product is not classified according to the Globally Harmonized System (GHS).* 

- · Label elements
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Other hazards Use only for intended scope of application
- · Results of PBT and vPvB assessment
- *PBT:* Not applicable.
- · vPvB: Not applicable.

## 3 Composition/information on ingredients

• Chemical characterization: Mixtures

• Description: Mixture of non-hazardous substances.

· Dangerous components: Void

## 4 First-aid measures

- · Description of first aid measures
- General information: No special measures required.
- After inhalation: Seek medical treatment in case of complaints.
- After skin contact: Generally the product does not irritate the skin.
- · After eye contact: Rinse opened eye for several minutes under running water.
- · 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.

(Contd. on page 2)

Printing date 12/16/2019

Reviewed on 12/16/2019

(Contd. of page 1)

Trade name: Registrado x-tra/Clear Base

· Advice for firefighters

· Protective equipment: No special measures required.

#### 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* No dangerous substances are released.

#### 7 Handling and storage

· Handling:

- *Precautions for safe handling* For dental use only.
- 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: See storage instructions on package
- Specific end use(s) No further relevant information available.

#### 8 Exposure controls/personal protection

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

· Control parameters

• Components with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

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

· Exposure controls

- · Personal protective equipment:
- General protective and hygienic measures:
- The usual precautionary measures for handling chemicals should be followed.

Not determined.

- Breathing equipment: Not required.
- **Protection of hands:** Not required.
- Material of gloves Not required.

# 9 Physical and chemical properties

- · Information on basic physical and chemical properties
- General Information
- Appearance: Form:
  - Form:PastyColor:Different according to coloring
- Odor: Characteristic
- · pH-value:
- · Change in condition
- Melting point/Melting range: Undetermined.
- Boiling point/Boiling range: Undetermined.

(Contd. on page 3)

US

Printing date 12/16/2019

Reviewed on 12/16/2019

Trade name: Registrado x-tra/Clear Base

	(Co	ontd. of page 2)
· Flash point:	Not applicable.	
· Auto igniting:	Product is not selfigniting.	
• Danger of explosion:	Product does not present an explosion hazard.	
· Density:	Not determined.	
• Solubility in / Miscibility with Water:	Not miscible or difficult to mix.	
<ul> <li>Viscosity:</li> <li>Dynamic:</li> <li>Kinematic:</li> <li>Other information</li> </ul>	Not determined. Not determined. 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.

## **11 Toxicological information**

· Information on toxicological effects

· Acute toxicity:

Primary irritant effect:

• on the skin:

*Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured* • *on the eye:* No irritating effect.

- Sensitization: No sensitizing effects known.
- Additional toxicological information:

The product is not subject to classification according to internally approved calculation methods for preparations:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer)

None of the ingredients is listed

· 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: No further relevant information available.
- · Persistence and degradability No further relevant information available.

· Behavior in environmental systems:

· Bioaccumulative potential No further relevant information available.

(Contd. on page 4)

US

Printing date 12/16/2019

Reviewed on 12/16/2019

(Contd. of page 3)

Trade name: Registrado x-tra/Clear Base

- · *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.

- · 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**

14 ITunsport information		
· UN-Number · DOT, ADR, ADN, IMDG, IATA	Void	
· UN proper shipping name · DOT, ADR, ADN, IMDG, IATA	Void	
· Transport hazard class(es)		
· DOT, ADR, ADN, IMDG, IATA · Class	Void	
· Packing group · DOT, ADR, IMDG, IATA	Void	
• Environmental hazards: • Marine pollutant:	No	
· Special precautions for user	Not applicable.	
• Transport in bulk according to Annex MARPOL73/78 and the IBC Code	II of Not applicable.	
· UN "Model Regulation":	Void	

# **15 Regulatory information**

 $\cdot$  Safety, health and environmental regulations/legislation specific for the substance or mixture  $\cdot$  Sara

· Section 355 (extremely hazardous substances):

None of the ingredients are listed.

• Section 313 (Specific toxic chemical listings):

None of the ingredients are listed.

• TSCA (Toxic Substances Control Act):

crosslinker

polysiloxane

(Contd. on page 5)

Printing date 12/16/2019

· Proposition 65

Reviewed on 12/16/2019

(Contd. of page 4)

Trade name: Registrado x-tra/Clear Base

· Chemicals known to cause cancer:

None of the ingredients are listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients are listed

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients are listed

· Chemicals known to cause developmental toxicity:

None of the ingredients are listed

· Cancerogenity categories

· EPA (Environmental Protection Agency)

None of the ingredients are listed

• TLV (Threshold Limit Value established by ACGIH)

Contact VOCO for more information.

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

None of the ingredients are listed

• GHS label elements Void

• Hazard pictograms Void

- Signal word Void
- Hazard statements Void

#### **16 Other information**

The information contained herein is based on our present knowledge and is believed to be correct at the date issued. The information is subject to change without notice. However, all information, statements, recommendations or suggestions shall not constitute any guarantee, representation or warranty, expressed or implied.

Final determination whether the product is fit and suitable for a particular purpose and the user's method of use or application is the sole responsibility of the user.

· Department issuing SDS: Scientific department

· Contact: Tel.: +49 (0)4721-719-0

· Date of preparation / last revision: 12/16/2019 / 6

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)
- 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

\* \* Data compared to the previous version altered.

Printing date 12/16/2019

Reviewed on 12/16/2019

# **1** Identification

- · Product identifier
- · Trade name: Registrado x-tra/Clear Catalyst
- · Application of the substance / the mixture Bite registration
- Details of the supplier of the safety data sheet • Manufacturer/Supplier: VOCO GmbH Anton-Flettner-Str. 1-3

D-27472 Cuxhaven

- Information department: Scientific department tel. +49 (0)4721-719-0
- Emergency telephone number: Scientific department tel. +49 (0)4721-719-0

## 2 Hazard(s) identification

Health effects are based on the unmixed/uncured material. Under FDA regulations this product is classified as a medical device. Medical devices are exempt from the labelling provisions of GHS according to the Hazard Communication Standard (HCS).

• *Classification of the substance or mixture The product is not classified according to the Globally Harmonized System (GHS).* 

- · Label elements
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Other hazards Use only for intended scope of application
- · Results of PBT and vPvB assessment
- *PBT:* Not applicable.
- · vPvB: Not applicable.

## 3 Composition/information on ingredients

• Chemical characterization: Mixtures

• Description: Mixture of non-hazardous substances.

· Dangerous components: Void

## 4 First-aid measures

- · Description of first aid measures
- General information: No special measures required.
- After inhalation: Seek medical treatment in case of complaints.
- After skin contact: Generally the product does not irritate the skin.
- · After eye contact: Rinse opened eye for several minutes under running water.
- · 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.

(Contd. on page 2)

Printing date 12/16/2019

Reviewed on 12/16/2019

(Contd. of page 1)

Trade name: Registrado x-tra/Clear Catalyst

· Advice for firefighters

· Protective equipment: No special measures required.

#### 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* No dangerous substances are released.

#### 7 Handling and storage

· Handling:

- *Precautions for safe handling* For dental use only.
- 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: See storage instructions on package
- Specific end use(s) No further relevant information available.

#### 8 Exposure controls/personal protection

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

· Control parameters

• Components with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

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

· Exposure controls

- · Personal protective equipment:
- General protective and hygienic measures:
- The usual precautionary measures for handling chemicals should be followed.

Not determined.

- Breathing equipment: Not required.
- **Protection of hands:** Not required.
- · Material of gloves Not required.

# 9 Physical and chemical properties

- · Information on basic physical and chemical properties
- General Information
- · Appearance: Form:
  - Form:PastyColor:Different according to coloring
- Odor: Characteristic

· pH-value:

· Change in condition

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined.

(Contd. on page 3)

US

Printing date 12/16/2019

Reviewed on 12/16/2019

Trade name: Registrado x-tra/Clear Catalyst

	(Contd. of page 2)
131 °C (268 °F)	
Product is not selfigniting.	
Product does not present an explosion hazard.	
Not determined.	
Not miscible or difficult to mix.	
Not determined. Not determined. No further relevant information available.	
	Product is not selfigniting.         Product does not present an explosion hazard.         Not determined.         Not miscible or difficult to mix.         Not determined.

## **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.

## **11 Toxicological information**

· Information on toxicological effects

· Acute toxicity:

Primary irritant effect:

• on the skin:

*Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured* • *on the eye:* No irritating effect.

- Sensitization: No sensitizing effects known.
- Additional toxicological information:

The product is not subject to classification according to internally approved calculation methods for preparations:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer)

None of the ingredients is listed

· 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: No further relevant information available.
- · Persistence and degradability No further relevant information available.

· Behavior in environmental systems:

· Bioaccumulative potential No further relevant information available.

(Contd. on page 4)

US

Printing date 12/16/2019

Reviewed on 12/16/2019

(Contd. of page 3)

Trade name: Registrado x-tra/Clear Catalyst

• *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.

· 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**

11 ITansport information	
· UN-Number · DOT, ADR, ADN, IMDG, IATA	Void
· UN proper shipping name · DOT, ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· DOT, ADR, ADN, IMDG, IATA · Class	Void
· Packing group · DOT, ADR, IMDG, IATA	Void
• Environmental hazards: • Marine pollutant:	No
Special precautions for user	Not applicable.
• Transport in bulk according to Annex II MARPOL73/78 and the IBC Code	of Not applicable.
· UN "Model Regulation":	Void

# **15 Regulatory information**

 $\cdot$  Safety, health and environmental regulations/legislation specific for the substance or mixture  $\cdot$  Sara

· Section 355 (extremely hazardous substances):

None of the ingredients are listed.

• Section 313 (Specific toxic chemical listings):

None of the ingredients are listed.

• TSCA (Toxic Substances Control Act):

One or more substances contained in this material are not listed on the TSCA Inventory. Contact VOCO for more information.

(Contd. on page 5)

Printing date 12/16/2019

Reviewed on 12/16/2019

(Contd. of page 4)

Trade name: Registrado x-tra/Clear Catalyst

· Proposition 65
Troposition 05

· Chemicals known to cause cancer:

None of the ingredients are listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients are listed

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients are listed

· Chemicals known to cause developmental toxicity:

None of the ingredients are listed

· Cancerogenity categories

· EPA (Environmental Protection Agency)

None of the ingredients are listed

• TLV (Threshold Limit Value established by ACGIH)

Contact VOCO for more information.

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

None of the ingredients are listed

· GHS label elements Void

· Hazard pictograms Void

· Signal word Void

· Hazard statements Void

#### **16 Other information**

The information contained herein is based on our present knowledge and is believed to be correct at the date issued. The information is subject to change without notice. However, all information, statements, recommendations or suggestions shall not constitute any guarantee, representation or warranty, expressed or implied.

Final determination whether the product is fit and suitable for a particular purpose and the user's method of use or application is the sole responsibility of the user.

· Department issuing SDS: Scientific department

· Contact: Tel.: +49 (0)4721-719-0

· Date of preparation / last revision: 12/16/2019 / 6 • 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) 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 • \* Data compared to the previous version altered.