

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

071704592

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

071704568 071704576 071704584 071704600 071704618 071705011 071705219 071705227

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

071705003 071705029 071705037 071705052 071705078 071705086 071705201

**DENTSPLY/International  
DENTSPLY/Caulk  
Safety Data Sheet**

**507895**

**1. Identification**

Product Name <b>CALIBRA®</b>	SDS Code Number <b>507895</b>
Substance Identity <b>CALIBRA® Esthetic Resin Cement</b>	Date of Last Revision <b>05/16/13</b>
Manufacturer: <b>DENTSPLY Caulk</b>	Address <b>38 West Clarke Avenue Milford DE 19963-1805 <a href="http://www.caulk.com">http://www.caulk.com</a>    <a href="http://www.dentsply.com">http://www.dentsply.com</a></b>
Grades or Minor Variant Identities <b>Not Applicable</b>	Information Telephone Number <b>(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)</b>
Product Use (for Canada) <b>Dual Curing Dental Crown and Bridge Cement</b>	Emergency Telephone Number <b>(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)</b>

**2. Hazard(s) Identification**



**WARNING**

**CAUSES SKIN IRRITATION**

**Wash hands thoroughly after handling.**

**Wear protective gloves.**

**IF ON SKIN: Wash with plenty of soap and water.**

**If skin irritation occurs: Get Medical Advice/attention.**

**Take off contaminated clothing and wash before reuse.**

**3. Composition/Information on Ingredients – Base Paste**

Hazardous Components	C.A.S. Number	Exposure Limits	%
Barium boron fluoro alumino silicate glass	65997-18-4	10 mg/m <sup>3</sup>	< than 70
Bis-GMA	1565-94-2	Not Established	< than 20
Polymerizable dimethacrylate resins	24448-20-2/109-16-0	Not Established	< than 15
Hydrophobic Amorphous Silica	67762-90-7	3 mg/m <sup>3</sup>	< than 5

Other Information: Colorants are inorganic iron oxides and titanium dioxide.

**3. Composition/Information on Ingredients – Catalyst Paste**

Hazardous Components	C.A.S. Number	Exposure Limits	%
Barium boron fluoro alumino silicate glass	65997-18-4	10 mg/m <sup>3</sup>	< than 70
Bis-GMA	1565-94-2	Not Established	< than 20
Polymerizable dimethacrylate resins	24448-20-2/109-16-0	Not Established	< than 15
Hydrophobic Amorphous Silica	67762-90-7	3 mg/m <sup>3</sup>	< than 5
Benzoyl peroxide	94-36-0	5 mg/m <sup>3</sup>	< than 5

**4. First Aid Measures**

Routes of Exposure	First Aid Instructions	Immediate Medical Attention	Delayed Effects
Eye	Rinse opened eye for several minutes under running water. If symptoms persist consult physician	Not Applicable	Not Applicable
Skin	Immediately wash with soap and water and rinse thoroughly	Not Applicable	Not Applicable
Inhalation	Not Applicable	Not Applicable	Not Applicable
Ingestion	Not Applicable	Not Applicable	Not Applicable
Mucosa	Rinse tissue for several minutes under running water. If symptoms persist consult physician	Not Applicable	Not Applicable

Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically.

**5. Fire Fighting Measures**

Flame Propagation or Burning Rate (for Solids) Not Applicable	Properties Contributing to Fire Intensity Not Applicable	Flammability Classification: Not Applicable	Other: Not Applicable
Extinguishing Media: CO <sub>2</sub> , extinguishing powder, foam carbon dioxide or water spray. Fight larger fires with water spray or alcohol resistant foam.		Extinguishing Media to Avoid: Water with full jet.	
Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.			
Unusual Fire and Explosion Hazards: Formation of toxic, irritating gases is possible from the decomposition of the dimethacrylate resins. Product does not present an explosion hazard.			

## 6. Accidental Release Measures

Containment Techniques: Material is a paste and as such will not flow.		
Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container. Avoid gross skin contact to minimize the possibility of contact dermatitis to susceptible persons. Ensure adequate ventilation.		
Evacuation Procedures: Not Applicable	Special Instructions: Not Applicable	Reporting Requirements: Not Applicable

## 7. Handling and Storage

Handling Practices and Warnings: Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals.
Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Protect from exposure to direct light. Store away from food and beverages.

## 8. Exposure Control / Personal Protection



Occupational Exposure Limits: Not Applicable		
Engineering Controls: Not Applicable		
Individual Protection Measures	Personal Protective Equipment for Normal Use	Personal Protective Equipment for Emergencies
Eye/Face	Safety Glasses	Not Applicable
Skin	The glove material has to be impermeable and resistant to the product.	Not Applicable
Inhalation	Not Required	Not Applicable
Body Protection	Protective work clothing	Not Applicable

## 9. Physical and Chemical Characteristics

Appearance: Creamy viscous paste. Multiple shades.		Odor: Characteristic sweet acrylic ester odor.
Normal Physical State: High Viscosity Liquid (Paste)		Melting Point: Not Applicable
Specific Gravity: 1.8 g/cm <sup>3</sup>	Solubility in Water: Not soluble	pH: Not Applicable
Vapor Pressure (mm Hg): Not Applicable	Vapor Density (AIR=1): Not Applicable	Evaporation Rate (Butyl Acetate =1): Not Applicable
Flashpoint Method: Not Applicable	Flammable (Explosive) Limits in Air LEL: Not Applicable UEL: Not Applicable	Autoignition Temperature: Not Applicable, Product will not autoignite.
Other: Not Applicable		

## 10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Strong Oxidizing materials.		
Hazardous Products Produced During Decomposition: No dangerous decomposition products known if used according to Directions for Use.		
Hazardous Polymerization: <input type="checkbox"/> May Occur <input checked="" type="checkbox"/> May Not Occur	Conditions to Avoid: None known	
Stability? <input checked="" type="checkbox"/> Stable <input type="checkbox"/> Unstable	Conditions to Avoid: None known	

## 11. Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data: Product is an irritant to the skin and mucous membranes. The unpolymerized product may be an irritant to the skin in susceptible persons. On the eye the product has an irritating effect. Sensitization: Repeated or prolonged contact with the unpolymerized material may cause sensitization for persons allergic to acrylates and methacrylates. This product shows the following dangers according to internally approved calculation methods for composite materials: Irritant.					
Emergency Overview Material is irritating to eyes, respiratory system and skin.					
Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s)	Target Organ(s)
Eye	Material can cause irritation.	Single	Moderate	Irritation and possible corneal damage	Not Applicable
Skin	Material may be an irritant	Single & Repeated	Moderate	Irritation or possible allergic response. Severe allergic response may result in breathing difficulties.	Not Applicable
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Ingestion	Material is not harmful if swallowed using clinically relevant quantities	Not Applicable	Mild	Not Applicable	Not Applicable

Mucosa	Material can cause irritation.	Single	Mild	Inflammation of the mucosa	Not Applicable
Medical Conditions Aggravated by Exposure Open sores and wounds of the skin. Individuals with known sensitivity to methacrylates, acrylates, or urethane dimethacrylate resin used in Dental restorative products.					
Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.					
Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.					
NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 1, Reactivity = 0					

## 12. Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water streams or sewage system.

## 13. Disposal Considerations

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

Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations

Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.

## 14. Transport Information

Regulated for Shipping: No. Not Regulated	DOT Shipping Name: Not Regulated	Packing Group: Not Applicable
Do Changes in Quantities, packaging, or shipment method change product classification? No	DOT Hazard Class: Not Applicable	UN Number: Not Applicable

## 15. Regulatory Information

This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations.

U.S. Federal Regulations: CERCLA 103 Reportable Quantity: This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations

Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None

Section 302 Extremely Hazardous Substances (TPQ): None

EPA Toxic Substances Control Act (TSCA) Status: All of the components of this product are listed on the TSCA inventory.

U.S. State Regulations California Proposition 65: This product does not contain any chemicals, which are on the California Proposition 65 list.

International Regulations: Canadian Environmental Protection Act:

This product is a medical device and not subject to chemical notification requirements.

European Community Labeling: Not a dangerous preparation.

European Inventory of New and Existing Chemicals Substances (EINECS):

This product is a medical device and not subject to chemical notification requirements.

Other: Not Applicable

## 16. Other Information

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex.

All components are synthetically produced; none are derived from animal products.

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

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer. For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

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

- **1.1 Product identifier**
- **Trade name:** Calibra Catalyst
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** Esthetic Resin Cement
- **Uses advised against** No further relevant information available.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
DENTSPLY DeTrey GmbH  
De-Trey-Str. 1  
D-78467 Konstanz  
GERMANY  
Tel.: +49-(0)7531-583-0  
Fax: +49-(0)7531-583-104  
email: KonstanzDEU.info-sdb@dentsplysirona.com
- **Further information obtainable from:**
  - Departement Research & Development for technical information
  - Departement Marketing & Sales for distribution of the safety data sheets
- **1.4 Emergency telephone number:** +49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)

## **SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
  - Skin Irrit. 2 H315 Causes skin irritation.
  - Eye Irrit. 2 H319 Causes serious eye irritation.
  - Skin Sens. 1 H317 May cause an allergic skin reaction.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**  
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)]bismethacrylate  
Ethoxylated Bisphenol A Dimethacrylate  
2,2'-ethylenedioxydiethyl dimethacrylate  
dibenzoyl peroxide
- **Hazard statements**  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H317 May cause an allergic skin reaction.
- **Precautionary statements**
  - P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
  - P280 Wear protective gloves / 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.
  - P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
  - P337+P313 If eye irritation persists: Get medical advice/attention.
  - P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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**Trade name:** Calibra Catalyst

(Contd. of page 1)

· **Additional information:**

As this product is a medical device in the meaning of Directive 93/42/EEC and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation (EC) 1272/2008.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

**SECTION 3: Composition/information on ingredients**

· **3.2 Chemical characterisation: Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 1565-94-2 EINECS: 216-367-7	(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	10 – 25%
CAS: 24448-20-2	Ethoxylated Bisphenol A Dimethacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	10 – 25%
CAS: 109-16-0 EINECS: 203-652-6	2,2'-ethylenedioxydiethyl dimethacrylate Skin Sens. 1, H317	2.5 – 10%
CAS: 94-36-0 EINECS: 202-327-6	dibenzoyl peroxide Org. Perox. B, H241; Eye Irrit. 2, H319; Skin Sens. 1, H317	≥ 0.1 – ≤ 1%

· **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**

· **After inhalation** Supply fresh air; consult doctor in case of complaints.

· **After skin contact** Immediately wash with water and soap and rinse thoroughly.

· **After eye contact**

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

· **After swallowing**

If symptoms persist consult doctor.

Rinse out mouth and then drink plenty of water.

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

· **Information for doctor** 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**

CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

· **For safety reasons unsuitable extinguishing agents** Water with full jet.

· **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

· **5.3 Advice for firefighters**

· **Protective equipment:** Self-contained respiratory protective device.

**Trade name: Calibra Catalyst**

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### **SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Pick up mechanically.  
Ensure adequate ventilation.  
Dispose contaminated material as waste according to item 13.
- **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** Observe normal care for working with chemicals.
- **Handling** Product is intended for dental use only.
- **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 the original receptacle.  
Information about storage in one common storage facility: Store away from oxidising agents.  
Further information about storage conditions:  
Keep receptacle tightly sealed.  
Protect from heat and direct sunlight.
- **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:**

CAS: 94-36-0 dibenzoyl peroxide

WEL Long-term value: 5 mg/m<sup>3</sup>

- **Regulatory information** WEL: EH40/2011
- **Additional information:** The lists valid during the making were used as basis.

#### **8.2 Exposure controls**

##### **Personal protective equipment**

##### **General protective and hygienic measures**

Keep away from foodstuffs, beverages and feed.  
Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of work.  
Avoid contact with the eyes and skin.

- **Respiratory protection:** Not necessary if room is well-ventilated.

##### **Protection of hands:**



Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

(Contd. on page 4)

**Trade name: Calibra Catalyst**

(Contd. of page 3)

· **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.

Natural rubber, NR

Recommended thickness of the material:  $\geq 0.12$  mm

Permeation: Level  $\geq 1$

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**



Tightly sealed goggles.

· **Body protection: Protective work clothing.**

## SECTION 9: Physical and chemical properties

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

· **General Information**

· **Appearance:**

Form:	Pasty
Colour:	Various colours
Odour:	Product specific
Odour threshold:	Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/freezing point:	undetermined
Initial boiling point and boiling range:	Undetermined.

· **Flash point:** Not applicable

· **Flammability (solid, gaseous)** Not determined.

· **Ignition temperature:** Not applicable

· **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 applicable.

Density:	Not determined
Relative density	Not determined.
Vapour density	Not applicable.
Evaporation rate	Not applicable.

· **Solubility in / Miscibility with Water:** Insoluble

· **Partition coefficient: n-octanol/water:** Not determined.

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**Trade name: Calibra Catalyst**

(Contd. of page 4)

- |                                |  |
|--------------------------------|--|
| · <b>Viscosity:</b>            |  |
| dynamic:                       | Not applicable.                            |
| kinematic:                     | Not applicable.                            |
| · <b>Solvent content:</b>      |  |
| Organic solvents:              | 0.0 %                                      |
| Solids content:                | 60.0 %                                     |
| · <b>9.2 Other information</b> | 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
- **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:**

**CAS: 1565-94-2 (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)]bismethacrylate**

Oral	LD50	> 5,000 mg/kg (rat)
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**CAS: 109-16-0 2,2'-ethylenedioxydiethyl dimethacrylate**

Oral	LD50	> 5,000 mg/kg (rat)
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Dermal	LD50	> 2,000 mg/kg (mouse)
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**CAS: 94-36-0 dibenzoyl peroxide**

Oral	LD50	7,710 mg/kg (rat)
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- **Primary irritant effect:**
- **Skin corrosion/irritation**  
Causes skin irritation.
- **Serious eye damage/irritation**  
Causes serious eye irritation.
- **Respiratory or skin sensitisation**  
Repeated or prolonged contact with the not polymerized product may cause sensitization for acrylates / methacrylates.  
May cause an allergic skin reaction.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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.

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Trade name: Calibra Catalyst

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**SECTION 12: Ecological information**

## · 12.1 Toxicity

## · Aquatic toxicity:

CAS: 109-16-0 2,2'-ethylenedioxydiethyl dimethacrylate

LC50/96h 16.4 mg/l (Fish acute toxicity study)

EC50/72h &gt; 100 mg/l (Pseudokirchnerella subcapitata)

## · 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:

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

## · 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

## · Recommendation



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

## · European waste catalogue

18 01 06\* chemicals consisting of or containing hazardous substances

HP 4 Irritant - skin irritation and eye damage

HP 13 Sensitising

## · Uncleaned packaging:

## · Recommendation: Disposal must be made according to official regulations.

**SECTION 14: Transport information**

## · 14.1 UN-Number

· ADR, ADN, IMDG, IATA

Void

## · 14.2 UN proper shipping name

· ADR, ADN, IMDG, IATA

Void

## · 14.3 Transport hazard class(es)

· ADR, ADN, IMDG, IATA

· Class

Void

## · 14.4 Packing group

· ADR, IMDG, IATA

Void

## · 14.5 Environmental hazards:

Not applicable.

## · 14.6 Special precautions for user

Not applicable.

(Contd. on page 7)

**Trade name: Calibra Catalyst**

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- |  |                 |
|--|-----------------|
| <b>· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable. |
| <b>· UN "Model Regulation":</b>  | Void            |

### **SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **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**

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

*The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.*

*For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.*

- **Relevant phrases**
  - H241 Heating may cause a fire or explosion.
  - H315 Causes skin irritation.
  - H317 May cause an allergic skin reaction.
  - H319 Causes serious eye irritation.
  - H335 May cause respiratory irritation.
- **Department issuing SDS:** Research & Development
- **Contact:** HotLine for urgent technical support: +49-7531-583-350
- **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
  - ELINCS: European List of Notified Chemical Substances
  - CAS: Chemical Abstracts Service (division of the American Chemical Society)
  - LC50: Lethal concentration, 50 percent
  - LD50: Lethal dose, 50 percent
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative
  - Org. Perox. B: Organic peroxides – Type B
  - Skin Irrit. 2: Skin corrosion/irritation – Category 2
  - 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
- **\* Data compared to the previous version altered.**