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

Printing date 15.04.2019 *Version number 1* *Revision: 15.04.2019*

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

· **1.1 Product identifier**

· **Trade name:** **Neo Spectra ST HV**
Neo Spectra ST LV
Neo Spectra ST Effects

· **Application:** Light curing composite
· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
· **Application of the substance / the mixture** Dental filling material
· **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:**
Ethoxylated Bisphenol A Dimethacrylate
Urethane modified Bis-GMA dimethacrylate resin
2,2´-ethylenedioxydiethyl dimetharcylate
· **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.

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P337+P313 *If eye irritation persists: Get medical advice/attention.*
P501 *Dispose of contents/container in accordance with local/regional/national/international regulations.*

· ***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: 41637-38-1	*Ethoxylated Bisphenol A Dimethacrylate* *Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335*	*2.5-<10%*
CAS: 126646-17-1	*Urethane modified Bis-GMA dimethacrylate resin* *Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335*	*2.5-<10%*
CAS: 109-16-0 *EINECS: 203-652-6*	*2,2´-ethylenedioxydiethyl dimetharcylate* *Skin Sens. 1, H317*	*2.5-<10%*
CAS: 13760-80-0 *EINECS: 237-354-2*	*ytterbium trifluoride* *Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335*	*2.5-<10%*
CAS: 128-37-0 *EINECS: 204-881-4*	*2,6-di-tert-butyl-p-cresol* *Aquatic Acute 1, H400; Aquatic Chronic 1, H410*	*0.1-<0.25%*

· ***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.*
· ***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***
CO2, 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***
Formation of toxic gases is possible during heating or in case of fire.

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· **5.3 Advice for firefighters**
· **Protective equipment:** No special measures required.

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

· **DNELs**		
CAS: 128-37-0 2,6-di-tert-butyl-p-cresol		
Inhalative	DNEL Werte	3.5 mg/m³ bw/day (rat)

· **Additional information:** The lists valid during the making were used as basis.

· **8.2 Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures**
Wash hands before breaks and at the end of work.
The usual precautionary measures are to be adhered to when handling chemicals.
Avoid contact with the eyes and skin.
· **Respiratory protection:** Not necessary if room is well-ventilated.

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· ***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

· ***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
Permeation: Level ≥1
Recommended thickness of the material: ≥ 0.12 mm

· ***Penetration time of glove material***
The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· ***Eye protection:*** *Safety glasses*

· ***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:	*According to product specification*
· ***Odour:***	*Characteristic*
· ***Odour threshold:***	*Not determined.*
· ***pH-value:***	*Not determined.*
· ***Change in condition***	
Melting point/freezing point:	*undetermined*
Initial boiling point and boiling range:	*Undetermined.*
· ***Flash point:***	*Not applicable*
· ***Flammability (solid, gaseous)***	*Not applicable.*
· ***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 determined.*
· ***Density:***	*Not determined*
· ***Relative density***	*Not determined.*
· ***Vapour density***	*Not determined.*

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· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with Water:**	Not miscible or difficult to mix
· **Partition coefficient: n-octanol/water:**	Not determined.
· **Viscosity:**	
dynamic:	Not determined.
kinematic:	Not determined.
· **Solvent content:**	
Organic solvents:	0.0 %
Solids content:	80.0 %
· **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
· **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: 109-16-0 2,2´-ethylenedioxydiethyl dimetharcylate		
Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (mouse)
CAS: 128-37-0 2,6-di-tert-butyl-p-cresol		
Oral	LD50	2,930 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rabbit)

· **Primary irritant effect:**
· **Skin corrosion/irritation**
The unpolymerized product may be irritant to the skin for succeptible persons.
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 (carcinogenity, 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.

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

SECTION 12: Ecological information

· ***12.1 Toxicity***

· ***Aquatic toxicity:***	
CAS: 109-16-0 2,2´-ethylenedioxydiethyl dimetharcylate	
LC50/96h	*16.4 mg/l (Fish acute toxicity study)*
EC50/72h	*>100 mg/l (Pseudokirchnerella subcapitata)*
CAS: 128-37-0 2,6-di-tert-butyl-p-cresol	
LC50/48h	*>0.57 mg/l (daphnia magna)*
LC50/96h	*>0.42 mg/l (Fish acute toxicity study)*
EC50/72h	*>0.42 mg/l (Algea, gowth inhibition test)*

· ***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 product 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*

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· **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.
· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	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.
· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
· **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**
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
· **Classification according to Regulation (EC) No 1272/2008** Calculation method

· **Department issuing SDS:** 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)
DNEL: Derived No-Effect Level (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

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