















	MATERIAL SAFETY DATA SHEET	FS-281
	CLINIC LINE	
	According to Regulation No. 1984/2012 (REACH)	
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1 IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING	
Product name	NOVA CAPS
Chemical formula	Contains Mercury
Recommended use	Dental filling material
Manufacturer	President Dental Gmbh Zehenstadelweg 7 , 81247 Munchen GERMANY Tel : +49 89 127 660 240 Fax : +49 89 127 660 269
Emergency telephone number	+49 89 127 660 268

2 HAZARDS IDENTIFICATION					
Classification	91/155/CE: T, R23, R33, N, R50/53 CLP: Repr 1B, Acute Tox 2, STOT RE 1, Aquatic Acute 1, Aquatic Chronic 1. H360D, H330, H372, H400, H410.				
Labelling	<table border="0" style="width: 100%;"> <tr> <td style="width: 50%; text-align: center;">  Danger (GHS06) </td> <td style="width: 50%; text-align: center;">  Danger (GHS08) </td> </tr> <tr> <td style="width: 50%; text-align: center;">  Danger (GHS09) </td> <td style="width: 50%; text-align: center;">  Toxic by inhalation  Toxic to aquatic organisms </td> </tr> </table>	 Danger (GHS06)	 Danger (GHS08)	 Danger (GHS09)	 Toxic by inhalation  Toxic to aquatic organisms
 Danger (GHS06)	 Danger (GHS08)				
 Danger (GHS09)	 Toxic by inhalation  Toxic to aquatic organisms				
Human health hazards	91/155/CE: R61- May cause harm to the unborn child. Also very toxic by inhalation. R48/23- Toxic: danger of serious damage to health by prolonged exposure through inhalation. CLP: H360D: May damage fertility or the unborn child. Exposition route: Inhalation H330: Fatal if inhaled. H372: Causes damage to organs through prolonged or repeated exposure. Route of exposure: Inhalation				
Environmental hazards	91/155/CE R50-53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. CLP: H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects.				

Drafted: RC	Revised	DT	Approved	DT	COPY	Date
					Non controlled	No.
Date: 30.09.2013					Assigned to :	

 <p>President Dental Germany</p>	MATERIAL SAFETY DATA SHEET	FS-281
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3 COMPOSITION INFORMATION ON INGREDIENTS				
Substance/preparation	I spill: alloy/mercury 400/377 mg II spill: alloy/mercury: 600/565 mg III spill: alloy/mercury: 800/753 mg			
Chemical name	Cas number	%	EC Number	Classification
Mercury	7439-97-6	100	231-106-7	T, R23, R33, N, R50753 H360D, H330, H372, H400, H410

4 FIRST AID MEASURES	
Inhalation	Allow the victim to rest in a well-ventilated area. Get medical attention immediately.
Ingestion	Have conscious person drink several glasses of water or milk. Get medical attention immediately. Subsequently administer: activated charcoal (20 - 40 g in 10 % slurry).
Skin contact	Wash contaminated skin with soap and water. Remove contaminated clothing and shoes.
Eye contact	Check for and remove any contact lenses. Rinse with plenty of running water. Seek medical attention.
Notes to physician	Call local Poison Control: Center for assistance.
Protection of first-aiders	Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective occupational exposure limits. Wear special protective clothing and positive pressure, self-contained breathing apparatus.

*See section 11 for more detailed information on health effects and symptoms.


5 FIRE-FIGHTING MEASURES	
Suitable extinguishing media	Use extinguishing media suitable for surrounding materials.
Hazardous thermal decomposition products	Mercury vapor.
Special protective equipment for fire-fighters	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.
Remark	None

6 ACCIDENTAL RELEASE MEASURES	
Personal precautions	Small spill and leak Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective occupational exposure limits.
Environmental precautions	Do not allow to enter drains or watercourses.
Methods for cleaning up	<u>Small spill</u> Small droplets of spilled Mercury can be collected with the aid of a 'Mercury-collecting forceps' or a small amount of freshly mixed amalgam. That will easily absorb liquid Mercury. NEVER use a vacuum-cleaner! <u>Large spill</u> Evacuate surrounding areas. Do not clean up spills or dispose of, except under supervision of a specialist. Consult your local or regional authorities.

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7 HANDLING AND STORAGE	
Handling	<p>Recommendations for safety precaution.</p> <p>Dental clinical personnel, when using silver amalgam, should exercise procedures to avoid personal contact with Mercury. Precaution should be taken to avoid exposure to Mercury vapour in the dental environment. Waste amalgam should be collected for disposal in a manner which will protect both those who handle the waste and the environment:</p> <ol style="list-style-type: none"> 1 Treat mercury and amalgam with care. Be MERCURY AWARE. 2 Handling of mercury and mixing of amalgam should be done on a separate section of the working table (not close to a source of heat), with raised edges on all sides. This will prevent any spilled Mercury spreading and will facilitate its recovery. The surgery floor should be smooth, without cracks and the surgery well ventilated. 3 Ideally a high-energy mixer should be equipped with a protective cap to cover the capsule whilst mixing. 4 Small droplets of spilled Mercury can be collected with the aid of a 'Mercury collecting forceps' or a small amount of freshly mixed amalgam. That will easily absorb liquid Mercury. NEVER use a vacuum-cleaner! 5 Removal of amalgam fillings must be done under water cooling and with effective suction. The use of eye protection and mouth mask is advisable. 6 The waste water drain of the spittoon should be equipped with an amalgam separator. Local regulations on the type and installation of such separator and handling/recycling of the amalgam waste should be taken in consideration. For details see for example JADA, august 2003, KEVIN R. MACMANUS, M.A., M.B.A.; P.L. FAN, Ph.D. "Purchasing, installing and operating dental amalgam separators, Practical issues". 7 Excess mixed amalgam should be kept in a special 'Mercontainer' or at least in a closed container filled with photographic fixer. 8 Empty capsules may retain product residues and can be hazardous.
Storage	Store in a dry, cool and well-ventilated area.
Recommended packing materials	Use original container.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION	
Exposure limit values (Spanish law)	
Mercury, vapour (CAS No. 7439-97-8)	
Limit admitted value (VLA): 0,02 mg/m ³ 8 hours – 0,15 mg/m ³ g 15 minutes	
EU OEL (Europe) TWA: 0,02 mg/mm ³ 8 hours	
Recommended monitoring procedures	Dräger Mercury vapor detection tube
Occupational exposure controls	Use only with adequate ventilation
Respiratory protection	Ventilation is normally required when handling or using this product.
Hand protection	<p>Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.</p> <p>4-8 hours (breakthrough time): nitrile rubber 1-4 hours (breakthrough time): PVC butyl rubber</p>
Eye protection	Safety glasses with side-shields
Environment exposure controls	Avoid release to the environment. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. No special protection is required.


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9 PHYSICAL AND CHEMICAL PROPERTIES	
Physical state	Liquid (Silvery)
Color	Silvery
Odor	Odorless
pH	NA
Boiling point	357 °C (674,6 °F)
Melting point	- 39 °C (-38,2 °F)
Oxidizing properties	NA
Vapor pressure	0,0002 kPa (0,002 mm Hg)
Density (20 °C – 68 °F)	13,6 g/cm ³ .
Solubility	Insoluble in the following materials: cold water
Octanol/water partition coefficient	The product is more soluble in octanol; log(octanol/water) = 4.5
Viscosity	Not established
Vapor density	6,9 (Air =1)

10 STABILITY AND REACTIVITY	
Chemical stability	The product is stable
Conditions to avoid	Keep away from heat and flame. Avoid release to the environment.
Hazardous decomposition products	Mercury vapour

11 INFORMACIÓN TOXICOLÓGICA				
Inhalation	R26- Very toxic by inhalation. R61- May cause harm to the unborn child. H360D: May damage fertility or the unborn child. Exposition route: Inhalation H330: Fatal if inhaled.			
Skin irritation	No known significant effects or critical hazards			
Chronic toxicity	R48/23- Toxic: danger of serious damage to health by prolonged exposure through inhalation. H372: Causes damage to organs through prolonged or repeated exposure. Route of exposure: Inhalation			
Developmental effects	R61- May cause harm to the unborn child. H360D: May damage fertility or the unborn child. Exposition route: Inhalation			
Product name	Result	Species	Dose	Exposure
Mercury	LCLo Inhalation vapour	Rabbit	29 mg/mm ³	24 hours





12 ECOLOGICAL INFORMATION	
Ecotoxicity	R50-53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects.

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13 DISPOSAL CONSIDERATIONS

Methods of disposal	Dispose of this material and its container at hazardous or special waste collection point.
European waste catalogue (EWC)	18 01 10* amalgam waste from dental care
Hazardous waste	Amalgam waste from dental care The classification of the product may meet the criteria for a hazardous waste


14 TRANSPORT INFORMATION

Regulatory Information	UN Number	Proper shipping name	Classes	Packing group	Label	Additional information
ADR/RID Class	2809	Mercury (metal) (Mercury)	8	III		Classification Code C9 Packaging instructions:P800
AND Class	2809	Mercury (metal) (Mercury)	8	III		
IMDG Class	2809	Mercury (metal) (Mercury)	8	III		Packaging instructions:P800
IATA-DGR Class	2809	Mercury (metal) (Mercury)	8	III		Packaging instructions:803

IMPORTANT: These notes only apply to the mercury when is shipped in bulk and not predosed into amalgam capsules.

15 REGULATORY INFORMATION

Hazard Symbol or symbols	91/155/CE: Toxic, Dangerous to the environment CLP: GHS06, GHS08, GHS09, Dgr
91/155/CE	
Risk Phrases	R26- Very toxic by inhalation. R50/53- Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R61- May cause harm to the unborn child. R48- Danger of serious damage to health by prolonged exposure.
Safety Phrases	S53- Avoid exposure - obtain special instructions before use. S45- In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). S60- This material and its container must be disposed of as hazardous waste. S61- Avoid release to the environment. Refer to special instructions/safety data sheet.
CLP	
H Phrases	H360D: May damage fertility or the unborn child. Exposition route: Inhalation H330: Fatal if inhaled. H372: Causes damage to organs through prolonged or repeated exposure. Route of exposure: Inhalation H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects.
P Phrases	P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood. P260: Do not breathe the vapours P264: Wash your hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P271: Use only outdoors or in a well-ventilated area. P273: Avoid release to the environment. P281: Use personal protective equipment as required. P284: In case of inadequate ventilation wear respiratory protection. P304+340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

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	P308+313: IF exposed or concerned: Get medical advice/attention. P310: Immediately call a POISON CENTER or doctor/physician. P320: Specific treatment (see this label). P391: Collect spillage. P403+233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of contents/container according to local regulations
Contains	Mercury
Product use	Dental filling material

16 OTHER INFORMATIONS

The information contained in this MSDS is additional to the technical instructions of use, but does not substitute the same.

This information included here is based on the knowledge and experience related to the safety of the materials, if they are used in an appropriate manner, and on the MSDS received from the producers of the raw materials used in the formulation of this product.

The user is obliged to know and apply the legal texts applicable to his/her activity and will assume the entire responsibility with respect to the precautions inherent in the usage of this product.

The instructions described above are aimed to help the user to comply with the acquired obligations when using this product.

This description is merely informative but not restrictive.

The user will also comply with any other legal obligations, specially those related to the usage of this product, being him the one responsible for his/her acts.