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|  | MATERIAL SAFETY DATA SHEET | | FS-2515 |
| | CLINIC LINE | | Revision: 01 |
| | According to Regulation No. 1907/2006 (REACH) | | 12.11.2012 |
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1 IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

| | |
|-----------------------------------|---|
| Product name | NOVA 70 CAPS |
| Chemical formula | Contains Mercury |
| Recommended use | Dental filling material |
| Manufacturer | President Dental GmbH. Zehenstadelweg 7 81247 MUNCHEN - GERMANY Tlf: +49 89 127660240 Fax: +49 89 127660269 |
| Emergency telephone number | +49 89 127609240 |

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 | CLP | 91/155/CE |
| |  Danger (GHS06) |  Toxic by inhalation |
| |  Danger (GHS08) |  Toxic to aquatic organisms |
| |  Danger (GHS09) | |
| 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. | |

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|-------------------------|----------------|----|-----------------|----|----------------|-------------|
| Drafted: RC | Revised | DT | Approved | DT | COPY | Date |
| | | | | | | |
| Date: 12.11.2012 | | | | | Assigned to: : | |

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| 3 COMPOSITION INFORMATION ON INGREDIENTS | | | | |
|--|--|----------|------------------|---|
| Substance/preparation | I spill: alloy/mercury 400/435 mg II spill: alloy/mercury: 600/653 mg III spill: alloy/mercury: 800/865 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

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| 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/m³ 8 hours – 0,15 mg/m³ g 15 minutes

EU OEL (Europe) TWA: 0,02 mg/mm³ 8 hours

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| 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

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|-------------------------------------|--|
| 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


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| 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

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|-----------------------|---|----------------|-----------------------|-----------------|
| 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



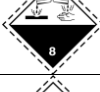

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| Ecotoxicity | R50-53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects. |
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13 DISPOSAL CONSIDERATIONS


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|---------------------------------------|---|
| 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 |

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. 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). |

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|--------------------|---|
| | 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.