## SAFETY DATA SHEET NU ALLOY DP / NU ALLOY DP ACTIVE / NU ALLOY DP 40 / HIGH ALLOY DPDDFS-011

# 1. IDENTIFICATION OF PRODUCT

new stetic

- 1.1. Chemical name: Not applicable.
- 1.2. Generic name: Alloy for dental amalgam.
- 1.3. Synonyms: Silver alloy for dental amalgam, silver amalgam.
- 1.4. Recommended use and product use restrictions: Product intended for restoration of cavities class I and class II in posterior teeth (molars and premolars). Only for dental use.
- 1.5. Emergency number: In case of emergency contact the Safety and Health at Work Coordination at the following numbers (+57 60 4) 403 87 60, ext. 1304, 1306.

### 2. IDENTIFICATION OF HAZARDS

2.1 GHS identification: (only for the mercury)

Health	Environment	Physical
Acute toxicity Categories 1 and 2	Acute toxicity	
Reproductive toxicity Category 1	Category 1 Chronic toxicity	N.A.
Target organ toxicity Category 1	Category 1	

2.2 GHS labelling (only for the mercury)

Symbol	Warning word	Danger indication
<b>S</b>	Danger	Fatal if swallowed (oral). Fatal in contact with skin (dermal). Fatal if is inhaled (gas, vapor, dust, mist).
	DangerProlonged or repeated exposure can cause damage kidney and central nervous system, inhalation of vap the main route of exposure.	
¥L.	2 Warning	Very toxic to aquatic life.
1/2		Very toxic to aquatic organisms with long lasting effects.

- 2.3 Caution indications: Mercury is highly toxic by inhalation. This alloy does not have serious implications in skin contact. However, powdered alloy must not be breathed. Toxic vapors are produced in contact with nitric acid.
- 2.4 Appearance in emergencies: Mercury vapors are colorless and odorless. Reddish vapors are

Creati	on Date	Elaborated by:	Revised by:			
2009	-12-29	Technical Coordinator of Medical Devices	Product Design and Development Coordinator			
Class	Page	Approved by:	Update	Version		
Е	1 of 7	Technical Coordinator of Medical Devices	2022-05-14	12		
REFEREN	REFERENCE DOCUMENT: DPDDPR-003					
JPDATE: 2020-11-17 VERSION: 06						



## SAFETY DATA SHEET NU ALLOY DP / NU ALLOY DP ACTIVE / NU ALLOY DP 40 / HIGH ALLOY DPDDFS-011

produced by reaction with nitric acid.

- 2.5 Potential adverse effects: This product does not present potential health hazards under normal conditions of use, handling and storage.
- 2.6 NFPA: 3-0-0 (only for the mercury).

new stetic

2.7 OSHA regulatory state: Considerate as hazardous material (29CFR1910.1200).

### 3. INFORMATION ABOUT COMPOSITION

HAZARDOUS COMPONENTS				
Common name Concentration <sup>(1)</sup> CAS Number				
Mercury	47,5 – 52,4%	7439-97-6		

NON-HAZARDOUS COMPONENTS						
Common name	Common name Concentration <sup>(2)</sup> CAS Number					
Silver	40 – 70%	7440-22-4				
Tin	18 – 31%	7440-31-5				
Copper	12 – 29%	7440-50-8				

<sup>(1)</sup> In relation with the alloy.

<sup>(2)</sup> Participation in weight in the alloy.

#### 4. FIRST AID MEASURES

- 4.1 Emergency procedures and first aid in case of:
- Inhalation: Provide fresh air in the area and see the doctor.
- Eye Contact: Wash with plenty of water. If irritation appears, see the doctor.
- Skin Contact: Wash with water and soap. Take off contaminated clothing.
- Swallowing: See the doctor immediately.
- 4.2 Most important symptoms/effects (acute and/or delayed): only for the mercury.

Creati	on Date	Elaborated by:	Revised by:	
2009	-12-29	Technical Coordinator of Medical Devices	Product Design and Development Coordinator	
Class	Page	Approved by:	Update Versio	
E	2 of 7	Technical Coordinator of Medical Devices	2022-05-14 12	
REFERENCE DOCUMENT: DPDDPR-003 UPDATE: 2020-11-17 VERSION: 06				

### SAFETY DATA SHEET NU ALLOY DP / NU ALLOY DP ACTIVE / NU ALLOY DP 40 / HIGH ALLOY DPDDFS-011

Inhalation	Short-term overexposure to high concentrations of mercury vapors can lead to breathing difficulties, cough, acute pneumonia and pulmonary edema. Depending on the concentration of overexposure, damage to kidney, liver or brain effects may occur. Long-term overexposure can lead to excessive salivation, gingivitis, anorexia, chills, fever, cardiac abnormalities, anemia, digestive problems, abdominal pain, frequent urination, inability to urinate, diarrhea, peripheral neuropathy, tremor, speech problems and visual disturbances.
Contact with skin	Prolonged contact can cause ulceration. Allergic reactions may occur in susceptible individuals. Dermatitis (redness and swelling of the skin) may occur after repeated exposures.
Contact with eyes	Can cause redness, pain and tearing.
Ingestion	Overexposure by ingestion may cause metallic taste in the mouth, nausea, vomiting, effects on the central nervous system and kidney damage. Metallic mercury is generally not sufficiently absorbed by the gastrointestinal tract to induce acute toxic response. Damage to the tissues of the mouth, throat, esophagus and other tissues of the digestive system may occur. Ingestion can be fatal due to the effects on the gastrointestinal tract and kidneys.

4.3 Antidote: Not applicable.

new stetic

4.4 Information for doctors: Not applicable.

#### 5. FIRE FIGHTING MEASURES

- 5.1 Flammability properties: This product is not flammable. Mercury is rapidly evaporated at high temperatures, generating highly toxic vapors.
- 5.2 Suitable extinction of fire: Use fire extinguishers according to materials that are burning.
- 5.3 Unsuitable extinction of fire: Any extinction media that could sweep along mercury towards canals, drainage and water corps.
- 5.4 Instructions for fire extinguishing: Use autonomous breathing equipment and safety clothing.
- 5.5 Firefighter's protection: Generation of mercury toxic vapors.
- 5.6 Protection equipment and firefighter's protection: For mercury vapors, breathing masks with specific cartridges should be used.

Creati	on Date	Elaborated by:	Revised by:		
2009	-12-29	Technical Coordinator of Medical Devices	Product Design and Development Coordinator		
Class	Page	Approved by:	Update	Version	
E	3 of 7	Technical Coordinator of Medical Devices	2022-05-14	12	
REFERENCE DOCUMENT: DPDDPR-003					
UPDATE: 2020-11-17 VERSION: 06					

## SAFETY DATA SHEET NU ALLOY DP / NU ALLOY DP ACTIVE / NU ALLOY DP 40 / HIGH ALLOY DPDDFS-011

# 6. ACCIDENTAL RELEASE MEASURES

new stetic

- 6.1 Techniques, procedures and materials in case of:
- Small spill: Pick up spilled product with a suction bottle, dropper or other similar. Avoid using vacuum cleaners. The alloy can be picked up manually.
- Large spill: Use breathing equipment with cartridges for mercury vapors. Use also safety glasses and gloves. Kits and vacuum cleaners designed for specific mercury spills can be used.
- 6.2 Environmental cautions: Dam up to prevent escape by canals and drains. Avoid reaching water sources.
- 6.3 Further considerations: Avoid separation of mercury in small drops. Use hermetic plastic containers for putting the spilled material and dispose it adequately (see section 13). It is advisable to perform environmental analysis of mercury to verify that the site is no longer contaminated.

# 7. HANDLING AND STORAGE OF PRODUCT

- 7.1 Handling: No special protective equipment is required for the normal handling of this product in its original package. For clinical activities, use gloves, safety glasses, and adequate clothing. Avoid breathing alloy powder and exposure to mercury vapors.
- 7.2 Storage: Storage this product in a cool and dry area, away from water sources, drainages, acetylene, ammonia, acids, and heat sources. Keep the container of the product sealed at a temperature of 28 °C maximum.

#### 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

- 8.1 Conditions to control the exposure: Use this product in a cool and ventilated area with continuous renovation of air. Do not manipulate recently prepared amalgam without gloves. Avoid any skin contact.
- 8.2 Engineering Controls: Use the product in a ventilated, cool and allow air renewal area. It must ensure that exposure is below of allowed occupational limits. The floors and walls must be non-porous and washable materials.
- 8.3 Personal protective equipment: Under adequate usage operations, no breathing equipment is needed. Use gloves and safety glasses.
- 8.4 Exposure parameters:

For mercury according to the American Conference of Governmental Industrial Hygienists of the United States (ACGIH) in its 2016 version:

- 0.025 mg Hg/m<sup>3</sup> of air.
- 10 µg Hg/L of blood.
- 20 µg Hg/g creatinine.

NOTE: These levels are not exceeded under normal conditions of clinic use of the product.

Creati	on Date	Elaborated by:	Revised by:			
2009	-12-29	Technical Coordinator of Medical Devices	Product Design and Development Coordinator			
Class	Page	Approved by:	Update	Version		
E	4 of 7	Technical Coordinator of Medical Devices	2022-05-14	12		
REFEREN	REFERENCE DOCUMENT: DPDDPR-003					
UPDATE: 2020-11-17						
VERSION	/ERSION: 06					

# SAFETY DATA SHEET NU ALLOY DP / NU ALLOY DP ACTIVE / NU ALLOY DP 40 / HIGH ALLOY DPDDFS-011

# 9. PHYSICAL AND CHEMICAL PROPERTIES

new stetic

Property	Alloy	Mercury
Appearance	Gray powder or tablet	Silver gray liquid
Odor	Odorless	Odorless
Odor threshold	Not applicable	Not applicable
рН	Not applicable	Not applicable
Vapor pressure	Not applicable	0.002 mmHg at 25 °C (77 °F)
Vapor density	Not applicable	7
Evaporation rate	Not applicable	Not available
Saturated vapor concentration	Not applicable	Not available
Fusion point	Not available	-38.9 °C (-38 °F)
Boling point	Not available	357 °C (675 °F)
Solubility in water	Not soluble	< 0.1%
Solubility in other colyanta	Soluble in nitric acid and	Soluble in nitric acid and hot
Solubility in other solvents	hot sulfuric acid.	sulfuric acid.
Density	Not available	13.55 g/cm <sup>3</sup>
Bulk density	Not available	Not available
Size of particles	< 103 µm	Not applicable
Content of volatile organic compounds	Not applicable	Not applicable
Volatility percentage	Not applicable	Not available
Softening point	Not available	Not available
Flashpoint or explosive limit	Not applicable	Not applicable
Auto-ignition temperature	Not applicable	Not applicable
Decomposition temperature	Not applicable	Not applicable
Viscosity	Not applicable	Not available
n-octanol/water partition coefficient	Not applicable	Not applicable
Molecular weight	Not applicable	200.6
Molecular formula	Not applicable	Hg

### **10. STABILITY AND REACTIVITY**

- 10.1 Chemical stability: This product is stable under normal manipulation and storage conditions.
- 10.2 Possibility of hazardous reactions: Exothermic reaction with generation of nitrous gases in contact with nitric acid.
- 10.3 Conditions to avoid: High Temperatures.
- 10.4 Incompatibility with other materials: Acids, ammonia and acetylene.
- 10.5 Dangerous breaking down products: Mercury vapors due to overheating or in presence of nitrous oxides (NOx) by reaction with nitric acid.
- 10.6 Dangerous polymerization: Not applicable.

Creati	on Date	Elaborated by:	Revised by:		
2009	-12-29	Technical Coordinator of Medical Devices	Product Design and Development Coordinator		
Class	Page	Approved by:	Update	Version	
E	5 of 7	Technical Coordinator of Medical Devices	2022-05-14	12	
REFERENCE DOCUMENT: DPDDPR-003					
JPDATE: 2020-11-17 VERSION: 06					

# SAFETY DATA SHEET NU ALLOY DP / NU ALLOY DP ACTIVE / NU ALLOY DP 40 / HIGH ALLOY DPDDFS-011

## **11. TOXICOLOGICAL INFORMATION**

new stetic

- 11.1 Possible routes of exposure: Respiratory, skin and digestive.
- 11.2 Acute toxicity:
- About the mercury: Acute toxicity is mainly produced by inhalation or ingestion of mercury vapors. It is apparent by erosive bronchitis that can result in respiratory failure. After a short period of time, a systemic intoxication is produced. Kidney failure, vomiting, foamed saliva, abdominal pain and diarrhea are produced by ingestion. Subsequently, failures include shock, low arterial blood pressure and tachycardia. Two or three days later, a tattoo on the gum (also known as gingival edge) appears.
- About the alloy: Copper vapors can cause fiver, nauseas, gastralgias and diarrhea. The tin powder is moderately irritant for eyes and airway, but if it is ingested in small quantities (mg), it will not be toxic. Ingestion of big quantities can produce vomit, but not permanent harms. The absorption of metallic tin by digestive way is minimum. The accidental penetration of small quantities of silver through skin can produce local argyria.
- 11.3 Chronic toxicity:
- **About the mercury:** It is characterized by the presence of neurological, psychiatric, and renal syndromes. fine quivering of fingers, eyelids, and tongue. There are also craziness manifestations due to absorption in the brain. This condition also produces insomnia, nervousness, irritability, judgment disturbance, memory failure, anxiety, depression and even paranoid conditions. The renal syndrome can result in chronic kidney failure with high blood pressure and retention of body liquids.
- **About the alloy:** The irritation of airways and lung tissues by tin can cause lung edema. Silver powder is irritant and it can cause ulceration in the skin and nasal septum.
- 11.4 Additional Information: Dental amalgam is a restorative material used on posterior teeth with wide and known use, without serious harmful effects proven on health.

#### 12. ECOLOGICAL INFORMATION

- 12.1 Ecotoxicity: Mercury is very toxic to aquatic life with long lasting effects.
- 12.2 Persistence and degradability: Mercury can cause adverse effects on the environment in the long term.
- 12.3 Potential for bioaccumulation: Mercury is bioaccumulative in living organisms and biomagnifies in the food chain.
- 12.4 Mobility in soil: Not available.
- 12.5 Other adverse effects: No additional information.

### **13. DISPOSAL CONSIDERATIONS**

Recycle this product if it is possible or dispose the wastes and polluted material in a safe way in accordance with regulations into effect. Never incinerate wastes or throw them into waterways.

Creati	on Date	Elaborated by:	Revised by:		
2009	-12-29	Technical Coordinator of Medical Devices	Product Design and Development Coordinator		
Class	Page	Approved by:	Update	Version	
E	6 of 7	Technical Coordinator of Medical Devices	2022-05-14	12	
REFEREN	REFERENCE DOCUMENT: DPDDPR-003				
UPDATE: 2020-11-17					
VERSION:	/ERSION: 06				

# SAFETY DATA SHEET NU ALLOY DP / NU ALLOY DP ACTIVE / NU ALLOY DP 40 / HIGH ALLOY DPDDFS-011

WARNING: Laws, regulations and local restrictions can change or be reinterpreted from one country to another and also, they can be different from the ones being into effect in Colombia. This is why considerations about waste disposal of product and its packing may differ from the ones appearing in this document.

### 14. TRANSPORT INFORMATION

new stetic

- 14.1 Hazardous material: Mercury.
- 14.2 Type of risk: Toxic.
- 14.3 UN number: 3506.
- 14.4 IATA classification: Mercury contained in manufactured product, Class 8.
- 14.5 Packing group: 3.
- 14.6 Marine pollutant (Yes/No): Yes.

## **15. INFORMATION ABOUT REGULATIONS INTO EFFECT**

15.1 In Colombia: Observe the applicable regulations.

Decree 2676:2000	By which the Integral Management of Hospital Wastes and Similar is regulated.		
Resolution 01164:2002	tion 01164:2002 By which the Procedures Manual for the Integral Management for the Hospital Wastes and Similar is adopted.		
Decree 4741:2005 By which the prevention and management of dangerous waster residues generated in the framework of the Integral Management partially regulated.			
Decree 351:2014	Integral management of waste generated in healthcare.		

15.2 International: Observe the applicable regulations.

### **16. IMPORTANT ADDITIONAL INFORMATION**

The information registered in this document is based on our current knowledge and is given in good faith but is not given an assurance express or implicit; neither is assumed any responsibility for the incorrect use of the product. This document is prepared according to:

- Colombian technical standard NTC 4435:2010 Transport of Goods. Material Safety Data Sheets. Preparation.
- GHS Globally Harmonized System of Classification and Labelling of Chemicals.

Other information sources:

- NORDBERG, Gunnar. Enciclopedia de Salud y Seguridad en el Trabajo. Chapter 63 Metales: Propiedades Químicas y Toxicidad. 2001. p. 63.14, 63.15, 63.18, 63.19, 63.37 y 63.38.
- Bethehem Apparatus Co., Inc. Mercury. Safety Data Sheet. Issue date: 11/19/2013.

Creation Date		Elaborated by:	Revised by:	
2009-12-29		Technical Coordinator of Medical Devices	Product Design and Development Coordinator	
Class	Page	Approved by:	Update	Version
E	7 of 7	Technical Coordinator of Medical Devices	2022-05-14	12
	2020-11-17	IENT: DPDDPR-003		