SAFETY DATA SHEET

Product name: **ANA 2000 HIGH COPPER ADMIX DUETT**

SDS Drawn up: 2006-04-03 SDS Revised: 2023-01-12

1. Identification of the substance / preparation and of the company

Trade name:	**ANA 2000 High Copper Admix Duett**		
Chemical name:	Mercury, Hg, CAS-no [7439-97-6] and metal powder (alloy)		
Field of application:	Metallic powder in tablet form + metallic mercury in a weld up bag, to produce amalgam for dental fillings		
Supplier:	Nordiska Dental AB		
Postal address:	Box 1082	Telephone no:	+46 431 443 360
Postcode and town:	S-262 21 Ängelholm	Fax no:	+46 431 443 399
Country:	Sweden	E-mail:	info@nordiskadental.se
Emergency telephone:	+46 431 443 360		

2. Hazards identification

The healthand physical hazards of this SDS are based on mercury.

Classification:

CORROSIVE TO METALS - Category 1

SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 1

GHS label elements:

Hazard statements :

H290 May be corrosive to metals.

H330 Toxic if inhaled.

H372 May cause damage to organs through prolonged or repeated exposure

Hazard pictograms :

Signal word: Danger

Precautionary statements

Prevention :

P202 Do not handle until all safety precautions have been read and understood.P281 Use personal protective equipment as required.

P264 Do not eat, drink or smoke when using this product. Wash hands thoroughly afterhandling.

Response :

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Storage : P403+P233 Store in a well-ventilated place. Keep container tightly closed.

Disposal : Dispose of contents and container in accordance with all local, regional, national and international regulations.

Hazards not otherwise classified: None known

Additional information: Medical devices as defined in EU MDR and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished stateand intended for the final user.

Results of PBT and vPvB assessment: n/a

3. Composition / information on ingredients

Component	CAS-no	Einecs-no	Content (%)
Hg in weld up bag Mercury, Hg	7439-97-6	231-106-7	50
Alloy in tablet form			
Silver, Ag	7440-22-4	231-131-3	>20
Tin, Sn	7440-31-5	231-141-8	<16
Copper, Cu	7440-50-8	231-159-6	<15

Mercury is a chemical known to the State of California to cause birth defects or other reproductive harm.

4. First aid measures

Skin: Wash thoroughly with soap and water. Use hand cream. If irritation persists, consult aphysician.
Eye: Flush with water for at least 15 minutes. Consult a physician.
Inhalation: Move to fresh air. If irritation persists, consult a physician.
Ingestion: Contact a physician/poison center. May cause neurotoxic/nephrotoxic effects.

Most important symptoms/effects, acute and delayed
Inhalation : Fatal if inhaled.
Ingestion : No known significant effects or critical hazards. Skin
contact : No known significant effects or critical hazards.
Eye contact : No known significant effects or critical hazards.

Over-exposure signs/symptoms
Skin: Irritant/Sensitizer/Neurotoxin/Nephrotoxin
Acute Exposure: May cause redness and irritation. **Chronic Exposure:** Possible sensitization, dermatitis and swelling. Mercury may be absorbed through intact skincausing urinary problems

Eyes: Irritant.
Acute Exposure: Contact may cause irritation. Mercury is corrosive and may cause corneal injury or burns. **Chronic Exposure:** Mercury may be deposited in the lens of theeye, causing visual disturbances.

Inhalation: Irritant/Sensitizer/Nerotoxin
Acute Exposure: Inhalation of mercury vapor can cause cough, fever, nausea,andvomiting.
Chronic Exposure: Inhalation of high concentrations mercury vapor over a long period causes mercurialism. Findings are extremely variable & includetremors, salivation, stomatitis, loosening of teeth, blue lines on gums, pain & numbness in extremities.

Ingestion: Neurotoxic/nephrotoxic
Acute Exposure: May cause nausea, vomiting, kidney damage and nerve effects.
ChronicExposure: Symptoms include Central Nervous System (CNS) disorders.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
Specific treatments : No specific treatment.
In case of major fire and large quantities: No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

5. Fire Fighting measures

Extinguishing Media: Carbon dioxide, dry chemical foam
Unsuitable extinguishing media: Do not use water jet.
Special Fire Fighting Procedures: Firefighters should wear self-contained breathing apparatus(SCBA) with a full face-piece operated in positive pressure mode when fighting a fire in an areacontaining mercury.
Specific hazards arising from the chemical: Fire water contaminated with this material mustbe contained and prevented from being discharged to any waterway, sewer or drain.
Special protective actions for fire fighters: In case of major fire and large quantities: Promptlyisolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
Hazardous thermal decomposition products: Decomposition products may include thefollowing materials: metal oxide/oxides - Mercuric oxide (HgO), Mercury (vapor)

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
For non-emergency personnel:
For professional use only. Handle with extreme care. Avoid contact with mercury. Avoidinhalation of mercury. Do not touch or walk through spilled material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriatepersonal protective equipment.

For emergency responders:
If specialized clothing is required to deal with the spillage, take note of any information in Section8 on suitable and unsuitable materials. See also the information in "For nonemergency personnel".

Environmental precautions:
Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.Inform the relevant authorities if the product has caused environmental pollution (sewers,waterways, soil or air). Water polluting material. May be harmful to the environment if released in large quantities.

Personal precautions: Avoid contact with skin.
Disposal: Dispose of according to local or state regulations.
Steps to be taken in case material is released or spilled: Isolate the area and begin clean-up immediately. Do not touch spilled material. For professional use only. Handle with extreme care.Avoid contact with mercury. Avoid inhalation of mercury. Do not touch or walk through spilled material. Prompt cleanup and removal are necessary. Cover all liquid droplets with a commercially available mercury vapor suppressant. Do not allow to flow off into the drains or waters.Never use a vacum cleaner to clean up mercury. The vacuum will put mercury into the air and increase exposure.
Collect the droplets using specialized mercury vacuum cleaners.

Section 7: Handling and Storage

Precautions for safe handling:
Put on appropriate personal protective equipment (see Section 8). Avoid exposure - obtain special instructions before use. Avoid exposure during pregnancy. Do not handle until all safetyprecautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. Avoid release to the environment. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container. Absorb spillageto prevent material damage.
General hygiene: Eating, drinking and smoking should be prohibited in areas where this materialis handled, stored and processed.

Waste Disposal Method: Material should not be allowed to enter sewers. All scrap mercuryliquid and set alloy must be sent for reclamation by a commercial
metal recycling facility.
Conditions for safe storage, including any incompatibilities
Store in a cool, dry place away from ignition sources. Store in accordance with local regulations.Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers.
Other precautions: Use according to directions. Wash hands thoroughly before smoking or eating.

8. Exposure controls/Personal controls

	Exposure limit
Mercury	OSHA PEL Z2 (United States, 2/2013,) International: CEIL: 1 mg/10m³ NIOSH REL (United States, 10/2013) International: Absorbed through skin.TWA: 0.05 mg/m³, (as Hg) 10 hours. Form: Hg Vapor CEIL: 0.1 mg/m³, (as Hg) Form: Other than Hg Vapor ACGIH TLV (United States, 6/2013), International: Absorbed through skin. TWA: 0.025 mg/m³, (as Hg) 8 hours. Form: Inorganic OSHA PEL 1989 (United States, 3/1989), International: Absorbed through skin.TWA: 0.05 mg/m³, (as Hg) 8 hours. Form: Vapor

Personal Protective Equipment (PPE)
Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Respiratory Protection (Specify Type): AVOID BREATHING OF VAPORS. HIGHLYTOXIC - IRRITANT - SENSITIZER. Use a properly fitted, particulate filter respirator complying with an approved standard if a risk assessment indicates this is necessary.
VENTILATION:
Local Exhaust: Use in a well ventilated area to keep exposure under 0.05mg/m3.
Protective Gloves: Chemical resistant or latex gloves required
Eye Protection: Safety glasses with side shields. Full face shields
Work/Hygiene Practices: USE ONLY ACCORDING TO DIRECTIONS.

Wash thoroughly after handling. Handle in accordance with good personal hygiene and safetypractices. These practices include avoiding unnecessary exposure.

9. Physical and Chemical Properties

Boiling Point:	674 ºF (mercury)	**Vapor Density:**	N/E
Specific Gravity (H20 = 1):	13.35	**Evaporation Rate:**	N/E
Vapor Pressure (mm Hg):	0.0012 mm Hg @ 68 ºF	**Solubility in Water:**	0.0002g/100g water @ 68 ºF
Physical state:	Solid. [Precapsulated dental amalgam: Metal alloy powder / Mercury (Mobile liquid.)]		
Appearance and Odor:	Powder: Odorless dark-gray alloy of silver, tin, copper and/or zinc. Liquid: Mercury is a silvery, mobile, odorless liquid.		

10. Stability and Reactivity

Stability: Stable
Conditions to Avoid: High temperatures.
Incompatibility (Material to Avoid): Halogens, ammonia, and strong oxidizing agents.
Hazardous Decomposition Byproducts: Mercury Vapor.
Hazardous Polymerization: Will not occur

11. Toxilogicol Information

Acute toxicity: Not Available
Summary: Based on the criteria of the protocol, this product is considered non-cytotoxic per ISO 10993-5.
Information on toxilogical effects Acute toxicity: Not available
Irritation/Corrosion
Skin : Corrosive to metal. Non-corrosive to skin.
Eyes : Corrosive to metal. Non-corrosive to the eyes.
Over-exposure signs/symptoms: Vapor may be irritating to eyes and respiratory system.
Respiratory : May cause respiratory irritation.
Over-exposure signs/symptoms: Inhalation of vapor/ mist may result in lung edema.

Test: Sensitization

Route of exposure	Species	Result
Skin	Guinea pig	Passed: Nonsensitizer
Oral Musocal	Hamster	Non irritant to oralmucosa

Carcinogenicity: Not Available Reproductive toxicity: Not available

Teratogenicity: Not available Aspiration hazard: Not available

Specific target organ toxicity (repeated exposure)

Name	Category	Route of exposure	Target organs
Mercury	Category 1	Not determined	Nervous system

Information on the likely routes of exposure:
Routes of entry anticipated: Oral, Dermal, Inhalation.

Potential acute health effects
Eye contact : No known significant effects or critical hazards.
Inhalation : Fatal if inhaled.
Ingestion : No known significant effects or critical hazards. Skin contact : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics:

Inhalation: Adverse symptoms may include the following:
reduced fetal weight, increase in fetal deaths, skeletal malformations, salivation, metallic taste,Eye irritation, respiratory tract irritation, coughing, pulmonary edema, wheezing and breathingdifficulties, headache, fever,

nausea or vomiting diarrhea, abdominal cramps and pain, muscle weakness / pain, mental confusion or disorientation
Eye contact : No specific data.
Skin contact: Adverse symptoms may include the following: reduced fetal weight, increase infetal deaths, skeletal malformations
Ingestion: Adverse symptoms may include the following: reduced fetal weight, increase in fetaldeaths, skeletal malformations.

Delayed & immediate effects, chronic effects from short and long term exposure
Short term exposure
Potential immediate effects : Not available. Potential delayed effects : Not available
Long term exposure:
Potential immediate effects : Not available. Potential delayed effects : Not available.

Potential chronic health effects: Not available

Conclusion/Summary : Prolonged or repeated exposure to mercury vapor and/or particles maycause mercury poisoning (Mercurialism). Chronic inhalation of mercury affects the nervous system (central nervous system and peripheral nervous system) and leads to neuropsychiatric disturbances.

General : Causes damage to organs through prolonged or repeated exposure.
Carcinogenicity : No known significant effects or critical hazards.
Mutagenicity : No known significant effects or critical hazards.
Teratogenicity : May damage the unborn child.
Developmental effects : No known significant effects or critical hazards.
Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity
Acute toxicity estimates
Route: Inhalation (dusts and mists)ATE value: 0.05011 mg/l
Further information: Avoid exposure of mercury to pregnant person

Ecotoxicity: The product must not enter effluent, ground water, surface water or the soil.Mobility : No

12. Ecological Information

data available
Persistence & degradability: No data available
Bioaccumulative potential: No data available

13. Disposable considerations

Any disposal practice must be in compliance with local and national regulations.
For disposal contact an expert for chemical waste, at your local-, federal or state waste department. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection & waste disposal legislation and any regionallocal authorities' requirements.

SECTION 14: Transport Information

IATA and IMDG:
Product: Amalgam Capsule **Contains:** Mercury
Shipping Name: Mercury contained in manufactured articles
UN Number: UN 3506

Packing Group: III **Class (sub risk):** 8 (6.1) Corrosive & Toxic

Material is regulated under Transport CFR 49 §173.4b De minimis exceptions.

15. Regulatory Information

This product is classified as a medical device under EC Directives, US and Canadian regulations

HMIS (Hazardous Material Identification System) Rating:
H3 F0 R0 (Health, Flammability, Instability/Reactivity)

[HMIS Index: 4 - Severe Hazard; 3 -Serious Hazard; 2 - Moderate Hazard; 1 - SlightHazard; 0 - Minimum Hazard]

California Proposition 65 WARNING:
This product contains mercury, a chemical known to the State of California to cause birth defectsor other reproductive harm.

Caution: This product contains mercury

16. Other Information

Key to abbreviations :
ATE = Acute Toxicity Estimate
GHS = Globally Harmonized System of Classification and Labelling of ChemicalsIATA = International Air Transport Association
IMDG = International Maritime Dangerous
UN = United Nations

CAUTION: PRODUCT FOR PROFESSIONAL USE
The information on this safety sheet is based on presently available data and to our best knowledge for the correct handling of the product under normal conditions. Any use of this product in any way not indicated on this sheet or use of this product together with any other process/procedure will be exclusively under the user's responsibility.