

Dentsply AH Plus Paste B

Dentsply (Australia) Pty Ltd

Chemwatch: 4993-63

Version No: 5.1.1.1

Safety Data Sheet according to WHS and ADG requirements

Chemwatch Hazard Alert Code: 1

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S.GHS.AUS.EN

SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

Product Identifier

Product name	Dentsply AH Plus Paste B
Synonyms	60620115 - AH Plus Jet Starter Kit, 60620118 - AH Plus Jet Refill
Other means of identification	Not Available

Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Root canal filling material.
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Details of the supplier of the safety data sheet

Registered company name	Dentsply (Australia) Pty Ltd
Address	11-21 Gilby Road Mount Waverley VIC 3149 Australia
Telephone	1300 55 29 29
Fax	1300 55 31 31
Website	www.dentsply.com.au
Email	clientservices@dentsplysirona.com

Emergency telephone number

Association / Organisation	Not Available
Emergency telephone numbers	1300 55 29 29
Other emergency telephone numbers	Not Available

SECTION 2 HAZARDS IDENTIFICATION

Classification of the substance or mixture

NON-HAZARDOUS CHEMICAL. NON-DANGEROUS GOODS. According to the WHS Regulations and the ADG Code.

CHEMWATCH HAZARD RATINGS

	Min	Max	
Flammability	0		
Toxicity	1		
Body Contact	1		
Reactivity	1		
Chronic	0		

0 = Minimum
1 = Low
2 = Moderate
3 = High
4 = Extreme

Poisons Schedule	S4
Classification	Not Applicable

Label elements

Hazard pictogram(s)	Not Applicable
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SIGNAL WORD	NOT APPLICABLE
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Hazard statement(s)

Not Applicable

Precautionary statement(s) Prevention

Not Applicable

Precautionary statement(s) Response

Not Applicable

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

Not Applicable

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS**Substances**

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
Not Available	2.5-10	n,n-dibenzyl-5-oxanonandiamin-1,9
768-94-5	2.5-10	<u>amantadine</u>

SECTION 4 FIRST AID MEASURES**Description of first aid measures**

Eye Contact	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> ▶ Wash out immediately with fresh running water. ▶ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. ▶ Seek medical attention without delay; if pain persists or recurs seek medical attention. ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	<p>If skin contact occurs:</p> <ul style="list-style-type: none"> ▶ Immediately remove all contaminated clothing, including footwear. ▶ Flush skin and hair with running water (and soap if available). ▶ Seek medical attention in event of irritation.
Inhalation	<ul style="list-style-type: none"> ▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▶ Other measures are usually unnecessary.
Ingestion	<ul style="list-style-type: none"> ▶ IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY. ▶ For advice, contact a Poisons Information Centre or a doctor. ▶ Urgent hospital treatment is likely to be needed. ▶ In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition. ▶ If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the SDS should be provided. Further action will be the responsibility of the medical specialist. ▶ If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the SDS. <p>Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:</p> <ul style="list-style-type: none"> ▶ INDUCE vomiting with fingers down the back of the throat, ONLY IF CONSCIOUS. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. <p>NOTE: Wear a protective glove when inducing vomiting by mechanical means.</p>

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

For amantadine intoxication:

- ▶ If overdose occurs the stomach should be emptied by aspiration and lavage.
- ▶ In particular, symptoms of excessive central stimulation with convulsions and psychosis should be treated appropriately.
- ▶ Anti-arrhythmic agents may be required.
- ▶ Bladder catheterisation may be required.
- ▶ Elimination of amantadine has been reported to be increased in acid urine

MARTINDALE: The Extra Pharmacopoeia, 27th Ed.

- ▶ There is no specific antidote for an overdose of However, slowly administered intravenous physostigmine in 1 and 2 mg doses in an adult at 1- to 2-hour intervals and 0.5 mg doses in a child at 5- to 10-minute intervals up to a maximum of 2 mg/hour have been reported to be effective in the control of central nervous system toxicity caused by amantadine hydrochloride.
- ▶ For acute overdosing, general supportive measures should be employed along with immediate gastric lavage or induction of emesis. Fluids should be forced, and if necessary, given intravenously.
- ▶ The pH of the urine has been reported to influence the excretion rate of the drug. Since the excretion rate of the drug increases rapidly when the urine is acidic, the administration of urine acidifying drugs may increase the elimination of the drug from the body.
- ▶ The blood pressure, pulse, respiration and temperature should be monitored.
- ▶ The patient should be observed for hyperactivity and convulsions; if required, sedation, and anticonvulsant therapy should be administered. The patient should be observed for the possible development of arrhythmias and hypotension; if required, appropriate antiarrhythmic and antihypotensive therapy should be given.
- ▶ Electrocardiographic monitoring may be required after ingestion, since malignant tachyarrhythmias can appear after overdose.
- ▶ Care should be exercised when administering adrenergic agents, such as isoproterenol, to patients with a drug overdose, since the dopaminergic activity of the drug has been reported to induce malignant arrhythmias.
- ▶ The blood electrolytes, urine pH and urinary output should be monitored. If there is no record of recent voiding, catheterisation should be done

RxList for Symmetrel

SECTION 5 FIREFIGHTING MEASURES**Extinguishing media**

- ▶ Foam.
- ▶ Dry chemical powder.
- ▶ BCF (where regulations permit).
- ▶ Carbon dioxide.

Special hazards arising from the substrate or mixture

Fire Incompatibility	<ul style="list-style-type: none"> ▶ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
Advice for firefighters	
Fire Fighting	<ul style="list-style-type: none"> ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Wear breathing apparatus plus protective gloves in the event of a fire. ▶ Prevent, by any means available, spillage from entering drains or water courses. ▶ Use fire fighting procedures suitable for surrounding area.
Fire/Explosion Hazard	<ul style="list-style-type: none"> ▶ The material is not readily combustible under normal conditions. ▶ However, it will break down under fire conditions and the organic component may burn. ▶ Not considered to be a significant fire risk. ▶ Heat may cause expansion or decomposition with violent rupture of containers. <p>Combustion products include:</p> <ul style="list-style-type: none"> , carbon monoxide (CO) , carbon dioxide (CO₂) , nitrogen oxides (NO_x) , other pyrolysis products typical of burning organic material. <p>May emit poisonous fumes. May emit corrosive fumes.</p>
HAZCHEM	Not Applicable

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	<ul style="list-style-type: none"> ▶ Clean up all spills immediately. ▶ Avoid contact with skin and eyes. ▶ Wear impervious gloves and safety goggles. ▶ Trowel up/scrape up.
Major Spills	<ul style="list-style-type: none"> ▶ Clear area of personnel and move upwind. ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Wear breathing apparatus plus protective gloves. ▶ Prevent, by any means available, spillage from entering drains or water course.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling

Safe handling	<ul style="list-style-type: none"> ▶ Avoid all personal contact, including inhalation. ▶ Wear protective clothing when risk of exposure occurs. ▶ Use in a well-ventilated area. ▶ Prevent concentration in hollows and sumps.
Other information	<ul style="list-style-type: none"> ▶ Store in original containers. ▶ Keep containers securely sealed. ▶ Store in a cool, dry, well-ventilated area. ▶ Store away from incompatible materials and foodstuff containers.

Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> ▶ Polyethylene or polypropylene container. ▶ Packing as recommended by manufacturer. ▶ Check all containers are clearly labelled and free from leaks.
Storage incompatibility	<ul style="list-style-type: none"> ▶ Avoid reaction with oxidising agents

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA

Not Available


EMERGENCY LIMITS

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
Dentsply AH Plus Paste B	Not Available	Not Available	Not Available	Not Available
Ingredient	Original IDLH	Revised IDLH		

Continued...

n,n-dibenzyl-5-oxanonandiamin-1,9	Not Available	Not Available
amantadine	Not Available	Not Available

Exposure controls

Appropriate engineering controls	<p>Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.</p> <p>The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the risk. Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Refer also to protective measures for the other component used with the product. Read both SDS before using; store and attach SDS together.</p>
Personal protection	
Eye and face protection	<ul style="list-style-type: none"> ▶ Safety glasses with side shields. ▶ Chemical goggles. ▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task.
Skin protection	See Hand protection below
Hands/feet protection	<ul style="list-style-type: none"> ▶ Wear chemical protective gloves, e.g. PVC. ▶ Wear safety footwear or safety gumboots, e.g. Rubber <p>NOTE:</p> <ul style="list-style-type: none"> ▶ The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact. ▶ Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed.
Body protection	See Other protection below
Other protection	<ul style="list-style-type: none"> ▶ Overalls. ▶ P.V.C. apron. ▶ Barrier cream.
Thermal hazards	Not Available

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	White paste with a characteristic odour; does not mix with water.		
Physical state	Non Slump Paste	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Available	Decomposition temperature	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Applicable	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	Not Applicable	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Applicable	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Applicable	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	Not Applicable	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water (g/L)	Immiscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

SECTION 10 STABILITY AND REACTIVITY

Reactivity	See section 7
Chemical stability	<ul style="list-style-type: none"> ▶ Unstable in the presence of incompatible materials. ▶ Product is considered stable. ▶ Hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7

Hazardous decomposition products

See section 5

SECTION 11 TOXICOLOGICAL INFORMATION
Information on toxicological effects

Inhaled	The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage.	
Ingestion	Accidental ingestion of the material may be damaging to the health of the individual.	
Skin Contact	There is some evidence to suggest that this material can cause inflammation of the skin on contact in some persons. Open cuts, abraded or irritated skin should not be exposed to this material Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.	
Eye	There is some evidence to suggest that this material can cause eye irritation and damage in some persons.	
Chronic	Based on experience with similar materials, there is a possibility that exposure to the material may reduce fertility in humans at levels which do not cause other toxic effects. Based on experience with animal studies, there is a possibility that exposure to the material may result in toxic effects to the development of the foetus, at levels which do not cause significant toxic effects to the mother. Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. There is limited evidence that, skin contact with this product is more likely to cause a sensitisation reaction in some persons compared to the general population.	
Dentsply AH Plus Paste B	TOXICITY	IRRITATION
	Not Available	Not Available
amantadine	TOXICITY	IRRITATION
	Oral (rat) LD50: 900 mg/kgd ^[2]	Not Available
Legend:	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances	

AMANTADINE	Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. Tremors, convulsions, ataxia recorded.
Dentsply AH Plus Paste B & AMANTADINE	Amantadine (an adamantane or amantane) has been associated with several central nervous system side effects, likely due to its dopaminergic and adrenergic activity, and to a lesser extent, its activity as an anti-cholinergic. Side-effects are multi-systemic and maybe dose dependent including discoloured spots or skin patches (livedo reticularis), visual disturbances, cardiovascular problems, psychiatric and psychotic conditions, suicidal ideation and even deaths. Neuroleptic Malignant Syndrome (NMS), a life threatening condition due to antipsychotic intake which presents with severely high body temperature, rigidity and autonomic deregulation have been reported in cases of dose reduction or withdrawal. It does not cause cancer or genetic defect but may cause reproductive or developmental toxicity from 2 weeks gestation especially at maternal toxic level.

Acute Toxicity	☐	Carcinogenicity	☐
Skin Irritation/Corrosion	☐	Reproductivity	☐
Serious Eye Damage/Irritation	☐	STOT - Single Exposure	☐
Respiratory or Skin sensitisation	☐	STOT - Repeated Exposure	☐
Mutagenicity	☐	Aspiration Hazard	☐

Legend: ✗ - Data available but does not fill the criteria for classification
✔ - Data available to make classification
☐ - Data Not Available to make classification

SECTION 12 ECOLOGICAL INFORMATION
Toxicity

	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Dentsply AH Plus Paste B	Not Available	Not Available	Not Available	Not Available
amantadine	LC50	96	Fish	22.106mg/L	3
	EC50	48	Crustacea	22.1mg/L	4
	EC50	96	Algae or other aquatic plants	3.776mg/L	3

Legend: Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data

DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
amantadine	HIGH	HIGH

Bioaccumulative potential

Ingredient	Bioaccumulation
amantadine	LOW (LogKOW = 2.44)

Mobility in soil

Ingredient	Mobility
amantadine	LOW (KOC = 384.6)

SECTION 13 DISPOSAL CONSIDERATIONS

Waste treatment methods

Product / Packaging disposal	Waste treatment methods
	<ul style="list-style-type: none"> ▶ Containers may still present a chemical hazard/ danger when empty. ▶ Return to supplier for reuse/ recycling if possible. Otherwise: <ul style="list-style-type: none"> ▶ If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill. ▶ Where possible retain label warnings and SDS and observe all notices pertaining to the product. ▶ Recycle wherever possible or consult manufacturer for recycling options. ▶ Consult State Land Waste Authority for disposal. ▶ Bury or incinerate residue at an approved site. ▶ Recycle containers if possible, or dispose of in an authorised landfill.

SECTION 14 TRANSPORT INFORMATION

Labels Required

Marine Pollutant	Label
Marine Pollutant	NO
HAZCHEM	Label
HAZCHEM	Not Applicable

Land transport (ADG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

SECTION 15 REGULATORY INFORMATION

Safety, health and environmental regulations / legislation specific for the substance or mixture

AMANTADINE(768-94-5) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

National Inventory	Status
Australia - AICS	Y
Canada - DSL	N (amantadine)
Canada - NDSL	Y
China - IECSC	N (amantadine)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (amantadine)
Korea - KECI	N (amantadine)
New Zealand - NZIoC	N (amantadine)
Philippines - PICCS	N (amantadine)
USA - TSCA	Y
Legend:	Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing (see specific ingredients in brackets)

SECTION 16 OTHER INFORMATION

Other information

Continued...

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

PC – TWA: Permissible Concentration-Time Weighted Average
PC – STEL: Permissible Concentration-Short Term Exposure Limit
IARC: International Agency for Research on Cancer
ACGIH: American Conference of Governmental Industrial Hygienists
STEL: Short Term Exposure Limit
TEEL: Temporary Emergency Exposure Limit,
IDLH: Immediately Dangerous to Life or Health Concentrations
OSF: Odour Safety Factor
NOAEL :No Observed Adverse Effect Level
LOAEL: Lowest Observed Adverse Effect Level
TLV: Threshold Limit Value
LOD: Limit Of Detection
OTV: Odour Threshold Value
BCF: BioConcentration Factors
BEI: Biological Exposure Index

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