

Printing date 29.01.2020 Version number 1 Revision: 29.01.2020

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- · Product identifier
- Trade name: AccuDent XD Tray Adhesive
- · Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Auxiliary for dental technology
- Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Ivoclar Vivadent Inc.

175 Pineview Drive, Amherst, N.Y. 14228

USA

Tel. +1 800 533 6825 Fax +1 716 691 2285

Importer:

Ivoclar Vivadent Pty. Ltd. 1-5 Overseas Drive

Noble Park North VIC 3174

Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645

· Further information obtainable from:

Regulatory Affairs

sds@ivoclarvivadent.com

· Emergency telephone number: 131 126 (Poisons Information Centre - 24 hours / 7 days)

2 Hazard(s) Identification

- · Classification of the substance or mixture
- Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2A H319 Causes serious eye irritation.

Repr. 2 H361 Suspected of damaging fertility or the unborn child.

STOT SE 3 H336 May cause drowsiness or dizziness.

STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.

Asp. Tox. 1 H304 May be fatal if swallowed and enters airways.

- · Label elements
- · GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms







GHS02 C

GHS07

GHS08

- · Signal word Danger
- · Hazard-determining components of labelling: toluene

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· Hazard statements

Highly flammable liquid and vapour.

Causes skin irritation.

Causes serious eye irritation.

Suspected of damaging fertility or the unborn child.

May cause drowsiness or dizziness.

May cause damage to organs through prolonged or repeated exposure.

May be fatal if swallowed and enters airways.

· Precautionary statements

Obtain special instructions before use.

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

Wear protective gloves/protective clothing/eye protection/face protection.

IF SWALLOWED: Immediately call a POISON CENTER/ doctor.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

In case of fire: Use to extinguish: CO2, powder or water spray.

Additional information:

Medical devices as defined in Directive 93/42/EEC 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 state and intended for the final user.

- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

3 Composition and Information on Ingredients

- · Chemical characterisation: Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:		
CAS: 67-63-0		50-100%
	Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336	
CAS: 108-88-3		10-25%
	Flam. Liq. 2, H225; Repr. 2, H361; STOT RE 2, H373; Asp. Tox. 1, H304; Skin Irrit. 2, H315; STOT SE 3, H336	

[·] Additional information: For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- · Description of first aid measures
- General information:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

In case of unconsciousness place patient stably in side position for transportation.

· After skin contact:

Immediately rinse with water.

If skin irritation continues, consult a doctor.

- · After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- · After swallowing: Do not induce vomiting; call for medical help immediately.
- Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.

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· Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Fire Fighting Measures

- · Extinguishing media
- · Suitable extinguishing agents: CO2, sand, extinguishing powder. Do not use water.
- · For safety reasons unsuitable extinguishing agents: Water with full jet
- · Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters
- · **Protective equipment:** No special measures required.
- · Additional information

Cool endangered receptacles with water spray.

See Section 14 for Hazchem Code.

6 Accidental Release Measures

· Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

- Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

Do not flush with water or aqueous cleansing agents

· Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and Storage

- · Handling:
- · Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

· Information about fire - and explosion protection:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- · Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: Store in a cool location.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

Keep container tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

Store receptacle in a well ventilated area.

• Specific end use(s) No further relevant information available.

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8 Exposure controls and personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · Control parameters

· Ingredients with limit values that require monitoring at the workplace:

CAS: 67-63-0 propan-2-ol

NES Short-term value: 1230 mg/m³, 500 ppm Long-term value: 983 mg/m³, 400 ppm WES Short-term value: 1230 mg/m³, 500 ppm Long-term value: 983 mg/m³, 400 ppm

CAS: 108-88-3 toluene

NES Short-term value: 574 mg/m³, 150 ppm Long-term value: 191 mg/m³, 50 ppm Sk WES Short-term value: 574 mg/m³, 150 ppm Long-term value: 191 mg/m³, 50 ppm

- · Additional information: The lists valid during the making were used as basis.
- · Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

Usual hygienic measures for dental practice and dental laboratories.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

· Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· Recommended filter device for short term use:

Filter A1

Filter A2

Filter A3

· Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. After use of gloves apply skin-cleaning agents and skin cosmetics.

· Material of gloves

Fluorocarbon rubber (Viton)

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

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· Eye protection:



Tightly sealed goggles

9 Physical and Chemical Properties

Information on basic physical and chemical properties

General Information

· Appearance:

Form: Fluid Colour: Yellow Odour: Characteristic · Odour threshold: Not determined. · pH-value: Not determined.

· Change in condition

Melting point/freezing point: Undetermined. **Initial boiling point and boiling range:** Undetermined.

12 °*C* · Flash point:

Product is not selfigniting. · Auto-ignition temperature:

Product is not explosive. However, formation of explosive air/ · Explosive properties:

Not determined.

Not determined.

vapour mixtures are possible.

· Explosion limits:

Lower:

Upper: · Vapour pressure: Not determined. · Density at 20 °C: 0.84 g/cm^3 · Relative density Not determined. · Vapour density Not determined. · Evaporation rate Not determined.

· Solubility in / Miscibility with

water: Not miscible or difficult to mix.

· Partition coefficient: n-octanol/water: Not determined.

Viscosity:

Not determined. Dynamic: Kinematic: Not determined.

· Other information No further relevant information available.

10 Stability and Reactivity

- · Reactivity No further relevant information available.
- · Chemical stability Stable under normal handling and storage conditions.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.

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· Hazardous decomposition products: None under normal conditions of storage and use.

11 Toxicological Information

- · Information on toxicological effects
- · Acute toxicity

· LD/LC50 values relevant for classification:			
CAS: 67-6	CAS: 67-63-0 propan-2-ol		
Oral	LD50	5045 mg/kg (rat)	
Dermal	LD50	12800 mg/kg (rabbit)	
Inhalative	LC50/4 h	30 mg/l (rat)	
CAS: 108-	CAS: 108-88-3 toluene		
Oral	LD50	5000 mg/kg (rat)	
Dermal	LD50	12124 mg/kg (rabbit)	
Inhalative	LC50/4 h	5320 mg/l (mouse)	

- · Skin corrosion/irritation Irritant to skin and mucous membranes.
- · Serious eye damage/irritation Irritating effect.
- · Additional toxicological information: No further relevant information available.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction) Repr. 2

12 Ecological Information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

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IIN Normhan	
UN-Number ADG, IMDG, IATA	UN1993
	0.11770
UN proper shipping name ADG	1993 FLAMMABLE LIQUID, N.O.S. (ISOPROPANO
1DU	(ISOPROPYL ALCOHOL), TOLUENE)
IMDG, IATA	FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL
,	(ISOPROPYL ALCOHOL), TOLUENE)
Transport hazard class(es)	
ADG	
2	
	2 /EI \ EI 11 11 11
Class Label	3 (F1) Flammable liquids. 3
	<i>y</i>
MDG, IATA	
3	
Class	3 Flammable liquids.
Label	3
Packing group	
ADG, IMDG, IATA	II
Environmental hazards:	
Marine pollutant:	No
Special precautions for user	Warning: Flammable liquids.
Danger code (Kemler):	33
Hazchem or Emergency Action Code:	•3YE
EMS Number:	F-E, <u>S-E</u>
Transport in bulk according to Annex II of M	Marpol
and the IBC Code	Not applicable.
Transport/Additional information:	
ADG	
Limited quantities (LQ)	IL
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml
Transport category	Maximum net quantity per outer packaging: 500 ml
ransport category Funnel restriction code	2 D/E
	<i>D</i> /L
MDG	

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	(Contd. of pag
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN ''Model Regulation'':	UN 1993 FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL), TOLUENE), 3, II

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Australian Inventory of Chemical Substances

All ingredients are listed.

· Standard for the Uniform Scheduling of Medicines and Poisons

CAS: 108-88-3 toluene

S6

- · GHS label elements
- The product is classified and labelled according to the Globally Harmonised System (GHS).
- · Hazard pictograms







GHS02

GHSO

GHS0

- · Signal word Danger
- · Hazard-determining components of labelling:

toluene

· Hazard statements

Highly flammable liquid and vapour.

Causes skin irritation.

Causes serious eye irritation.

Suspected of damaging fertility or the unborn child.

May cause drowsiness or dizziness.

May cause damage to organs through prolonged or repeated exposure.

May be fatal if swallowed and enters airways.

· Precautionary statements

Obtain special instructions before use.

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

Wear protective gloves/protective clothing/eye protection/face protection.

IF SWALLOWED: Immediately call a POISON CENTER/doctor.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

In case of fire: Use to extinguish: CO2, powder or water spray.

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Seveso category P5c FLAMMABLE LIQUIDS
- · Qualifying quantity (tonnes) for the application of lower-tier requirements 5000 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 50000 t
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Relevant phrases

H225 Highly flammable liquid and vapour.

H304 May be fatal if swallowed and enters airways.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

H361 Suspected of damaging fertility or the unborn child.

H373 May cause damage to organs through prolonged or repeated exposure.

· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

Repr. 2: Reproductive toxicity – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

Asp. Tox. 1: Aspiration hazard – Category 1

ΑU



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Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- · Product identifier
- · Trade name: AccuDent XD Tray Material
- Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Dental impression material
- Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Ivoclar Vivadent Inc.

175 Pineview Drive, Amherst, N.Y. 14228

USA

Tel. +1 800 533 6825 Fax +1 716 691 2285

Importer:

Ivoclar Vivadent Pty. Ltd. 1- 5 Overseas Drive Noble Park North VIC 3174

Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645

· Further information obtainable from:

Regulatory Affairs

sds@ivoclarvivadent.com

· Emergency telephone number: 131 126 (Poisons Information Centre - 24 hours / 7 days)

2 Hazard(s) Identification

· Classification of the substance or mixture

Carc. 1B H350 May cause cancer.

- · Label elements
- · GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms



GHS08

- · Signal word Danger
- · Hazard-determining components of labelling: phenolphthalein
- · Hazard statements

May cause cancer.

Precautionary statements

Avoid release to the environment.

Do not expose to temperatures exceeding 50 °C/122 °F.

· Additional information:

Medical devices as defined in Directive 93/42/EEC 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 state and intended for the final user.

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- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.

3 Composition and Information on Ingredients

- · Chemical characterisation: Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:		
CAS: 16919-27-0	dipotassium hexafluorotitanate	2.5-10%
	Eye Dam. 1, H318; Acute Tox. 4, H302; Skin Irrit. 2, H315; STOT SE 3, H335	
CAS: 1314-13-2	zinc oxide	<2.5%
CAS: 77-09-8	phenolphthalein	<2.5%
	Muta. 2, H341; Carc. 1B, H350; Repr. 2, H361	
CITIC		

\cdot SVHC

CAS: 77-09-8 phenolphthalein

· Additional information: For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- · Description of first aid measures
- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact: Rinse with water.
- · After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- · After swallowing: Seek medical treatment.
- Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire Fighting Measures

- · Extinguishing media
- · Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.
- Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters
- · Protective equipment:

Do not inhale explosion gases or combustion gases.

Wear self-contained respiratory protective device.

6 Accidental Release Measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up: Pick up mechanically.
- · Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

7 Handling and Storage

- · Handling:
- Precautions for safe handling

Only adequately trained personnel should handle this product.

For use in dentistry only.

- · Information about fire and explosion protection: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

Store receptacle in a well ventilated area.

Protect from heat and direct sunlight.

· Specific end use(s) No further relevant information available.

8 Exposure controls and personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · Control parameters
- Ingredients with limit values that require monitoring at the workplace:

CAS: 1314-13-2 zinc oxide

NES Short-term value: 10** mg/m³
Long-term value: 10* 5** mg/m³
*dust **fume

WES Short-term value: 10** mg/m³
Long-term value: 10* 5** mg/m³
*dust **fume

- · Additional information: The lists valid during the making were used as basis.
- · Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

Usual hygienic measures for dental practice and dental laboratories.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

- Respiratory protection: Use suitable respiratory protective device in case of insufficient ventilation.
- Recommended filter device for short term use:

Filter P1

Filter P2

Filter P3

· Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. After use of gloves apply skin-cleaning agents and skin cosmetics.

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

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· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection: Safety glasses

9 Physical and Chemical Properties

- · Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Powder Colour: Blue

· Odour: like peppermint · Odour threshold: Not determined.

· pH-value: Not applicable.

· Change in condition

Melting point/freezing point: Undetermined. **Initial boiling point and boiling range:** Undetermined.

· Flash point: Not applicable.

· Flammability (solid, gas): Not determined.

· Auto-ignition temperature: Product is not selfigniting.

· Explosive properties: Product does not present an explosion hazard.

Not determined.

· Explosion limits:

Lower:

Upper: Not determined. · Vapour pressure: Not applicable. Not determined. · Density:

· Relative density Not determined. · Vapour density Not applicable. · Evaporation rate Not applicable.

· Solubility in / Miscibility with

Partly miscible. Not determined.

· Partition coefficient: n-octanol/water:

Viscosity:

Dynamic: Not applicable. Kinematic: Not applicable.

· Other information No further relevant information available.

10 Stability and Reactivity

- · Reactivity No further relevant information available.
- · Chemical stability Stable under normal handling and storage conditions.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.

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Trade name: AccuDent XD Tray Material

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· Hazardous decomposition products: None under normal conditions of storage and use.

11 Toxicological Information

- · Information on toxicological effects
- · Acute toxicity
- LD/LC50 values relevant for classification:

CAS: 1314-13-2 zinc oxide

Oral | *LD50* | > 5000 mg/kg (rat)

· CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

Carc. 1B

12 Ecological Information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Ecotoxical effects:
- · Remark: Harmful to fish
- · Additional ecological information:
- · General notes:

Harmful to aquatic organisms

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · **vPvB**: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system. Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

Void

- · Uncleaned packaging:
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- · UN-Number
- · ADG, ADN, IMDG, IATA Void
- · UN proper shipping name
- · ADG, ADN, IMDG, IATA

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	(Contd. of page
· Transport hazard class(es)	
· ADG, ADN, IMDG, IATA · Class	Void
· Packing group · ADG, IMDG, IATA	Void
Environmental hazards:	Not applicable.
Special precautions for user	Not applicable.
Transport in bulk according to Annex II of and the IBC Code	Marpol Not applicable.
· Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· UN ''Model Regulation'':	Void

15 Regulatory information

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

· Australian Inventory of Chemical Substances		
CAS: 1314-13-2	zinc oxide	
CAS: 77-09-8	phenolphthalein	
· Standard for the Uniform Scheduling of Medicines and Poisons		
CAS: 77-09-8 pt	henolphthalein S4	

GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms



GHS08

- · Signal word Danger
- · Hazard-determining components of labelling: phenolphthalein
- · Hazard statements

May cause cancer.

· Precautionary statements

Avoid release to the environment.

Do not expose to temperatures exceeding 50 °C/122 °F.

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · National regulations:
- · Other regulations, limitations and prohibitive regulations

The product is a medical device according to the Directive 93/42/EEC.

· Substances of very high concern (SVHC) according to REACH, Article 57

CAS: 77-09-8 phenolphthalein

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Trade name: AccuDent XD Tray Material

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· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Relevant phrases

H302 Harmful if swallowed.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H335 May cause respiratory irritation.

H341 Suspected of causing genetic defects.

H350 May cause cancer.

H361 Suspected of damaging fertility or the unborn child.

· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Muta. 2: Germ cell mutagenicity – Category 2

Carc. 1B: Carcinogenicity - Category 1B

Repr. 2: Reproductive toxicity – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

AU