

Printing date 09.11.2018 Revision: 29.10.2018

1 Identification of the substance/mixture and of the company/undertaking

· Product identifier

· Trade name: Chromaclone™ Tray Adhesive

· Article number: 5101

· Index number: SDS 315-001.03

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

Professional Dental Impression Tray Adhesive

· Application of the substance / the mixture Professional Dental Impression Tray Adhesive

Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

Ultradent Products Inc.

505 W. Ultradent Drive (10200 S)

South Jordan, UT 84095-3942

USA

onlineordersupport@utradent.com

EC Responsible Person

Ultradent Products GmbH

Am Westhover Berg 30

51149 Cologne Germany

Email: infoDe@ultradent.com

Emergency Phone: +49(0)2203-35-92-0

· Further information obtainable from: Customer Service

· Emergency telephone number:

CHEMTREC (NORTH AMERICA) :(800) 424-9300 (INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

- · Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008



GHS02 flame

Flam. Liq. 3 H226 Flammable liquid and vapour.



GHS08 health hazard

Repr. 2 H361d Suspected of damaging the unborn child.

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.



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

STOT SE 3 H335 May cause respiratory irritation.

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- · Label elements
- · Labelling according to Regulation (EC) No 1272/2008 Void
- · Hazard pictograms GHS02, GHS07, GHS08
- · Signal word Danger

· Hazard-determining components of labelling:

Toluene

Ethylbenzene

· Hazard statements

H226 Flammable liquid and vapour.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H361d Suspected of damaging the unborn child.

H335 May cause respiratory irritation.

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

H304 May be fatal if swallowed and enters airways.

· Precautionary statements

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P103 Read label before use.

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.

P321 Specific treatment (see on this label).

P331 Do NOT induce vomiting.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/

shower.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P362+P364 Take off contaminated clothing and wash it before reuse.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

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

3 Composition/information on ingredients

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

· Dangerous compone	ents:	
CAS: 1330-20-7	Xylene, mixture of isomers	20-30%
EINECS: 215-535-7	Flam. Liq. 3, H226; Acute Tox. 4, H312; Acute Tox. 4, H332; Skin Irrit. 2, H315	
CAS: 108-88-3	Toluene	10-20%
EINECS: 203-625-9	♦ Flam. Liq. 2, H225; ♦ Repr. 2, H361d; STOT RE 2, H373; Asp. Tox. 1, H304; ♦ Skin Irrit. 2, H315; STOT SE 3, H336	
CAS: 100-41-4	Ethylbenzene	9-19%
EINECS: 202-849-4	 Flam. Liq. 2, H225; STOT RE 2, H373; Asp. Tox. 1, H304; ↑ Acute Tox. 4, H332 	
CAS: 34590-94-8	Dipropylene Glycol Monomethyl Ether	1-3%
EINECS: 252-104-2	substance with a Community workplace exposure limit	
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· 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:

Immediately remove any clothing soiled by the product.

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

· After inhalation:

Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention immediately. In case of unconsciousness place patient stably in side position for transportation.

· After skin contact:

Remove contaminated clothing. Immediately wash with water and soap and rinse thoroughly. Get medical advice/attention immediately. Wash contaminated clothing before using it again.

· After eye contact:

Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.

· After swallowing:

Get medical advice/attention immediately. Do not induce vomiting. Do not administer anything not explicitly authorised by a doctor.

- Information for doctor:
- · Most important symptoms and effects, both acute and delayed

For symptoms and effects caused by the contained substances, see Section 11.

· Indication of any immediate medical attention and special treatment needed Information not available

5 Firefighting measures

- · Extinguishing media
- · Suitable extinguishing agents:

Extinguishing substances are: carbon dioxide, foam, chemical powder. For product loss or leakage that has not caught fire, water spray can be used to disperse flammable vapours and protect those trying to stem the leak. UNSUITABLE EXTINGUISHING EQUIPMENT

Do not use jets of water. Water is not effective for putting out fires but can be used to cool containers exposed to flames to prevent explosions.

· Special hazards arising from the substance or mixture

During heating or in case of fire poisonous gases are produced.

- Advice for firefighters:
- · Protective equipment:

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

Mouth respiratory protective device.

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6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

Mount respiratory protective device.

Wear protective equipment. Keep unprotected persons away.

· Environmental precautions:

The product must not penetrate into the sewer system or come into contact with surface water or ground water. Dilute with plenty of water.

Do not allow to enter sewers/surface or ground water.

· Methods and material for containment and cleaning up:

Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. Check incompatibility for container material in section 7. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

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

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

· Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

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:

Keep away from heat, sparks and naked flames; do not smoke or use matches or lighters. Vapours may catch fire and an explosion may occur; vapour accumulation is therefore to be avoided by leaving windows and doors open and ensuring good cross ventilation. Without adequate ventilation, vapours may accumulate at ground level and, if ignited, catch fire even at a distance, with the danger of backfire. Avoid bunching of electrostatic charges. When performing transfer operations involving large containers, connect to an earthing system and wear antistatic footwear. Vigorous stirring and flow through the tubes and equipment may cause the formation and accumulation of electrostatic charges. In order to avoid the risk of fires and explosions, never use compressed air when handling. Open containers with caution as they may be pressurised. Do not eat, drink or smoke during use. Avoid leakage of the product into the environment.

Ensure good ventilation/exhaustion at the workplace.

Open and handle receptacle with care.

Prevent formation of aerosols.

· Information about fire - and explosion protection:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

Keep respiratory protective device available.

· Conditions for safe storage, including any incompatibilities

- Storage:
- · Requirements to be met by storerooms and receptacles:

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Store in a well ventilated place, keep far away from sources of heat, naked flames and sparks and other sources of ignition. Keep containers away from any incompatible materials, see section 10 for details.

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- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

See product labelling.

Keep container tightly sealed.

· Specific end use(s) Professional Dental Impression Tray Adhesive

8 Exposure controls/personal protection

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

· Control parameters				
· Ingredients with limi	it values that require monitoring at the workplace:			
1330-20-7 Xylene, mixture of isomers				
WEL (Great Britain)	Short-term value: 441 mg/m³, 100 ppm			
	Long-term value: 220 mg/m³, 50 ppm Sk; BMGV			
108-88-3 Toluene				
WEL (Great Britain)	Short-term value: 384 mg/m³, 100 ppm			
	Long-term value: 191 mg/m³, 50 ppm			
	Sk			
100-41-4 Ethylbenze	ne			
WEL (Great Britain)	Short-term value: 552 mg/m³, 125 ppm			
	Long-term value: 441 mg/m³, 100 ppm			
	Sk			
34590-94-8 Dipropyl	ene Glycol Monomethyl Ether			
WEL (Great Britain)	Long-term value: 308 mg/m³, 50 ppm			
	Sk			
· Ingredients with biol	logical limit values:			
1330-20-7 Xylene, m	ixture of isomers			
BMGV (Great Britaii	n) 650 mmol/mol creatinine			
,	Medium: urine			
	Sampling time: post shift			
	Parameter: methyl hippuric acid			

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

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local ventilation. Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Exposure levels must be kept as low as possible to avoid significant build-up in the organism. Manage personal protective equipment so as to guarantee maximum protection (e.g. reduction in replacement times). The usual precautionary measures are to be adhered to when handling chemicals.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work..

Store protective clothing separately.

Avoid contact with the eyes and skin.

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· Respiratory protection:

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type A filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

· Protection of hands:

Protect hands with category III work gloves (see standard EN 374).

The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of 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 breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eve protection:

Wear airtight protective goggles (see standard EN 166).



Tightly sealed goggles

Body protection:

Wear category II professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

9 Physical and chemical properties

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

Form: Fluid
Colour: Red
Odour: Solvent-like
Odour threshold: Not available

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pH-value:	Not determined.
Change in condition Melting point/freezing point: Initial boiling point and boiling range	Undetermined. :: 113°C
Flash point:	27 °C
Flammability (solid, gas):	Not applicable.
Decomposition temperature:	Not determined.
Auto-ignition temperature:	Product is not selfigniting.
Explosive properties:	Product is not explosive. However, formation of explosive air/vapoumixtures are possible.
Explosion limits: Lower: Upper:	Not determined. Not determined.
Vapour pressure:	Not determined.
Density: Relative density at 20 °C Vapour density Evaporation rate	Not determined. 1.011 kg/l Not determined. Not determined.
Solubility in / Miscibility with water:	Partly miscible.
Partition coefficient: n-octanol/water:	Not determined.
Viscosity: Dynamic: Kinematic:	Not determined. Not determined.
Solvent content: Organic solvents: VOC (EC)	40-72 % 40-72 %
Solids content: Other information	<60.0 % No further relevant information available.

10 Stability and reactivity

· Reactivity

There are no particular risks of reaction with other substances in normal conditions of use. TOLUENE: breaks down in sunlight

- · Chemical stability
- · Thermal decomposition / conditions to be avoided:

The product is stable in normal conditions of use and storage.

· Possibility of hazardous reactions:

The vapours may also form explosive mixtures with the air.

TOLUENE: risk of explosion on contact with fuming sulphuric acid, nitric acid, silver perchlorates, nitrogen dioxide, non-metal halogenides, acetic acid, organic nitrocompounds. Can form explosive mixtures with the air. May react dangerously with: strong oxidising agents, strong acids, sulphur (in the presence of heat).

· Conditions to avoid: Avoid overheating. Avoid bunching of electrostatic charges. Avoid all sources of ignition.

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- · Incompatible materials: Information not available
- · Hazardous decomposition products:

In the event of thermal decomposition or fire, gases and vapours that are potentially dangerous to health may be released.

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50 1	· LD/LC50 values relevant for classification:			
ATE (Acut	ATE (Acute Toxicity Estimates)			
Dermal	LD50	6,667-10,000 mg/kg (rabbit)		
Inhalative	LC50/4 h	22.4-37.9 mg/l		
1330-20-7	Xylene, m	ixture of isomers		
Oral	LD50	4,300 mg/kg (rat)		
Dermal	LD50	2,000 mg/kg (rabbit)		
108-88-3 T	108-88-3 Toluene			
Oral	LD50	5,000 mg/kg (rat)		
Dermal	LD50	12,124 mg/kg (rabbit)		
Inhalative	LC50/4 h	5,320 mg/l (mouse)		
100-41-4 E	Ethylbenzei	ne		
Oral	LD50	3,500 mg/kg (rat)		
Dermal	LD50	17,800 mg/kg (rabbit)		
34590-94-8	34590-94-8 Dipropylene Glycol Monomethyl Ether			
Oral	LD50	5,135 mg/kg (rat)		
Dermal	LD50	>19,000 mg/kg (rab)		

- Primary irritant effect:
- · Skin corrosion/irritation

Causes skin irritation.

· Serious eve damage/irritation

Causes serious eye irritation.

- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity

Suspected of damaging the unborn child.

· STOT-single exposure

May cause respiratory irritation.

· STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure.

· Aspiration hazard

May be fatal if swallowed and enters airways.

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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 Information not 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:

12.5. Results of PBT and vPvB assessment.

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

- · vPvB: Not applicable.
- · Other adverse effects Information not available

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

Reuse, when possible. Product residues should be considered special hazardous waste (HP 5). The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

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

· Europe	· European waste catalogue		
HP 3	P 3 Flammable		
HP 4	Irritant - skin irritation and eye damage		
HP 5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity		
HP 6	Acute Toxicity		
HP 10	Toxic for reproduction		

- · Uncleaned packaging:
- Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

14 Transport information

- · UN-Number
- · ADR, IMDG, IATA

UN1133

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UN proper shipping name	
ADR	1133 ADHESIVES
· IMDG, IATA	ADHESIVES
Transport hazard class(es)	
ADR, IMDG, IATA	

Class	3 Flammable liquids.
Label	3
Packing group	
ADR, IMDG, IATA	III
Environmental hazards:	Not applicable.
Special precautions for user	Warning: Flammable liquids.
Danger code (Kemler):	30
EMS Number:	F- E , S - D
Stowage Category	A
Transport in bulk according to Annex II of	
and the IBC Code	Not applicable.
Transport/Additional information:	
ADR	
Limited quantities (LQ)	5L
Excepted quantities (EQ)	Code: E1
	Maximum net quantity per inner packaging: 30 ml
Tuguspout agtagous	Maximum net quantity per outer packaging: 1000 ml 3
Transport category Tunnel restriction code	D/E
	D/U
IMDG	5L
Limited quantities (LQ) Excepted quantities (EQ)	5L Code: E1
Excepted quantities (EQ)	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
UN "Model Regulation":	UN 1133 ADHESIVES, 3, III

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture Seveso category. 6

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.

Product.

Point. 3 - 40

Contained substance.

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Safety data sheet according to 1907/2006/EC, Article 31

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Point. 48 TOLUENE

Substances in Candidate List (Art. 59 REACH).: None.

Substances subject to authorisarion (Annex XIV REACH).: None.

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012: None.

Substances subject to the Rotterdam Convention: None.

Substances subject to the Stockholm Convention: None.

Healthcare controls.

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

- · Directive 2012/18/EU
- · Seveso category P5c FLAMMABLE LIQUIDS
- Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t
- · Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t
- · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3, 48
- · 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

- H225 Highly flammable liquid and vapour.
- H226 Flammable liquid and vapour.
- H304 May be fatal if swallowed and enters airways.
- H312 Harmful in contact with skin.
- H315 Causes skin irritation.
- H332 Harmful if inhaled.
- H336 May cause drowsiness or dizziness.
- H361d Suspected of damaging the unborn child.
- H373 May cause damage to organs through prolonged or repeated exposure.
- · Department issuing SDS: Regulatory Affairs
- · Contact: Customer Service
- · 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

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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)

VOC: Volatile Organic Compounds (USA, EU)

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

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Safety data sheet according to 1907/2006/EC, Article 31

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Flam. Liq. 3: Flammable liquids – Category 3 Acute Tox. 4: Acute toxicity – Category 4 Skin Irrit. 2: Skin corrosion/irritation – Category 2 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

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

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