

Clone™ Bite - Base

Version No: 4.1

Safety Data Sheet according to OSHA HazCom Standard (2012) requirements

Issue Date: **25/10/2024**Print Date: **15/11/2024**

S.GHS.USA.EN.E

SECTION 1 Identification**Product Identifier**

Product name	Clone™ Bite - Base
Chemical Name	Not Applicable
Synonyms	68426, B000075
Chemical formula	Not Applicable
Article Number	SDS 257-001.04R01, 7600

Recommended use of the chemical and restrictions on use

Relevant identified uses	For professional use only. Addition silicone for dental impression. Use according to manufacturer's directions.
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Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party

Registered company name	Manufactured by Zhermack for Ultradent Products Inc
Address	505 West Ultradent Drive 10200 South, South Jordan UT 84095 United States
Telephone	+1 (801) 572-4200
Fax	Not Available
Website	https://www.ultradent.com/
Email	onlineordersupport@ultradent.com

Emergency phone number

Association / Organisation	CHEMTREC CUSTOMER SERVICE
Emergency telephone number(s)	+1 (800) 424-9300 (North America)
Other emergency telephone number(s)	1 (703) 527-3887 (International)

SECTION 2 Hazard(s) identification**Classification of the substance or mixture**

NFPA 704 diamond



Note: The hazard category numbers found in GHS classification in section 2 of this SDSs are NOT to be used to fill in the NFPA 704 diamond. Blue = Health Red = Fire Yellow = Reactivity White = Special (Oxidizer or water reactive substances)

Classification	Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2A
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Label elements

Hazard pictogram(s)	
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Signal word	Warning
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Hazard statement(s)

H315	Causes skin irritation.
H319	Causes serious eye irritation.

Hazard(s) not otherwise classified

Not Applicable

Precautionary statement(s) Prevention

P280	Wear protective gloves, protective clothing, eye protection and face protection.
P264	Wash all exposed external body areas thoroughly after handling.

Precautionary statement(s) Response

P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice/attention.
P302+P352	IF ON SKIN: Wash with plenty of water and soap.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.

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
14464-46-1	30-60	<u>crystalite</u>
68037-59-2	10-30	<u>dimethylsiloxane, methylhydrogen-</u>
68083-19-2	10-30	<u>dimethylsiloxane polymer, vinyl-terminated</u>
7631-86-9	10-30	<u>silica amorphous</u>
63148-62-9	<1	<u>polydimethylsiloxane(s)</u>
5567-15-7	<1	<u>C.I. Pigment Yellow 83</u>
12227-78-0	<1	<u>C.I. Food Red 14:1</u>
123-92-2	<1	<u>iso-amyl acetate</u>
141-78-6	<1	<u>ethyl acetate</u>
Not Available	balance	Ingredients determined not to be hazardous

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

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. <p>For thermal burns:</p> <ul style="list-style-type: none"> ▶ Decontaminate area around burn. ▶ Consider the use of cold packs and topical antibiotics.

Continued...

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	<p>For first-degree burns (affecting top layer of skin)</p> <ul style="list-style-type: none"> ▶ Hold burned skin under cool (not cold) running water or immerse in cool water until pain subsides. ▶ Use compresses if running water is not available. ▶ Cover with sterile non-adhesive bandage or clean cloth. ▶ Do NOT apply butter or ointments; this may cause infection. ▶ Give over-the counter pain relievers if pain increases or swelling, redness, fever occur. <p>For second-degree burns (affecting top two layers of skin)</p> <ul style="list-style-type: none"> ▶ Cool the burn by immerse in cold running water for 10-15 minutes. ▶ Use compresses if running water is not available. ▶ Do NOT apply ice as this may lower body temperature and cause further damage. ▶ Do NOT break blisters or apply butter or ointments; this may cause infection. ▶ Protect burn by cover loosely with sterile, nonstick bandage and secure in place with gauze or tape. <p>To prevent shock: (unless the person has a head, neck, or leg injury, or it would cause discomfort):</p> <ul style="list-style-type: none"> ▶ Lay the person flat. ▶ Elevate feet about 12 inches. ▶ Elevate burn area above heart level, if possible. ▶ Cover the person with coat or blanket. ▶ Seek medical assistance. <p>For third-degree burns Seek immediate medical or emergency assistance. In the mean time:</p> <ul style="list-style-type: none"> ▶ Protect burn area cover loosely with sterile, nonstick bandage or, for large areas, a sheet or other material that will not leave lint in wound. ▶ Separate burned toes and fingers with dry, sterile dressings. ▶ Do not soak burn in water or apply ointments or butter; this may cause infection. ▶ To prevent shock see above. ▶ For an airway burn, do not place pillow under the person's head when the person is lying down. This can close the airway. ▶ Have a person with a facial burn sit up. ▶ Check pulse and breathing to monitor for shock until emergency help arrives.
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"> ▶ Immediately give a glass of water. ▶ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

Most important symptoms and effects, both acute and delayed

See Section 11

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 Fire-fighting measures

Extinguishing media

- ▶ There is no restriction on the type of extinguisher which may be used.
- ▶ Use extinguishing media suitable for surrounding area.

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
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Special protective equipment and precautions for fire-fighters

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. ▶ DO NOT approach containers suspected to be hot. ▶ Cool fire exposed containers with water spray from a protected location. ▶ If safe to do so, remove containers from path of fire. ▶ Equipment should be thoroughly decontaminated after use.
Fire/Explosion Hazard	<ul style="list-style-type: none"> ▶ Non combustible. ▶ Not considered a significant fire risk, however containers may burn. <p>Decomposes on heating and produces: carbon dioxide (CO₂) nitrogen oxides (NO_x) silicon dioxide (SiO₂) metal oxides other pyrolysis products typical of burning organic material. May emit poisonous fumes. May emit corrosive fumes.</p>

CARE: Water in contact with hot liquid may cause foaming and a steam explosion with wide scattering of hot oil and possible severe burns. Foaming may cause overflow of containers and may result in possible fire.

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 breathing vapours and contact with skin and eyes. ▶ Control personal contact with the substance, by using protective equipment. ▶ Contain and absorb spill with sand, earth, inert material or vermiculite. ▶ Wipe up. ▶ Place in a suitable, labelled container for waste disposal.
Major Spills	<ul style="list-style-type: none"> ▶ Silicone fluids, even in small quantities, may present a slip hazard. ▶ It may be necessary to rope off area and place warning signs around perimeter. ▶ Clean up area from spill, with suitable absorbant, as soon as practically possible. ▶ Final cleaning may require use of steam, solvents or detergents. <p>Moderate hazard.</p> <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. ▶ Stop leak if safe to do so. ▶ Contain spill with sand, earth or vermiculite. ▶ Collect recoverable product into labelled containers for recycling. ▶ Neutralise/decontaminate residue (see Section 13 for specific agent). ▶ Collect solid residues and seal in labelled drums for disposal. ▶ Wash area and prevent runoff into drains. ▶ After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using. ▶ If contamination of drains or waterways occurs, advise emergency services.

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"> ▶ DO NOT allow clothing wet with material to stay in contact with skin ▶ Avoid all personal contact, including inhalation. ▶ Wear protective clothing when risk of exposure occurs. ▶ Use in a well-ventilated area. ▶ Avoid contact with moisture. ▶ Avoid contact with incompatible materials. ▶ When handling, DO NOT eat, drink or smoke. ▶ Keep containers securely sealed when not in use. ▶ Avoid physical damage to containers. ▶ Always wash hands with soap and water after handling. ▶ Work clothes should be laundered separately. Launder contaminated clothing before re-use. ▶ Use good occupational work practice. ▶ Observe manufacturer's storage and handling recommendations contained within this SDS. ▶ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.
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. ▶ Protect containers against physical damage and check regularly for leaks. ▶ Observe manufacturer's storage and handling recommendations contained within this SDS.

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 strong acids, bases. ▶ Avoid reaction with oxidising agents

SECTION 8 Exposure controls / personal protection

Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA


Source	Ingredient	Material name	TWA	STEL	Peak	Notes
US OSHA Permissible Exposure Limits (PELs) Table Z-1	cristobalite	Cristobalite - respirable	0.05 mg/m3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-3	cristobalite	Silica: Crystalline: Cristobalite	Not Available	Not Available	Not Available	Use ½ the value calculated from the count or mass formulae for quartz.
US NIOSH Recommended Exposure Limits (RELs)	cristobalite	Particulates not otherwise regulated	Not Available	Not Available	Not Available	See Appendix D
US OSHA Permissible Exposure Limits (PELs) Table Z-1	silica amorphous	Particulates Not Otherwise Regulated (PNOR)- Total dust	15 mg/m3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-1	silica amorphous	Particulates Not Otherwise Regulated (PNOR)- Respirable fraction	5 mg/m3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-3	silica amorphous	Amorphous, including natural diatomaceous earth	80 (%SiO2) mg/m3 / 20 mppcf	Not Available	Not Available	Not Available
US NIOSH Recommended Exposure Limits (RELs)	silica amorphous	Silica, amorphous	6 mg/m3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-1	C.I. Food Red 14:1	Particulates Not Otherwise Regulated (PNOR)- Total dust	15 mg/m3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-1	C.I. Food Red 14:1	Particulates Not Otherwise Regulated (PNOR)- Respirable fraction	5 mg/m3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-3	C.I. Food Red 14:1	Inert or Nuisance Dust: Respirable fraction	5 mg/m3 / 15 mppcf	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-3	C.I. Food Red 14:1	Inert or Nuisance Dust: Total Dust	15 mg/m3 / 50 mppcf	Not Available	Not Available	Not Available
US NIOSH Recommended Exposure Limits (RELs)	C.I. Food Red 14:1	Particulates not otherwise regulated	Not Available	Not Available	Not Available	See Appendix D
US OSHA Permissible Exposure Limits (PELs) Table Z-1	iso-amyl acetate	Isoamyl acetate	100 ppm / 525 mg/m3	Not Available	Not Available	Not Available
US NIOSH Recommended Exposure Limits (RELs)	iso-amyl acetate	Isoamyl acetate	100 ppm / 525 mg/m3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-1	ethyl acetate	Ethyl acetate	400 ppm / 1400 mg/m3	Not Available	Not Available	Not Available
US NIOSH Recommended Exposure Limits (RELs)	ethyl acetate	Ethyl acetate	400 ppm / 1400 mg/m3	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
cristobalite	Not Available	Not Available
dimethylsiloxane, methylhydrogen-	Not Available	Not Available
dimethylsiloxane polymer, vinyl-terminated	Not Available	Not Available
silica amorphous	3,000 mg/m3	Not Available
polydimethylsiloxane(s)	Not Available	Not Available
C.I. Pigment Yellow 83	Not Available	Not Available
C.I. Food Red 14:1	Not Available	Not Available
iso-amyl acetate	1,000 ppm	Not Available
ethyl acetate	Not Available	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
dimethylsiloxane, methylhydrogen-	E	≤ 0.1 ppm
C.I. Pigment Yellow 83	C	> 0.1 to ≤ milligrams per cubic meter of air (mg/m ³)
Notes:	<i>Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.</i>	

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:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>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. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use. Employers may need to use multiple types of controls to prevent employee overexposure.</p> <p>Local exhaust ventilation usually required. If risk of overexposure exists, wear approved respirator. Correct fit is essential to obtain adequate protection. Supplied-air type respirator may be required in special circumstances. Correct fit is essential to ensure adequate protection.</p> <p>An approved self contained breathing apparatus (SCBA) may be required in some situations.</p> <p>Provide adequate ventilation in warehouse or closed storage area. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.</p> <table border="1" style="width: 100%;"> <thead> <tr> <th>Type of Contaminant:</th> <th>Air Speed:</th> </tr> </thead> <tbody> <tr> <td>solvent, vapours, degreasing etc., evaporating from tank (in still air).</td> <td>0.25-0.5 m/s (50-100 f/min.)</td> </tr> <tr> <td>aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)</td> <td>0.5-1 m/s (100-200 f/min.)</td> </tr> <tr> <td>direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)</td> <td>1-2.5 m/s (200-500 f/min.)</td> </tr> <tr> <td>grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).</td> <td>2.5-10 m/s (500-2000 f/min.)</td> </tr> </tbody> </table> <p>Within each range the appropriate value depends on:</p> <table border="1" style="width: 100%;"> <thead> <tr> <th>Lower end of the range</th> <th>Upper end of the range</th> </tr> </thead> <tbody> <tr> <td>1: Room air currents minimal or favourable to capture</td> <td>1: Disturbing room air currents</td> </tr> <tr> <td>2: Contaminants of low toxicity or of nuisance value only.</td> <td>2: Contaminants of high toxicity</td> </tr> <tr> <td>3: Intermittent, low production.</td> <td>3: High production, heavy use</td> </tr> <tr> <td>4: Large hood or large air mass in motion</td> <td>4: Small hood-local control only</td> </tr> </tbody> </table> <p>Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2 m/s (200-400 f/min) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.</p>	Type of Contaminant:	Air Speed:	solvent, vapours, degreasing etc., evaporating from tank (in still air).	0.25-0.5 m/s (50-100 f/min.)	aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)	direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min.)	grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).	2.5-10 m/s (500-2000 f/min.)	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Individual protection measures, such as personal protective equipment																					
Eye and face protection	<ul style="list-style-type: none"> ▶ Safety glasses with side shields. ▶ Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent] ▶ 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. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59]. 																				
Skin protection	See Hand protection below																				
Hands/feet protection	The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical 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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The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.

Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:

- frequency and duration of contact,
- chemical resistance of glove material,
- glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).

- When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
- When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
- Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use.
- Contaminated gloves should be replaced.

As defined in ASTM F-739-96 in any application, gloves are rated as:

- Excellent when breakthrough time > 480 min
- Good when breakthrough time > 20 min
- Fair when breakthrough time < 20 min
- Poor when glove material degrades

For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended.

It should be emphasised that glove thickness is not necessarily a good predictor of glove resistance to a specific chemical, as the permeation efficiency of the glove will be dependent on the exact composition of the glove material. Therefore, glove selection should also be based on consideration of the task requirements and knowledge of breakthrough times.

Glove thickness may also vary depending on the glove manufacturer, the glove type and the glove model. Therefore, the manufacturers technical data should always be taken into account to ensure selection of the most appropriate glove for the task.

Note: Depending on the activity being conducted, gloves of varying thickness may be required for specific tasks. For example:

- Thinner gloves (down to 0.1 mm or less) may be required where a high degree of manual dexterity is needed. However, these gloves are only likely to give short duration protection and would normally be just for single use applications, then disposed of.
- Thicker gloves (up to 3 mm or more) may be required where there is a mechanical (as well as a chemical) risk i.e. where there is abrasion or puncture potential

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

- ▶ Wear chemical protective gloves, e.g. PVC.
- ▶ Wear safety footwear or safety gumboots, e.g. Rubber

Body protection

See Other protection below

Other protection

- ▶ Overalls.
- ▶ P.V.C apron.
- ▶ Barrier cream.
- ▶ Skin cleansing cream.
- ▶ Eye wash unit.

Respiratory protection

Type AK-P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Where the concentration of gas/particulates in the breathing zone, approaches or exceeds the "Exposure Standard" (or ES), respiratory protection is required. Degree of protection varies with both face-piece and Class of filter; the nature of protection varies with Type of filter.

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	AK-AUS P2	-	AK-PAPR-AUS / Class 1 P2
up to 50 x ES	-	AK-AUS / Class 1 P2	-
up to 100 x ES	-	AK-2 P2	AK-PAPR-2 P2 ^

^ - Full-face

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

If inhalation risk above the TLV exists, wear approved dust respirator.

Use respirators with protection factors appropriate for the exposure level.

- ▶ Up to 5 X TLV, use valveless mask type; up to 10 X TLV, use 1/2 mask dust respirator
- ▶ Up to 50 X TLV, use full face dust respirator or demand type C air supplied respirator

Continued...

- ▶ Up to 500 X TLV, use powered air-purifying dust respirator or a Type C pressure demand supplied-air respirator
 - ▶ Over 500 X TLV wear full-face self-contained breathing apparatus with positive pressure mode or a combination respirator with a Type C positive pressure supplied-air full-face respirator and an auxiliary self-contained breathing apparatus operated in pressure demand or other positive pressure mode
 - ▶ Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content.
 - ▶ The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.
 - ▶ Cartridge performance is affected by humidity. Cartridges should be changed after 2 hr of continuous use unless it is determined that the humidity is less than 75%, in which case, cartridges can be used for 4 hr. Used cartridges should be discarded daily, regardless of the length of time used
- Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
 - The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
 - Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.
 - Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
 - Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU)
 - Use approved positive flow mask if significant quantities of dust becomes airborne.
 - Try to avoid creating dust conditions.
- Where significant concentrations of the material are likely to enter the breathing zone, a Class P3 respirator may be required.
- Class P3 particulate filters are used for protection against highly toxic or highly irritant particulates.
- Filtration rate: Filters at least 99.95% of airborne particles
- Suitable for:
- Relatively small particles generated by mechanical processes eg. grinding, cutting, sanding, drilling, sawing.
 - Sub-micron thermally generated particles e.g. welding fumes, fertilizer and bushfire smoke.
 - Biologically active airborne particles under specified infection control applications e.g. viruses, bacteria, COVID-19, SARS
 - Highly toxic particles e.g. Organophosphate Insecticides, Radionuclides, Asbestos
- Note: P3 Rating can only be achieved when used with a Full Face Respirator or Powered Air-Purifying Respirator (PAPR). If used with any other respirator, it will only provide filtration protection up to a P2 rating.

SECTION 9 Physical and chemical properties

Information on basic physical and chemical properties

Appearance	Orange coloured viscous liquid with bubblegum odour; does not mix with water.		
Physical state	Liquid	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

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pH (as supplied)	Not Applicable	Decomposition temperature (°C)	Not Available
Melting point / freezing point (°C)	Not Applicable	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	>130	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Applicable	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Immiscible	pH as a solution (1%)	Not Applicable
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available
Heat of Combustion (kJ/g)	Not Available	Ignition Distance (cm)	Not Available
Flame Height (cm)	Not Available	Flame Duration (s)	Not Available
Enclosed Space Ignition Time Equivalent (s/m3)	Not Available	Enclosed Space Ignition Deflagration Density (g/m3)	Not Available

SECTION 10 Stability and reactivity

Reactivity	See section 7
Chemical stability	<ul style="list-style-type: none"> ▶ Silicone fluids are stable under normal storage conditions. ▶ Hazardous polymerisation will not occur. ▶ At temperatures > 150 C, silicones can slowly react with the oxygen in air. ▶ When heated > 300 C, silicones can slowly depolymerise to volatile siloxanes whether or not air is present. ▶ 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	For paste and fluid products there is no exposure to cristobalite/quartz during the normal use of this product because it's bound within the polymer matrix . Therefore this product must not be classified for inhalation hazard.
Ingestion	The material has NOT been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence.
Skin Contact	<p>This material can cause inflammation of the skin on contact in some persons.</p> <p>The material may accentuate any pre-existing dermatitis condition</p> <p>Open cuts, abraded or irritated skin should not be exposed to this material</p> <p>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.</p>
Eye	This material can cause eye irritation and damage in some persons.
Chronic	<p>Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.</p> <p>Amorphous silicas generally are less hazardous than crystalline silicas, but the former can be converted to the latter on heating and subsequent cooling. Inhalation of dusts containing crystalline silicas may lead to silicosis, a disabling lung disease that may take years to develop.</p> <p>Soluble silicates do not exhibit sensitizing potential. Testing in bacterial and animal experiments have not shown any evidence of them causing mutations or birth defects.</p> <p>Overexposure to the breathable dust may cause coughing, wheezing, difficulty in breathing and impaired lung function. Chronic symptoms may include decreased vital lung capacity and chest infections. Repeated exposures in the workplace to high levels of fine-divided dusts may produce a condition known as pneumoconiosis, which is the lodgement of any inhaled dusts in the lung, irrespective of the effect. This is particularly true when a significant number of particles less than 0.5 microns (1/50000 inch) are present. Lung shadows are seen in the X-ray. Symptoms of pneumoconiosis may include a progressive dry cough, shortness of breath on exertion, increased chest expansion, weakness and weight loss. As the disease progresses, the cough produces stringy phlegm, vital capacity decreases further, and shortness of breath becomes more severe. Other signs or symptoms</p>

Continued...

Clone™ Bite - Base

include changed breath sounds, reduced oxygen uptake during exercise, emphysema and rarely, pneumothorax (air in the lung cavity).
Removing workers from the possibility of further exposure to dust generally stops the progress of lung abnormalities. When there is high potential for worker exposure, examinations at regular period with emphasis on lung function should be performed.
Inhaling dust over an extended number of years may cause pneumoconiosis, which is the accumulation of dusts in the lungs and the subsequent tissue reaction. This may or may not be reversible.

Clone Bite - Base	TOXICITY	IRRITATION
	Not Available	Not Available
cristobalite	TOXICITY	IRRITATION
	Not Available	Not Available
dimethylsiloxane, methylhydrogen-	TOXICITY	IRRITATION
	Not Available	Not Available
dimethylsiloxane polymer, vinyl-terminated	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >15840 mg/kg ^[2] Oral (Rat) LD50: >15840 mg/kg ^[2]	Not Available
silica amorphous	TOXICITY	IRRITATION
	dermal (rat) LD50: >2000 mg/kg ^[1] Inhalation (Rat) LC50: >0.09<0.84 mg/l4h ^[1] Oral (Rat) LD50: >1000 mg/kg ^[1]	Eye (Rodent - rabbit): 25mg/24H - Mild Eye: no adverse effect observed (not irritating) ^[1] Skin: no adverse effect observed (not irritating) ^[1]
polydimethylsiloxane(s)	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >2000 mg/kg ^[2] Oral (Rat) LD50: >17000 mg/kg ^[2]	Eye (Rodent - rabbit): 100mg/1H - Mild Eye (Rodent - rabbit): 100uL/24H - Mild Eye (Rodent - rabbit): 100uL/24H - Moderate Skin (Rodent - rabbit): 500uL/24H - Mild
C.I. Pigment Yellow 83	TOXICITY	IRRITATION
	dermal (rat) LD50: >3000 mg/kg ^[1] Inhalation (Rat) LC50: >0.23 mg/L4h ^[1] Oral (Rat) LD50: >5000 mg/kg ^[2]	Eye: no adverse effect observed (not irritating) ^[1] Skin (Rodent - rabbit): 500mg - Mild Skin: no adverse effect observed (not irritating) ^[1]
C.I. Food Red 14:1	TOXICITY	IRRITATION
	dermal (rat) LD50: >2000 mg/kg ^[1] Oral (Rat) LD50: >2000 mg/kg ^[1]	Eye: adverse effect observed (irritating) ^[1] Skin: no adverse effect observed (not irritating) ^[1]
iso-amyl acetate	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >5000 mg/kg ^[1] Oral (Rat) LD50: 16600 mg/kg ^[2]	Eye: no adverse effect observed (not irritating) ^[1] Skin (Rodent - rabbit): 10mg/24H - Mild Skin: no adverse effect observed (not irritating) ^[1]
ethyl acetate	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >18000 mg/kg ^[2] Inhalation (Mouse) LC50: >18 mg/l4h ^[1] Oral (Mouse) LD50; 4100 mg/kg ^[2]	Eye (Human): 400ppm Eye: no adverse effect observed (not irritating) ^[1] Skin: no adverse effect observed (not irritating) ^[1]

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

CRISTOBALITE Inhalation (human) TClO: 16 mppcf*/8H/17.9y-l * Millions of particles per cubic foot
WARNING: For inhalation exposure ONLY: This substance has been classified by the IARC as Group 1: **CARCINOGENIC TO HUMANS**

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	<p>The International Agency for Research on Cancer (IARC) has classified occupational exposures to respirable (<5 um) crystalline silica as being carcinogenic to humans . This classification is based on what IARC considered sufficient evidence from epidemiological studies of humans for the carcinogenicity of inhaled silica in the forms of quartz and cristobalite. Crystalline silica is also known to cause silicosis, a non-cancerous lung disease. Intermittent exposure produces; focal fibrosis, (pneumoconiosis), cough, dyspnoea, liver tumours.</p> <p>* Millions of particles per cubic foot (based on impinger samples counted by light field techniques). NOTE : the physical nature of quartz in the product determines whether it is likely to present a chronic health problem. To be a hazard the material must enter the breathing zone as respirable particles.</p>
<p>SILICA AMORPHOUS</p>	<p>Reports indicate high/prolonged exposures to amorphous silicas induced lung fibrosis in experimental animals; in some experiments these effects were reversible. [PATTYS] For silica amorphous: Derived No Adverse Effects Level (NOAEL) in the range of 1000 mg/kg/d. In humans, synthetic amorphous silica (SAS) is essentially non-toxic by mouth, skin or eyes, and by inhalation. Epidemiology studies show little evidence of adverse health effects due to SAS. Repeated exposure (without personal protection) may cause mechanical irritation of the eye and drying/cracking of the skin. When experimental animals inhale synthetic amorphous silica (SAS) dust, it dissolves in the lung fluid and is rapidly eliminated. If swallowed, the vast majority of SAS is excreted in the faeces and there is little accumulation in the body. Following absorption across the gut, SAS is eliminated via urine without modification in animals and humans. SAS is not expected to be broken down (metabolised) in mammals. After ingestion, there is limited accumulation of SAS in body tissues and rapid elimination occurs. Intestinal absorption has not been calculated, but appears to be insignificant in animals and humans. SASs injected subcutaneously are subjected to rapid dissolution and removal. There is no indication of metabolism of SAS in animals or humans based on chemical structure and available data. In contrast to crystalline silica, SAS is soluble in physiological media and the soluble chemical species that are formed are eliminated via the urinary tract without modification. Both the mammalian and environmental toxicology of SASs are significantly influenced by the physical and chemical properties, particularly those of solubility and particle size. SAS has no acute intrinsic toxicity by inhalation. Adverse effects, including suffocation, that have been reported were caused by the presence of high numbers of respirable particles generated to meet the required test atmosphere. These results are not representative of exposure to commercial SASs and should not be used for human risk assessment. Though repeated exposure of the skin may cause dryness and cracking, SAS is not a skin or eye irritant, and it is not a sensitiser. Repeated-dose and chronic toxicity studies confirm the absence of toxicity when SAS is swallowed or upon skin contact. Long-term inhalation of SAS caused some adverse effects in animals (increases in lung inflammation, cell injury and lung collagen content), all of which subsided after exposure. Numerous repeated-dose, subchronic and chronic inhalation toxicity studies have been conducted with SAS in a number of species, at airborne concentrations ranging from 0.5 mg/m3 to 150 mg/m3. Lowest-observed adverse effect levels (LOAELs) were typically in the range of 1 to 50 mg/m3. When available, the no-observed adverse effect levels (NOAELs) were between 0.5 and 10 mg/m3. The difference in values may be explained by different particle size, and therefore the number of particles administered per unit dose. In general, as particle size decreases so does the NOAEL/LOAEL. Neither inhalation nor oral administration caused neoplasms (tumours). SAS is not mutagenic in vitro. No genotoxicity was detected in in vivo assays. SAS does not impair development of the foetus. Fertility was not specifically studied, but the reproductive organs in long-term studies were not affected. For Synthetic Amorphous Silica (SAS) Repeated dose toxicity Oral (rat), 2 weeks to 6 months, no significant treatment-related adverse effects at doses of up to 8% silica in the diet. Inhalation (rat), 13 weeks, Lowest Observed Effect Level (LOEL) =1.3 mg/m3 based on mild reversible effects in the lungs. Inhalation (rat), 90 days, LOEL = 1 mg/m3 based on reversible effects in the lungs and effects in the nasal cavity. For silane treated synthetic amorphous silica: Repeated dose toxicity: oral (rat), 28-d, diet, no significant treatment-related adverse effects at the doses tested. There is no evidence of cancer or other long-term respiratory health effects (for example, silicosis) in workers employed in the manufacture of SAS. Respiratory symptoms in SAS workers have been shown to correlate with smoking but not with SAS exposure, while serial pulmonary function values and chest radiographs are not adversely affected by long-term exposure to SAS. The substance is classified by IARC as Group 3: NOT classifiable as to its carcinogenicity to humans. Evidence of carcinogenicity may be inadequate or limited in animal testing.</p>
<p>POLYDIMETHYLSILOXANE(S)</p>	<p>NOTE: Tumorigenic in rats : Neoplastic by RTECS criteria. Product subject to review for use in body implants Chronic exposure Carcinogenicity-rat-Implant Tumorigenic:Neoplastic by RTECS criteria. Lungs, Thorax, or Respiration:Tumors. Endocrine:Tumors</p>
<p>C.I. PIGMENT YELLOW 83</p>	<p>Diarylide (disazo) pigments generally show no acute toxicity and are not irritating to the skin or mucous membranes. They do not seem to cause cancer. In summary, diarylide pigments do not cause health risk.</p> <p>For 3,3'-dichlorobenzidine: Various tumours developed after oral or subcutaneous administration of 3,3'-dichlorobenzidine to mice, rats, hamsters and dogs. Tumours have not yet been identified in persons exposed to the substance alone. The substance can be absorbed through the skin in dangerous quantities. Increases in temperature and relative humidity promote dermal absorption. Upper respiratory infection and sore throat were listed among several principal reasons for visits to a company s medical clinic by workers handling 3,3 -dichlorobenzidine dihydrochloride However, there is no conclusive evidence that these effects were due to inhalation of 3,3 -dichlorobenzidine dihydrochloride. No adverse health effects were observed in male rats exposed by inhalation to 3,3 - dichlorobenzidine free base (23,700 mg/m3) 2 hours per day for 7 days . In another study, 10 rats were exposed to an unspecified concentration of 3,3 - dichlorobenzidine dihydrochloride dust particles for 1 hour and then observed for 14 days. Slight-to-moderate pulmonary congestion and one pulmonary abscess were observed upon necropsy . The effects observed in the study using the ionized</p>

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(hydrochloride) form of 3,3 -dichlorobenzidine may have been due to the irritative properties of hydrochloric acid released from the salt in combination with particulate toxicity.

Gastrointestinal upset was one of the symptoms reported by employees who worked with 3,3 -dichlorobenzidine dihydrochloride. However, there is no conclusive evidence that the gastrointestinal effects, or other symptoms reported by employees, resulted specifically from inhalation of 3,3 -dichlorobenzidine dihydrochloride.

The only relevant information regarding neurological effects in humans exposed to 3,3 -dichlorobenzidine was found in an early study which reported that headache and dizziness were among several principal reasons why employees working with 3,3 -dichlorobenzidine in a chemical manufacturing plant visited the company medical clinic. However, there is no conclusive evidence that these symptoms were caused specifically by 3,3 -dichlorobenzidine since there was exposure to other chemicals as well. In a 3,3 -dichlorobenzidine carcinogenicity study, 1 of 6 dogs exhibited convulsions after 21, 28, or 42 months of oral treatment with 10.4 mg/kg/day over a period of 3.5 years

Carcinogenicity: Several epidemiological studies have investigated cancer incidences among workers occupationally exposed to 3,3 -dichlorobenzidine . Exposure may have been by both inhalation and dermal routes. Due, in part, to structure-activity considerations, epidemiological studies of potential cancer effects of occupational exposure to 3,3 -dichlorobenzidine have been particularly concerned with bladder tumors, since 3,3 -dichlorobenzidine is structurally similar to benzidine, a chemical which is known to be a human bladder carcinogen. No bladder tumors were found in a group of 35 workers who handled only 3,3 -dichlorobenzidine; in the same dyestuff plant, bladder tumors occurred in 3 out of 14 workers exposed to both benzidine and 3,3 -dichlorobenzidine. The investigator reported a total exposure time of 68,505 hours, equivalent to nearly 140 full-time working years. No cases of bladder tumors were found in an epidemiology study of 259 workers exposed to dry and semidry 3,3 -dichlorobenzidine base and hydrochloride. Workers were exposed to an average of less than 16 years each to 3,3 -dichlorobenzidine, which means that an adequate exposure duration and/or the latent period following exposure may not have been reached for tumor expression.

In a retrospective epidemiological study of workers employed in a dye and pigment manufacturing plant that used 3,3 -dichlorobenzidine as chemical precursor, no bladder tumors were observed in a cohort of 207 workers, most of whom had been exposed for up to 15 years. Limitations of this study included using data from a very small and incomplete sample of workers; focusing solely on the occurrence of bladder tumors; and using data that may have been misleading and, at times, apparently inaccurate.

A statistically significant increased incidence of hepatomas was observed in male ICR/JCL mice exposed to 0.1% 3,3 -dichlorobenzidine in the diet (170 mg/kg/day) at 6 months (8 of 8 treated as opposed to 0 of 5 controls) and 12 months (18 of 18 treated as opposed to 2 of 21 controls). Hepatic tumors were observed in 4/18 strain D mice exposed to 11.2-1.9 mg 3,3 -dichlorobenzidine/kg/day in the diet for 10 months

No bladder carcinomas were observed in rats exposed to 0.03% 3,3 -dichlorobenzidine in the diet (27 mg/kg/day) for 4 or 40 weeks , nor were any mammary tumors observed in rats administered approximately 49 mg 3,3 -dichlorobenzidine dihydrochloride/kg/day by gavage once every 3 days over a 30-day period and sacrificed 8 months later. In a study in which rats were exposed to 10-20 mg 3,3 -dichlorobenzidine per day (120 mg/kg/day) in feed 6 days per week for 12 months, tumors were observed at a variety of sites, including the Zymbal gland (7 of 29 animals), mammary gland (7/29), bladder (3/29), hematopoietic system (3/29), skin (3/29), ileum (2/29), connective tissue (2/29), salivary gland (2/29), liver (1/29), and thyroid (1/29).

In another rat study, 3,3 -dichlorobenzidine was administered to 50 male (70 mg/kg/day) and 50 female (80 mg/kg/day) Sprague-Dawley rats, in a standard diet for up to 16 months . In rats fed 3,3 -dichlorobenzidine in the diet for a total of 349 days (females) and 353 days (males), histopathological evaluations revealed mammary adenocarcinoma (16% incidence), malignant lymphoma (14%) granulocytic leukemia (20%), carcinoma of the Zymbal gland (18%) in males, and mammary adenocarcinoma (59%) in females. The authors noted that most of these tumors appeared to arise in the bone marrow and haematopoietic foci in the spleen and liver with subsequent metastasis to other organs.

Haematological Effects. Although haematological effects may not be sensitive indicators for 3,3 -dichlorobenzidine toxicity, haemoglobin adducts have been detected in female Wistar rats orally administered single 127 or 253 mg/kg doses of 3,3 -dichlorobenzidine or with repeated doses between 0.3 and 5.8 mg/kg/day . It was suggested that metabolically formed nitroso derivatives and the formation of a sulfinic acid amide with cysteine residues in haemoglobin may be the mechanism of adduct formation.

Hepatic Effects. Limited animal evidence suggests that chronic-duration oral exposure to 3,3 -dichlorobenzidine results in mild-to-moderate liver injury.

Genotoxic effects: Genotoxic effects have been reported in animals treated with 3,3 -dichlorobenzidine. A single dose of 3,3 -dichlorobenzidine (1,000 mg/kg) administered to male and pregnant female mice induced micronuclei in polychromatic erythrocytes in the bone marrow of the males and in the liver of the fetuses, but not in bone marrow of the dams.

In another study, an increase in unscheduled deoxyribonucleic acid synthesis (UDS) was observed in cultured liver cells from male mice previously pretreated orally with single doses of . 500 mg/kg 3,3 -dichlorobenzidine; no response was observed at a dose of .200 mg/kg. 3,3 -Dichlorobenzidine was also shown to bind extensively to tissue deoxyribonucleic acid (DNA) in rats and mice

C.I. FOOD RED 14:1

There has been public concern that food colourings may cause ADHD-like behavior in children. These concerns have led the FDA and other food safety authorities to regularly review the scientific literature, and led the UK FSA to commission a study by researchers at Southampton University of the effect of a mixture of six food dyes (Tartrazine, Allura Red AC, Ponceau 4R, Quinoline Yellow WS, Sunset Yellow and Carmoisine (dubbed the "Southampton 6")) and sodium benzoate (a preservative) on children in the general population, who consumed them in beverages; the study published in 2007. The study found "a possible link between the consumption of these artificial colours and a sodium benzoate preservative and increased hyperactivity" in the children; the advisory committee to the FSA that evaluated the study also determined that because of study limitations, the results could not be extrapolated to the general population, and further testing was recommended". The European regulatory community, with a stronger emphasis on the precautionary principle, required labelling and temporarily reduced the acceptable daily intake (ADI) for the food colourings; the UK FSA called for voluntary withdrawal of the colourings by food manufacturers. However, in 2009 the EFSA re-evaluated the data at hand and determined that "the available scientific evidence does not substantiate a link between the colour additives and behavioural effects". There is no evidence to support broad claims that food colouring causes food intolerance and ADHD-like behaviour in children. It is possible that certain food colouring may act as a trigger in those who are genetically predisposed, but the evidence is weak. Topical, oral, and intravenous use of fluorescein usually causes nausea, diarrhoea, hives, acute hypotension, hyper allergic reaction, heart attack and even sudden death. As such, health care staff should use prophylactic antihistamines and always prepare for possible emergency resuscitation to reduce risk and prevent death from emergencies. Adverse reaction is 25 times more common in those with prior adverse reaction and this may be elicited with a pin prick test. Reaction to lip stick

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	containing eosin (which is derived from fluorescein) has caused skin inflammation. Reports have also suggested that eosin may cause photosensitivity.
ETHYL ACETATE	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. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production.
DIMETHYLSILOXANE, METHYLHYDROGEN- & DIMETHYLSILOXANE POLYMER, VINYL-TERMINATED & POLYDIMETHYLSILOXANE(S)	Siloxanes may impair liver and hormonal function, as well as the lung and kidney. They have not been found to be irritating to the skin and eyes. They may potentially cause cancer (tumours of the womb in females) and may cause impaired fertility or infertility.
DIMETHYLSILOXANE, METHYLHYDROGEN- & DIMETHYLSILOXANE POLYMER, VINYL-TERMINATED & C.I. FOOD RED 14:1	No significant acute toxicological data identified in literature search.

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 either not available or does not fill the criteria for classification
 ✓ – Data available to make classification

SECTION 12 Ecological information

Toxicity

	Endpoint	Test Duration (hr)	Species	Value	Source
Clone Bite - Base	Not Available	Not Available	Not Available	Not Available	Not Available
crystalite	Not Available	Not Available	Not Available	Not Available	Not Available
dimethylsiloxane, methylhydrogen-	Not Available	Not Available	Not Available	Not Available	Not Available
dimethylsiloxane polymer, vinyl-terminated	Not Available	Not Available	Not Available	Not Available	Not Available
silica amorphous	EC50	72h	Algae or other aquatic plants	14.1mg/l	2
	EC50	96h	Algae or other aquatic plants	217.576mg/l	2
	EC0(ECx)	24h	Crustacea	>=10000mg/l	1
	EC50	48h	Crustacea	>86mg/l	2
	LC50	96h	Fish	1033.016mg/l	2
polydimethylsiloxane(s)	Not Available	Not Available	Not Available	Not Available	Not Available
C.I. Pigment Yellow 83	Endpoint	Test Duration (hr)	Species	Value	Source

Continued...

Clone™ Bite - Base

	EC50	72h	Algae or other aquatic plants	>100mg/l	2
	EC50	48h	Crustacea	>100mg/l	2
	NOEC(ECx)	24h	Fish	>=0.1mg/l	2
	LC50	96h	Fish	>0.1mg/l	2
C.I. Food Red 14:1	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	51.7mg/l	2
	EC50(ECx)	48h	Crustacea	27.5mg/l	2
	EC50	48h	Crustacea	27.5mg/l	2
	LC50	96h	Fish	>100mg/l	2
iso-amyl acetate	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	96h	Algae or other aquatic plants	235mg/l	2
	EC50	72h	Algae or other aquatic plants	156mg/l	2
	NOEC(ECx)	48h	Crustacea	3.77mg/l	2
	EC50	48h	Crustacea	26.3mg/l	2
	LC50	96h	Fish	11.1mg/l	2
ethyl acetate	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	96h	Algae or other aquatic plants	2500mg/L	4
	EC50	72h	Algae or other aquatic plants	1800-3200mg/L	4
	NOEC(ECx)	72h	Algae or other aquatic plants	>100mg/l	1
	EC50	48h	Crustacea	164mg/l	1
	LC50	96h	Fish	>75.6mg/l	2
Legend:	Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 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
silica amorphous	LOW	LOW
C.I. Pigment Yellow 83	HIGH	HIGH
iso-amyl acetate	LOW	LOW
ethyl acetate	LOW (Half-life = 14 days)	LOW (Half-life = 14.71 days)

Bioaccumulative potential

Ingredient	Bioaccumulation
silica amorphous	LOW (LogKOW = 0.5294)
C.I. Pigment Yellow 83	LOW (LogKOW = 8.6648)
iso-amyl acetate	LOW (LogKOW = 2.264)
ethyl acetate	HIGH (BCF = 3300)

Mobility in soil

Ingredient	Mobility
silica amorphous	LOW (Log KOC = 23.74)
C.I. Pigment Yellow 83	LOW (Log KOC = 1126000)
iso-amyl acetate	LOW (Log KOC = 32.24)
ethyl acetate	LOW (Log KOC = 6.131)

SECTION 13 Disposal considerations

Waste treatment methods

Continued...

Product / Packaging disposal	<ul style="list-style-type: none"> ▶ DO NOT allow wash water from cleaning or process equipment to enter drains. ▶ It may be necessary to collect all wash water for treatment before disposal. ▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. ▶ Where in doubt contact the responsible authority. ▶ 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.
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SECTION 14 Transport information

Labels Required

Marine Pollutant	NO
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Land transport (DOT): 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

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

Not Applicable

14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
cristobalite	Not Available
dimethylsiloxane, methylhydrogen-	Not Available
dimethylsiloxane polymer, vinyl-terminated	Not Available
silica amorphous	Not Available
polydimethylsiloxane(s)	Not Available
C.I. Pigment Yellow 83	Not Available
C.I. Food Red 14:1	Not Available
iso-amyl acetate	Not Available
ethyl acetate	Not Available

14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
cristobalite	Not Available
dimethylsiloxane, methylhydrogen-	Not Available
dimethylsiloxane polymer, vinyl-terminated	Not Available
silica amorphous	Not Available
polydimethylsiloxane(s)	Not Available
C.I. Pigment Yellow 83	Not Available
C.I. Food Red 14:1	Not Available
iso-amyl acetate	Not Available
ethyl acetate	Not Available

SECTION 15 Regulatory information

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

- cristobalite is found on the following regulatory lists
- Chemical Footprint Project - Chemicals of High Concern List
- International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)
- US - Alaska Air Quality Control - Concentrations Triggering an Air Quality Episode for Air Pollutants Other Than PM-2.5

US - California Proposition 65 - Carcinogens
US - California Safe Drinking Water and Toxic Enforcement Act of 1986 - Proposition 65 List
US - Massachusetts - Right To Know Listed Chemicals
US - New Jersey Right to Know - Special Health Hazard Substance List (SHHSL): Carcinogens
US - New Jersey Right to Know Hazardous Substances
US - Pennsylvania - Hazardous Substance List
US DOE Temporary Emergency Exposure Limits (TEELs)
US Environmental Defense Scorecard Recognized Carcinogens
US NIOSH Carcinogen List
US NIOSH Recommended Exposure Limits (RELs)
US OSHA Carcinogens Listing
US OSHA Permissible Exposure Limits (PELs) Table Z-1
US OSHA Permissible Exposure Limits (PELs) Table Z-1 (Spanish)
US OSHA Permissible Exposure Limits (PELs) Table Z-3
US OSHA Permissible Exposure Limits (PELs) Table Z-3 (Spanish)
US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

dimethylsiloxane, methylhydrogen- is found on the following regulatory lists

US DOE Temporary Emergency Exposure Limits (TEELs)
US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

dimethylsiloxane polymer, vinyl-terminated is found on the following regulatory lists

US DOE Temporary Emergency Exposure Limits (TEELs)
US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

silica amorphous is found on the following regulatory lists

Chemical Footprint Project - Chemicals of High Concern List
International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Not Classified as Carcinogenic
International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)
US - Alaska Air Quality Control - Concentrations Triggering an Air Quality Episode for Air Pollutants Other Than PM-2.5
US - California - Biomonitoring - Priority Chemicals
US - California Proposition 65 - Carcinogens
US - California Safe Drinking Water and Toxic Enforcement Act of 1986 - Proposition 65 List
US - Massachusetts - Right To Know Listed Chemicals
US - New Jersey Right to Know Hazardous Substances
US - Pennsylvania - Hazardous Substance List
US DOE Temporary Emergency Exposure Limits (TEELs)
US Environmental Defense Scorecard Recognized Carcinogens
US NIOSH Carcinogen List
US NIOSH Recommended Exposure Limits (RELs)
US OSHA Carcinogens Listing
US OSHA Permissible Exposure Limits (PELs) Table Z-1
US OSHA Permissible Exposure Limits (PELs) Table Z-1 (Spanish)
US OSHA Permissible Exposure Limits (PELs) Table Z-3
US OSHA Permissible Exposure Limits (PELs) Table Z-3 (Spanish)
US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

polydimethylsiloxane(s) is found on the following regulatory lists

US DOE Temporary Emergency Exposure Limits (TEELs)
US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

C.I. Pigment Yellow 83 is found on the following regulatory lists

Chemical Footprint Project - Chemicals of High Concern List
International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs
International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Group 1: Carcinogenic to humans
US - California Proposition 65 - Carcinogens
US - California Safe Drinking Water and Toxic Enforcement Act of 1986 - Proposition 65 List
US National Toxicology Program (NTP) 15th Report Part A Known to be Human Carcinogens
US NIOSH Carcinogen List
US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

C.I. Food Red 14:1 is found on the following regulatory lists

International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)
US - Alaska Air Quality Control - Concentrations Triggering an Air Quality Episode for Air Pollutants Other Than PM-2.5
US NIOSH Recommended Exposure Limits (RELs)
US OSHA Permissible Exposure Limits (PELs) Table Z-1

- US OSHA Permissible Exposure Limits (PELs) Table Z-1 (Spanish)
- US OSHA Permissible Exposure Limits (PELs) Table Z-3
- US OSHA Permissible Exposure Limits (PELs) Table Z-3 (Spanish)
- US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

iso-amyl acetate is found on the following regulatory lists

- US - Massachusetts - Right To Know Listed Chemicals
- US - New Jersey Right to Know - Special Health Hazard Substance List (SHHSL): Flammables
- US - New Jersey Right to Know Hazardous Substances
- US - Pennsylvania - Hazardous Substance List
- US CWA (Clean Water Act) - List of Hazardous Substances
- US DOE Temporary Emergency Exposure Limits (TEELs)
- US New York City Community Right-to-Know: List of Hazardous Substances
- US NIOSH Recommended Exposure Limits (RELs)
- US OSHA Permissible Exposure Limits (PELs) Table Z-1
- US OSHA Permissible Exposure Limits (PELs) Table Z-1 (Spanish)
- US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

ethyl acetate is found on the following regulatory lists

- US - Massachusetts - Right To Know Listed Chemicals
- US - New Jersey Right to Know - Special Health Hazard Substance List (SHHSL): Flammables
- US - New Jersey Right to Know Hazardous Substances
- US - Pennsylvania - Hazardous Substance List
- US DOE Temporary Emergency Exposure Limits (TEELs)
- US EPA Integrated Risk Information System (IRIS)
- US New York City Community Right-to-Know: List of Hazardous Substances
- US NIOSH Recommended Exposure Limits (RELs)
- US OSHA Permissible Exposure Limits (PELs) Table Z-1
- US OSHA Permissible Exposure Limits (PELs) Table Z-1 (Spanish)
- US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory
- US TSCA Section 4/12 (b) - Sunset Dates/Status

Additional Regulatory Information

Not Applicable

Federal Regulations

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Section 311/312 hazard categories

Flammable (Gases, Aerosols, Liquids, or Solids)	No
Gas under pressure	No
Explosive	No
Self-heating	No
Pyrophoric (Liquid or Solid)	No
Pyrophoric Gas	No
Corrosive to metal	No
Oxidizer (Liquid, Solid or Gas)	No
Organic Peroxide	No
Self-reactive	No
In contact with water emits flammable gas	No
Combustible Dust	No
Carcinogenicity	No
Acute toxicity (any route of exposure)	No
Reproductive toxicity	No
Skin Corrosion or Irritation	Yes
Respiratory or Skin Sensitization	No
Serious eye damage or eye	Yes

Continued...

irritation	
Specific target organ toxicity (single or repeated exposure)	No
Aspiration Hazard	No
Germ cell mutagenicity	No
Simple Asphyxiant	No
Hazards Not Otherwise Classified	No

US. EPA CERCLA Hazardous Substances and Reportable Quantities (40 CFR 302.4)

Name	Reportable Quantity in Pounds (lb)	Reportable Quantity in kg
iso-amyl acetate	5000	2270
ethyl acetate	5000	2270

US. EPCRA Section 313 Toxic Release Inventory (TRI) (40 CFR 372)

None Reported

Additional Federal Regulatory Information

Not Applicable

State Regulations

US. California Proposition 65

⚠ WARNING: This product can expose you to chemicals including **crystalite, silica amorphous, C.I. Pigment Yellow 83**, which are known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov

Additional State Regulatory Information

Not Applicable

National Inventory Status

National Inventory	Status
Australia - AIIIC / Australia Non-Industrial Use	Yes
Canada - DSL	Yes
Canada - NDSL	No (crystalite; dimethylsiloxane, methylhydrogen-; dimethylsiloxane polymer, vinyl-terminated; polydimethylsiloxane(s); C.I. Pigment Yellow 83; C.I. Food Red 14:1; iso-amyl acetate; ethyl acetate)
China - IECSC	Yes
Europe - EINEC / ELINCS / NLP	No (dimethylsiloxane, methylhydrogen-; dimethylsiloxane polymer, vinyl-terminated; polydimethylsiloxane(s))
Japan - ENCS	Yes
Korea - KECI	No (C.I. Food Red 14:1)
New Zealand - NZIoC	Yes
Philippines - PICCS	No (C.I. Food Red 14:1)
USA - TSCA	All chemical substances in this product have been designated as TSCA Inventory 'Active'
Taiwan - TCSI	Yes
Mexico - INSQ	No (C.I. Pigment Yellow 83; C.I. Food Red 14:1)
Vietnam - NCI	Yes
Russia - FBEPH	No (dimethylsiloxane, methylhydrogen-; C.I. Food Red 14:1)
Legend:	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.

SECTION 16 Other information

Revision Date	25/10/2024
Initial Date	20/09/2024

SDS Version Summary

Clone™ Bite- Base

Version	Date of Update	Sections Updated
3.1	23/09/2024	Composition / information on ingredients - Ingredients
4.1	25/10/2024	Toxicological information - Acute Health (inhaled), Toxicological information - Chronic Health, Hazards identification - Classification, Composition / information on ingredients - Ingredients

Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources 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
- ▶ ES: Exposure Standard
- ▶ 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
- ▶ DNEL: Derived No-Effect Level
- ▶ PNEC: Predicted no-effect concentration
- ▶ MARPOL: International Convention for the Prevention of Pollution from Ships
- ▶ IMSBC: International Maritime Solid Bulk Cargoes Code
- ▶ IGC: International Gas Carrier Code
- ▶ IBC: International Bulk Chemical Code

- ▶ AIIC: Australian Inventory of Industrial Chemicals
- ▶ DSL: Domestic Substances List
- ▶ NDSL: Non-Domestic Substances List
- ▶ IECSC: Inventory of Existing Chemical Substance in China
- ▶ EINECS: European Inventory of Existing Commercial chemical Substances
- ▶ ELINCS: European List of Notified Chemical Substances
- ▶ NLP: No-Longer Polymers
- ▶ ENCS: Existing and New Chemical Substances Inventory
- ▶ KECl: Korea Existing Chemicals Inventory
- ▶ NZIoC: New Zealand Inventory of Chemicals
- ▶ PICCS: Philippine Inventory of Chemicals and Chemical Substances
- ▶ TSCA: Toxic Substances Control Act
- ▶ TCSI: Taiwan Chemical Substance Inventory
- ▶ INSQ: Inventario Nacional de Sustancias Químicas
- ▶ NCI: National Chemical Inventory
- ▶ FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances