Version: 3.0

SECTION 1: IDENTIFICATION

<u>Product Identifier</u> <u>Product Form:</u> Mixture

Product Name: OPOTOW® TEMPORARY CEMENT

Product Code: 052117-000

Recommended use of the chemical and restrictions on use

Designed for luting of cast crowns and bridges on a semi-permanent basis as well as for temporary cementation of provisional restorations where prolonged evaluation is required. For professional dental use only.

Name, Address, and Telephone of the Responsible Party

Company

Water Pik, Inc.

1730 East Prospect Road Fort Collins, CO 80553-0001 800/525-2020 (8 am- 4pm MST)

Emergency Telephone Number

Emergency Number : 800/424-9300 (24 Hr: CHEMTREC)

SECTION 2: HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

Classification (GHS-US)

Skin corrosion/irritation – Category 2 (Part A)

Skin sensitization - Category 1 (Part A)

Serious eye damage/eye irritation – Category 2A (Part A)

Hazardous to the aquatic environment – Acute – Category 1 (Part B)

Hazardous to the aquatic environment – Chronic – Category 1 (Part B)

Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US) :



Signal Word (GHS-US) : Warning

Hazard Statements (GHS-US) : H315 - Causes skin irritation.

H317 - May cause an allergic skin reaction. H319 - Causes serious eye irritation. H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

Precautionary Statements (GHS-US): P261 - Avoid breathing vapors, mist, spray.

P264 - Wash hands, forearms, and exposed areas thoroughly after handling. P272 - Contaminated work clothing must not be allowed out of the workplace.

P273 - Avoid release to the environment.

P280 - Wear protective clothing, protective gloves, eye protection.

P391 - Collect spillage.

P302 + P352 IF ON SKIN: Wash with plenty of water.

P333 + P317 If skin irritation or rash occurs: Get medical help.

P337 + P317 If eye irritation persists get medical help.

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

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P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P501 - Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Classification system adopted

Hazard Communication Standard (HCS) 29 CFR: 1910.1200 - Appendix A (OSHA).

Adoption of the Globally Harmonized System of Classification and Labeling of Chemicals

(GHS), United Nations, 9 ed.

<u>Other Hazards</u> Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions. If heated to the point of fume generation, zinc fumes may cause metal fume fever. Otherwise, zinc is non-toxic.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Part A

Name	CAS number	% (w/w)	Classification (GHS-US)**
Dimerized rosin	65997-05-09	20 – 63	Not classified as hazardous
Eugenol	97-53-0	10 – 20	H302; H315; H317; H319
Oil Castor	8001-79-04	1-7	Not classified as hazardous
Butyl acetyl ricinoleate	140-04-05	1-6.9	Not classified as hazardous
Euphorbia cerifera (candelilla) wax	8006-44-08	1 – 2.7	Not classified as hazardous
Acetic Acid*	64-19-7	0.1 - 0.8	H226; H312; H314; H318; H335; H402

Part B

Name	CAS number	% (w/w)	Classification (GHS-US)
Zinc oxide	1314-13-2	40 – 78.9	H400; H410
Oil Castor	8001-79-4	5 – 13.2	Not classified as hazardous
Mineral Oil*	8012-95-1	1-5	H304; H413
Petrolatum white USP	8009-03-08	1-2.5	Not classified as hazardous
Beeswax substitute	8012-89-3	0.1 – 0.75	Not classified as hazardous

^{*} The ingredients are classified as dangerous, however, it is not in sufficient concentration to extrapolate the dangers for the product.

SECTION 4: FIRST AID MEASURES

Inhalation: When symptoms occur: go into open air and ventilate suspected area.

Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. Obtain medical attention if irritation persists.

Ingestion: Rinse mouth. Do NOT induce vomiting.

Most Important Symptoms and Effects Both Acute and Delayed

Exposure to the product causes skin irritation with redness, dryness, and peeling, and causes eye irritation with pain, dryness, redness, and tearing. Exposure to the product may cause allergic skin reactions with dermatitis and itching.

Indication of Any Immediate Medical Attention and Special Treatment Needed

Avoid contact with the product when helping the victim. Treatment of exposure should be directed towards controlling the patient's symptoms and clinical status. In case of skin contact, do not rub the affected area.

SECTION 5: FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Compatible with alcohol resistant foam, water spray, dry chemical, or carbon dioxide (CO₂).

Unsuitable Extinguishing Media: Use of heavy stream of water may spread fire.

Special Hazards Arising From the Substance or Mixture

Fire Hazard: Product is not flammable.

Explosion Hazard: Product is not explosive.

The combustion of the chemical products or containers may form toxic and irritating gases such as carbon monoxide (CO), carbon dioxide (CO_2) and zinc oxides.

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^{**}Full text of H-phrases: see section 16

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Specific extinguishing methods

Precautionary Measures Fire: Wear self-contained respiratory protective equipment (SCBA) with positive pressure and full

protective clothing.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions

Do not smoke. Do not touch damaged containers or spilled material without wearing suitable clothing. Avoid exposure to the product, avoid the formation of dust. Use personal protective equipment as described in section 8.

Protective equipment

Use protective equipment as described in Section 8.

Emergency Procedures: Wear complete personal protection equipment (PPE) with safety glasses, protective gloves, suitable protective clothing, and closed shoes. In case of large leaks, where exposure is high, the use of a respiratory protective mask with a filter against mists and vapors is recommended. Evacuate the area within a radius of at least 50 meters. Keep unauthorized people away from the area. Stop the leak if it can be done without risk.

Environmental Precautions

Prevent the product from reaching the soil and water courses. Notify the relevant authorities if the product has caused environmental.

Methods and Material for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents.

Methods for Cleaning Up: Collect spilled product and place in suitable containers. Adsorb the remaining product with dry sand, earth, vermiculite, or any other inert material. Place adsorbed material in appropriate containers and remove to a safe place. For final disposal, proceed as per Section 13 of this SDS.

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling

Handle in a ventilated area or with a general ventilation/local exhaust system. Avoid formation of mists and vapors. Avoid product exposure. Avoid contact with incompatible materials. Use personal protective equipment as described in section 8. Handle in a ventilated area or with a general local ventilation / exhaust system. Wash hands and face thoroughly after handling and before eating, drinking, smoking, or using the bathroom. Contaminated clothing must be changed and washed before reuse. Remove contaminated clothing and protective equipment before entering eating areas.

Conditions for Safe Storage, Including Any Incompatibilities

Storage Conditions: Store in a well-ventilated, dry, cool place away from sunlight. Keep the packaging tightly closed and in an area accessible only to authorized persons. Keep away from sources of ignition and heat. Keep away from incompatible materials.

Incompatible Materials: Strong acids. Strong bases. Strong oxidizers.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Permissible concentration

For substances listed in section 3 that are not listed here, there are no established Exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), OSHA (PEL), Canadian provincial governments, or the Mexican government.

Occupational exposure limit

Chemical name	TLV – TWA (ACGIH, 2021)	PEL – TWA (OSHA, 2019)	REL – TWA (NIOSH, 2019)
Acetic acid	TWA 10 ppm STEL 15 ppm	10 ppm (ST) 15 ppm (C) 40 ppm	10 ppm (ST) 15 ppm
Mineral oil	5 mg/m³ (I) pure, highly, and severely refined (A4)	5 mg/m³ (excluding vapor)	5 mg/m³ (ST) 10 mg/m³
Zinc oxide	TWA 2 mg/m³ (R) STEL 10 mg/m³	10 mg/m³ dust total 5 mg/m³ respirable fraction	5 mg/m (C) 15 mg/m ³

TWA - Time weighted average

STEL – Short-term exposure limit

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A4 - Not Classifiable as a Human Carcinogen

C - Ceiling limit

ST - Short Term Exposure Limit

Biological limit - Not established.

Exposure Controls

Appropriate Engineering Controls: Promote direct mechanical ventilation and exhaust system to the outside environment. These measures help reduce exposure to product. Maintain atmospheric concentrations, of the constituents of the product, below occupational exposure limits indicated.

Personal Protective Equipment: Protective clothing. Gloves. Protective goggles.







Materials for Protective Clothing: Chemically resistant materials and fabrics. Hand Protection: Nitrile gloves, suitable protective clothing, and closed shoes. Eye Protection: Safety glasses or goggles are recommended when using product.

Respiratory Protection: Respirator with filter for mists and vapours. It is recommended that a risk assessment be carried out to

define respiratory protection depending on the conditions of use of the product.

Special precautions: Not established.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties

Physical State : Liquid

Appearance : A two part mixture, tan-colored

Odor: Clove-likeOdor Threshold: Not availablepH: Not availableEvaporation Rate: Not availableMelting Point: Not availableFreezing Point: Not availableBoiling Point: Not available

Flash Point : 350 °F (176.67 °C) open cup

Auto-ignition Temperature : Not available
Decomposition Temperature : Not available
Flammability (solid, gas) : Not available
Lower Flammable Limit : Not available
Upper Flammable Limit : Not available
Vapor Pressure : Not available
Relative Vapor Density at 20 °C : Not available

Specific Gravity : 1 - 3

Solubility : Not soluble in water

Partition Coefficient: N-Octanol/Water: Not availableViscosity: Not available

Explosion Data – Sensitivity to Mechanical Impact : Not expected to present an explosion hazard due to mechanical impact. Explosion Data – Sensitivity to Static Discharge : Not expected to present an explosion hazard due to static discharge.

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SECTION 10: STABILITY AND REACTIVITY

Reactivity: Hazardous reactions are unlikely to occur under normal circumstances.

Chemical Stability: Stable under recommended handling and storage conditions (see section 7).

<u>Possibility of Hazardous Reactions</u>: No hazardous reactions are known with the product. Hazardous polymerization will not occur. <u>Conditions to Avoid</u>: Direct sunlight, extremely high or low temperatures, open flames, sources of ignition and incompatible

materials.

Incompatible Materials: Strong acids. Strong bases. Strong oxidizers.

Hazardous Decomposition Products: Decomposition of product may generate toxic gases such as CO, CO₂ and zinc oxide.

SECTION 11: TOXICOLOGICAL INFORMATION

Acute Toxicity: The product is not expected to present toxicity for the oral, dermal and inhalation routes.

Zinc oxide:

LD₅₀ (oral, rats): 2,000 - 5,000 mg/kg. LD₅₀ (dermal, rats): 2000 mg/kg.

 LC_{50} (inhalation, rats, 4h): 1.79 – 5.7 mg/L.

Acetic acid:

LD₅₀ (oral, rats): 3,310 mg/kg.

LC₅₀ (inhalation, rats, 4h): 40,000 mg/m³. LD₅₀ (dermal, rabbits): 1060 mg/kg.

Mineral Oil:

LD₅₀ (oral, rats): \leq 2 000 mg/kg. LD₅₀ (dermal, rabbit): > 2.000 mg/kg. LC₀ (inhalation, rat): 210 mg/m³.

Eugenol:

 DL_{50} (oral, rats): 1,930 mg/kg. LC_{50} (inhalation, rats): > 2.6 mg/L.

Skin Corrosion/Irritation: Exposure to the product causes skin irritation with redness, dryness, and peeling.

Serious Eye Damage/Irritation: Causes eye irritation with pain, dryness, redness and tearing.

Eugenol:

Eye irritation test performed in rabbits (OECD 405) showed that the compound causes eye irritation.

Respiratory or Skin Sensitization: May cause an allergic skin reaction.

Eugenol:

Skin sensitization test - mouse local lymph node assay (LLNA, OECD 429) in mice, showed positive results.

Germ Cell Mutagenicity: The product is not expected to cause mutagenicity in germ cells.

Zinc oxide:

Ames test - negative result.

Chromosomal aberration test - negative result.

Acetic acid:

Ames test. Result: negative.

Mutagenicity study, clastogenicity in Chinese hamster ovary cells. Result: negative.

Sister switches chromatid. Result: negative.

Eugenol:

Ames test: not mutagenic in S. typhimurium TA98, TA 100, TA 1535, TA 1537, TA1538 and E. coli WP2 (OECD 471).

Carcinogenicity: The product is not expected to cause cancer.

Mineral oil pure, highly, and severely refined ACGIH classifies as group A4 - Not Classifiable as a Human Carcinogen.

Reproductive Toxicity: The product is not expected to cause reproductive toxicity.

Acetic acid:

Reproductive toxicity test, doses < 1600 mg/kg/day, in rats. Result: No adverse effects on fertility were observed.

Oxide zinc

Reproductive and developmental toxicity test doses of 4000 ppm in rats. Result: resorption and death of fetuses.

Specific Target Organ Toxicity (Single Exposure): The product is not expected to cause specific target organ toxicity by single exposure.

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Specific Target Organ Toxicity (Repeated Exposure): The product is not expected to cause specific target organ toxicity by repeated

Aspiration Hazard: It is not expected that the product presents aspiration hazard.

SECTION 12: ECOLOGICAL INFORMATION

Environmental effects, behavior, and fate of the product

Ecotoxicity: Very toxic to aquatic life with long lasting effects.

Zinc oxide:

CL₅₀ (Peixes, 96h) 112 - 8 062 µg/L.

CL₅₀ (Peixes, 96h) 330 μg/L.

NOEC (Peixes, 5 meses): $50 - 130 \mu g/L$.

 CE_{50} (Daphnia, 48 h) 155 - 100.000 µg/L.

 CE_{50} (Algas, 96h dias) 300 - 1.940 μ g/L.

NOEC (Algas, 9 meses) $33,3 - 100 \mu g/L$.

NOEC (Algas, 7 meses) 100 μg/L.

NOEC (Algas, 6 meses) 100 μg/L.

Acetic acid:

LC₅₀ (Pimephales promelas, 96h): 79 mg/L.

LC₅₀ (Lepomis macrochirus, 96h): 75 mg/L.

EC₅₀ (Daphnia magna, 48h): 65 mg/L.

Persistence and Degradability It is expected that the product exhibits persistence and is not readily degradable.

Bioaccumulative Potential The product is expected to have low bioaccumulative potential in aquatic organisms.

Acetic acid:

Log kow: -0.31 (at 20°C).

BCF: 3.0 Eugenol:

Log kow: 1.83 (at 30°C).

Mobility in Soil Not available.

Other Adverse Effects

Other Information: There are not known adverse environmental effects of the product.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal Recommendations: Must be disposed of as hazardous waste in compliance with local regulations. The treatment and disposal should be evaluated for each specific product. Keep product residues in their original containers and properly closed. Disposal should be in accordance with the regulations for the product. Do not reuse empty containers. These may contain product residues and should be kept closed and sent for appropriate disposal as established for the product.

Ecology – Waste Materials: This material is hazardous to the aquatic environment. Keep out of sewers and waterways.

SECTION 14: TRANSPORT INFORMATION

In Accordance with DOT

UN - "United Nations" Recommendations on the TRANSPORT OF DANGEROUS GOODS. Model Regulations

Number UN: 3082

UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Zinc oxide)

Transport hazard class(es): 9

Subsidiary risk: NA Packing Group: III

In Accordance with IMDG

Number UN: 3082

UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Zinc oxide)

Transport hazard class(es): 9

Subsidiary risk: NA Packing Group: III

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EmS: F-A, S-F

Environmental hazards: Product is considered a marine pollutant

In Accordance with IATA

Number UN: 3082

UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Zinc oxide)

Transport hazard class(es): 9

Subsidiary risk: NA Packing Group: III

SECTION 15: REGULATORY INFORMATION

US Federal Regulations

OPOTOW®	TEMPORA	RY CEMENT

SARA Section 311/312 Hazard Classes

Immediate (acute) health hazard

Castor oil (8001-79-4)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Paraffin oils (8012-95-1)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Zinc oxide (1314-13-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Butyl acetyl ricinoleate (140-04-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Eugenol (97-53-0)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Acetic acid (64-19-7)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

US State Regulations

Paraffin oils (8012-95-1)

- U.S. Massachusetts Right To Know List
- U.S. New Jersey Right to Know Hazardous Substance List
- U.S. Pennsylvania RTK (Right to Know) List

Zinc oxide (1314-13-2)

- U.S. Massachusetts Right To Know List
- U.S. New Jersey Right to Know Hazardous Substance List
- U.S. Pennsylvania RTK (Right to Know) Environmental Hazard List
- U.S. Pennsylvania RTK (Right to Know) List

Butyl acetyl ricinoleate (140-04-5)

- U.S. Massachusetts Right To Know List
- U.S. Pennsylvania RTK (Right to Know) List

Acetic acid (64-19-7)

- U.S. Massachusetts Right To Know List
- U.S. New Jersey Right to Know Hazardous Substance List
- U.S. Pennsylvania RTK (Right to Know) Environmental Hazard List
- U.S. Pennsylvania RTK (Right to Know) List

Canadian Regulations

OPOTOW® TEMPORARY CEMENT

WHMIS Classification Class D Division 2 Subdivision B - Toxic material causing other toxic effects

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•	•		
Castor oil (8001-79-4)			
Listed on the Canadian DSL (Domestic Substances List)			
Listed on the Canadian IDL (Ingredient Disclosure List)			
IDL Concentration 1 %	IDL Concentration 1 %		
WHMIS Classification	Uncontrolled product according to WHMIS classification criteria		
Paraffin oils (8012-95-1)			
Listed on the Canadian DSL (D	omestic Substances List)		
Listed on the Canadian IDL (In	gredient Disclosure List)		
IDL Concentration 1 %			
WHMIS Classification	Uncontrolled product according to WHMIS classification criteria		
Zinc oxide (1314-13-2)			
Listed on the Canadian DSL (D	omestic Substances List)		
Listed on the Canadian IDL (In	gredient Disclosure List)		
IDL Concentration 1 %	IDL Concentration 1 %		
WHMIS Classification	Uncontrolled product according to WHMIS classification criteria		
Butyl acetyl ricinoleate (140-	·		
Listed on the Canadian DSL (D	omestic Substances List)		
WHMIS Classification	Uncontrolled product according to WHMIS classification criteria		
Eugenol (97-53-0)			
Listed on the Canadian DSL (D	Listed on the Canadian DSL (Domestic Substances List)		
WHMIS Classification	Class D Division 2 Subdivision B - Toxic material causing other toxic effects		
Acetic acid (64-19-7)			
Listed on the Canadian DSL (Domestic Substances List)			
Listed on the Canadian IDL (Ingredient Disclosure List)			
IDL Concentration 1 %			
WHMIS Classification	Class B Division 3 - Combustible Liquid		
	Class E - Corrosive Material		

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all of the information required by CPR.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 13, octuber. 2021.

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA

Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

H226	Flammable liquid and vapor
H302	Harmful if swallowed
H304	May be fatal if swallowed and enters airways
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation.
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H319	Causes serious eye irritation
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life

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H402	Harmful to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H413	May cause long lasting harmful effects to aquatic life

Abbreviations:

ACGIH - American Conference of Governmental Industrial Hygienists

BCF - Bioconcentration factor

CAS - Chemical Abstracts Service

LC₅₀ – Lethal Concentration 50%

LD₅₀ – Lethal Dose 50%

ERPG - Emergency Response Planning Guidelines

NIOSH – National Institute of Occupational Safety and Health

OSHA - Occupational Safety & Health Administration

PEL - Permissible Exposure Limit

REL – Recommended Exposure Limit

STEL - Short Term Exposure Limit

TLV - Threshold Limit Value

TWA - Time Weighted Average

Bibliographic references:

ACGIH. AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIALS HYGIENISTS. TLVs® and BEIs®: Based on the Documentation of the Threshold Limit Values (TLVs®) for Chemical Substances and Physical Agents & Biological Exposure Indices (BEIs®). Cincinnati-USA, 2021.

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Party Responsible for the Preparation of This Document

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This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

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