SECTION 1. PRODUCT/ MIXTURE AND COMPANY IDENTIFICATION

1.1 Product Identifier

Product name	ORASAN OxyGel
Other means of identification	Not Available

1.2 Details of the supplier of the safety data sheet

Manufacturer/Supplier	EUROGRIN IKE
Address	FILOPIMENOS 3, ACHARNES 13671 GREECE
Telephone	+30 210 2824437
Fax	-
Website	------
Email	info@eurogrin.com.gr
Emergency Telephone	+30 210 2824437

1.3 Description of the Product

ORASAN OxyGel is a pre operatory gel based on Carbamide Peroxide and Disodium EDTA to be used sub and supra gingivally to dissolve plaque and soften tartar deposits. Before starting the scaling procedures, the gel is easily flowed inside the sulcus and in a short time the gel is softening the microbial plaque and tartar facilitating their dissolution. This pre-treatment will allow speed-up a lot the hygiene procedure working with minimal or no water spray during ultrasonic scaling, thus dramatically reducing the production of aerosols.

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Hazardous mixture according to directive (EC) No 1272/2008.
Not classified as Dangerous Goods for transport purposes.

Classification according to regulation (EC) No 1272/2008 [CLP] [1]	**Eye Irritation Category 2** **Skin Irritation, Category 2**
[1]	Classification drawn from EC Directive 1272/2008 - Annex VI

2.2 Label element(s)

CLP label element Pictogram GHS07	
SIGNAL WORD	WARNING
Hazard statement(s)	
H319 H315	Causes serious irritation on eye and skin
Supplementary statement(s)	
Not Applicable	
Precautionary statement(s) Prevention	
P280	Wear protective gloves/protecting clothing/eye protection/face protection
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.

Precautionary statement(s) Storage

P273	Avoid release to the environment

Precautionary statement(s) Disposal

P501	Dispose of in compliance with governmental regulation. (EC1975L0442-10/11/2003)

2.3 Other hazards

Cumulative effects may result following exposure*.

May produce skin discomfort*.

REACh - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Description

Gel for application on teeth and gums.

Hazardous components

3.1 Substances

Not Applicable

3.2 Mixtures/ Chemical characterization

CAS No	EC No	REACH No	Description	% w/w	Classification according to Regulation EC No 1272/2008 (GLP)
124-43-6	204-701-4	Not Available	Urea hydrogen peroxide	≤15	Oxidizing Solid Category 3, Metal Corrosion Category 1, Acute Toxicity (Oral) Category 4, Acute Toxicity (Inhalation) Category 4, Skin Corrosion/Irritation Category 1B, Serious Eye Damage Category 1; H272, H290, H302, H332, H314, H318 [1]
7757-79-1	231-818-8	Not Available	Potassium Nitrate	< 3.00	H271, H272
1310-73-2	215-185-5		Sodium Hydroxide	< 2.00	Skin Corr.,Cat. 1B; H314
57-55-6	200-338-0	01-2119456809-23-XXXX	Propylene Glycol	12.00	Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008
6381-92-6	205-358-3	Not Available	Disodium EDTA	< 2.00	Acute Tox. 4; STOT RE 2; H332, H373
9067-32-7		Not Available	Sodium Hyaluronate	< 1.00	Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008
56-81-5	200-289-5	Not Available	Glycerol	50.00 < X < 80.00	Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008
9003-01-4		Not Available	Polyacrylic acid	< 5.00	R36, R37, R38

For full text of H-statements and R-phrases: see SECTION 16.

SECTION 4. FIRST AID MEASURES

General information

The intended use is for application for the patient at dental office and patient home following the instructions of the dentist.

Skin contact

Immediately rinse with a lot of water and a mild soap. If irritation develops consult a doctor.

Eye contact

Rinse opened eye for several minutes under running water. Then consult a doctor.

After swallowing

No risk at small doses at intended use. Rinse out mouth and then drink plenty of water. In case of high dose consult doctor.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing agents

Water spray. Use fire extinguishing methods suitable to surrounding conditions.

For safety reasons unsuitable extinguishing agents

Water with full jet, CO2

Protective equipment

No special measures.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Person-related safety precautions

Wear protective equipment. Keep unprotected persons away. Dilute with plenty of water.

Measures for cleaning/collecting.

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

Measures for environmental protection (see section 12)

Dispose contaminated material as waste according to item 13.

SECTION 7. HANDLING AND STORAGE

Handling

Safe Handling

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.
- DO NOT enter confined spaces until atmosphere has been checked.
- DO NOT allow material to contact humans, exposed food or food utensils.
- 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.

Information about fire - and explosion protection

Ensure good ventilation/exhaustion at the workplace. No special measures required.

Storage

Requirements to be met by storerooms and receptacles

Store in dry and well-ventilated area at 5°C to 25°C. Avoid the direct contact with light and heat

Information about storage in one common storage facility

- Store away from flammable substances.
- Store away from reducing agents.
- Store away from metals.

Further information about storage conditions

- Keep receptacle tightly sealed.
- Protect from heat and direct sunlight.
- Store in a cool place.
- Heat will increase pressure and may lead to the receptacle bursting.

SECTION 8. EXPOSURE CONTROLS/ PERSONAL PROTECTION

General protective measures

Avoid contact with eyes and skin

Hygienic measures

Immediately remove all soiled and contaminated clothing

8.1 Control parameters				
Exposure limits (EH40)				
CAS No	**Substance**	**TEEL-1***	**TEEL-2***	**TEEL-3***
-	Urea peroxide	1.2 mg/m3	13mg/m3	79 mg/m3

***TEEL-3** is the airborne concentration (expressed as ppm [parts per million] or mg/m^3 [milligrams per cubic meter]) of a substance above which it is predicted that the general population, including susceptible individuals, when exposed for more than one hour, could experience life-threatening adverse health effects or death.

***TEEL-2** is the airborne concentration (expressed as ppm or mg/m^3) of a substance above which it is predicted that the general population, including susceptible individuals, when exposed for more than one hour, could experience irreversible or other serious, long-lasting, adverse health effects or an impaired ability to escape.

***TEEL-1** is the airborne concentration (expressed as ppm or mg/m^3) of a substance above which it is predicted that the general population, including susceptible individuals, when exposed for more than one hour, could experience notable discomfort, irritation, or certain asymptomatic, nonsensory effects. However, these effects are not disabling and are transient and reversible upon cessation of exposure.

Exposure Limits / Engineering Controls Chemical Components	**ACGIH – TLV***	**NIOSH – REL***	**OSHA – Final PELs***
Carbamide Peroxide	None listed	None listed	None listed
Sodium Fluoride	2.5 mg/m3	2.5 mg/m3	2.5 mg/m3

*** TLV – Threshold Limit Value** (should not be exceeded at any time) **/ REL – Recommended Exposure Limit** (should not be exceeded at any time) **/ PEL – Permissible Exposure Limit** (averaged over an 8-hour workshift)

8.2. Personal Protective Equipment (PPE) Information

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.

Skin: S36/37: Wear suitable protective clothing and gloves.

Clothing: Wear appropriate protective clothing to prevent skin exposure.

Respiratory: S38: In case of insufficient ventilation, wear suitable respiratory equipment.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

ORASAN OxyGel

Form: Clear Gel

Colour: Colourless

Odour: Characteristic

	Value	**Temperature**
pH-value	5.0-7.5	
Boiling point	n/a	
Vapour pressure	n/a	**20°C**

Density	1.100-1.300 g/cm3	**25°C**
Solubility in water	Yes	
Viscosity	**30,000-70,000 cPs**	**25°C**

SECTION 10. STABILITY AND REACTIVITY

Stability
Product is stable at room temperature in closed containers under normal storage and handling conditions.

Dangerous reactions
Reacts with various metals
Reacts with reducing agents Reacts with catalysts
Acts as an oxidizing agent on organic materials such as wood, paper and fats

Hazardous decomposition products
Decomposition by combustion, may release oxides of carbon and nitrogen.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Inhaled	The material is not thought to produce adverse health effects or irritation of the respiratory tract. Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting
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. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.
Skin contact	Limited evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant inflammation when applied to the

	healthy intact skin, for up to four hours, such inflammation being present twenty-four hours or more after the end of the exposure period. Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis (nonallergic). The dermatitis is often characterised by skin redness (erythema) and swelling (oedema) which may progress to blistering (vesiculation), scaling and thickening of the epidermis. At the microscopic level there may be intercellular oedema of the spongy layer of the skin (spongiosis) and intracellular oedema of the epidermis. Open cuts, abraded or irritated skin should not be exposed to this material Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds 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. IRRITANT
Eye	Evidence exists, or practical experience predicts, that the material may cause eye irritation in a substantial number of individuals and/or may produce significant ocular lesions. Repeated or prolonged eye contact may cause inflammation characterised by temporary redness (similar to windburn) of the conjunctiva (conjunctivitis); Temporary impairment of vision and/or other transient eye damage/ulceration may occur. STRONG IRRITANT WITH DANGER OF SEVER EYE INJURY
Chronic	Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.
Toxicity	No data available
Teratogenicity	No data available
Reproductive Effects	No data available
Mutagenicity	No data available

SECTION 12. ECOLOGICAL/ENVIROMENTAL INFORMATION

Under normal and foreseeable uses, there are no concerns for aquatic organisms exposed to product ingredients at the anticipated environmental concentrations. Relevant environmental data have been reviewed and these indicate that the product is compatible with down-the-drain disposal routes, including municipal wastewater treatment processes and septic tank systems. This product is intended for dispersive use and should not be disposed of directly into the environment.

SECTION 13. DISPOSAL CONSIDERATIONS

Product	**Small amounts may be diluted with plenty of water and washed away. Dispose of bigger amounts in accordance with governmental regulation. (EC 1975L0442-20/11/2003).**
Uncleaned packaging	Empty contaminated packaging thoroughly. They may be recycled after thorough and proper cleaning. Recommended cleansing agents: Water, if necessary together with cleansing agents.
Waste treatment options	Not Available
Sewage disposal options	Not Available

SECTION 14. TRANSPORT INFORMATION

14.1 Labels Required	
Marine Pollutant	NO
HAZCHEM	Not Applicable

14.2 General transport information	
Land transport ADR/RID (GGV SE)	No dangerous good in sense of these transport regulations
Inland waterways transport (ADN)	No dangerous good in sense of these transport regulations
Sea transport IMDG (GGV See)	No dangerous good in sense of these transport regulations
Air transport (ICAO)	No dangerous good in sense of these transport regulations

SECTION 15. REGULATORY INFORMATION

15.1. Safety, health and environmental regulations / legislation specific for the substance or mixture	
UREA HYDROGEN PEROXIDE (124-43-6 IS FOUND ON THE FOLLOWING REGULATORY LISTS)	
European Customs Inventory of Chemical Substances ECICS (English) Regulation 1223/2009 on Cosmetics	European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)

SECTION 16. OTHER INFORMATION

16.1 Full text Hazard (H) and Risk (R) codes (not classification of ready mixed product)	
H-phrases	
H225	Highly flammable liquid and vapour
H271	May cause fire or explosion; strong oxidiser.
H272	May intensify fire; oxidizer.
H290	May be corrosive to metals.
H301	Toxic if swallowed.
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage
H330	Fatal if inhaled.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.

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