



# Safety Data Sheet

According To Regulation (EC) No 1907/2006 (REACH),  
(EC) No. 1272/2008 (CLP)

## OPREZAN

Version: 2.0  
Form No: 027012

Prep Date: 31.10.2016  
Rev. Date: 30.05.2017

### 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1 Product Identifier

Name of Product	OPREZAN
SDS <sup>1</sup> Form No	027012
Product Description	Mixture

#### 1.2 Relevant Identified Uses Of The Product And Uses Advised Against

Relevant Identified Uses	Medical device disinfectant
Uses Advised Against	There are no uses advised against.

#### 1.3 Details Of The Supplier The Safety Data Sheet

Manufacturer/Supplier	Kuzey Sağlık Ürünleri ve Kimya Sanayi A.Ş. <a href="http://www.kuzeysaglik.com.tr">www.kuzeysaglik.com.tr</a>
Address	İstanbul Yolu Ergazi Mahallesi Gersan Sanayi Sitesi 2310 Sok No: 47 Yenimahalle Ankara / Turkey
Telephone	+90 (312) 256 6696
Fax	+90 (312) 256 6697
E-mail Address of Competent Person Responsible for the SDS	Handan YAĞIŞ <a href="mailto:handanyagis@bg-ilac.com">handanyagis@bg-ilac.com</a>

#### 1.4 Emergency Telephone Number

Company Emergency	+90 (312) 256 6696
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### 2. HAZARDS IDENTIFICATION

#### 2.1 Classification Of The Product

##### 2.1.1. Classification According to Regulation (EC) No 1272/2008

- This mixture is classified as hazardous according to regulation (EC) 1272/2008 [CLP/GHS].
- Skin Irrit. 2; H315
- Eye Irrit. 2; H319

#### 2.2 Label elements

##### 2.2.1. Labeling According to Regulation (EC) No 1272/2008 [CLP<sup>2</sup>/GHS<sup>3</sup>]

Product Identifier	
Hazard Component for Labeling	
	<ul style="list-style-type: none"> <li>· Non-ionic surfactants</li> <li>· Sodium carbonate</li> </ul>


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<b>Hazard Pictograms</b>	
· GHS07	
<b>Signal Word</b>	
· WARNING	
<b>Hazard Statements</b>	
H302	Harmful if swallowed
H315	Causes skin irritation
H319	Causes serious eye irritation
<b>Precautionary Statements</b>	
<b>General</b>	
-	
<b>Prevention</b>	
P264	Wash with water thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
<b>Response</b>	
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor/if you feel unwell.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
P332+P313	If skin irritation occurs: Get medical advice/attention
P337+P313	If eye irritation persists get medical advice/attention.
P362	Take off contaminated clothing
<b>Storage</b>	
-	
<b>Disposal</b>	
-	
<b>Supplemental Hazard Information (EU) Statements</b>	
No data available.	
<b>2.2.2. Special Rules For Supplemental Label Elements For Certain Mixtures</b>	
· None.	
<b>2.2.3. Additional Labeling</b>	

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· Not Applicable

### 2.3 Other Hazards

Substance not meets the criteria for PBT/ vPvB according to Regulation (EC) No. 1907/2006, Annex XIII: None

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Description Of The Substances

CAS <sup>4</sup> No	EC <sup>5</sup> No	Name	Conc. %	Classification according to Regulation (EC) No 1278/2008 (CLP)
15630-89-4	239-707-6	Sodium carbonate peroxohydrat (Sodium carbonate, hydrogen peroxide compound (2: 3))	>50	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319
10543-57-4	234-123-8	Tetraacetyl etilendiamin	>35	Not classified as hazardous

The remaining mixture is non-hazardous.

### 3.2 Additional information

Specific Concentration limits: None

M-Factor: None

Notes: None

## 4. FIRST AID MEASURES

### 4.1 Description of first aid measures

#### 4.1.1 General notes

· When in doubt or if symptoms are observed, get medical advice and show SDS.

#### 4.1.2 Following inhalation

- Remove victim to fresh air and keep at rest in a position comfortable for breathing.
- If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel.
- Get medical attention immediately.
- Move the unconscious person to the side position.



#### 4.1.3 Following skin contact

- Remove contaminated clothing. Immediately flush skin with large amounts of water and follow by washing with soap and water if available.
- Get medical attention immediately.



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### 4.1.4 Following eye contact

- Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Continue to rinse for at least 15 minutes.
- Check for and remove any contact lenses.
- Get medical attention immediately.



### 4.1.5 Following ingestion

- Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing.
- If material has been swallowed and the exposed person is conscious, give small quantities of water to drink.
- If unconscious, place in recovery position and get medical attention immediately.
- Get medical attention immediately.



### 4.1.6 Self-protection of the first aider

- No data available

### 4.1.7 Most important symptoms and effects, both acute and delayed

- **Potential acute health effects**  
Eye contact: Causes serious eye irritation.  
Inhalation: It can cause inhalation irritation.  
Skin contact: Causes skin irritation.
- Ingestion: It can cause ingestion irritation.

### 4.2. Indication of any immediate medical attention and special treatment needed

- Treat symptomatically.

## 5. FIRE-FIGHTING MEASURES

### 5.1 Extinguishing media:

#### Suitable extinguishing media

- Water spray, Carbon dioxide (CO<sub>2</sub>), Fire-extinguisher powder

#### Unsuitable extinguishing media

- None known.

### 5.2 Special hazards arising from the product.

- Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.

### 5.3 Advice for fire-fighters

#### 5.3.1. Special protective actions for fire-fighters

- Use cold water spray to cool fire-exposed containers to minimize the risk of rupture.
- Wear full chemical protective clothing. In case of fire: Self-Contained Breathing Apparatus (SCBA) with chemical resistant gloves.
- Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or



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without suitable training. Move containers from fire area if this can be done without risk.

- Fight fire from protected location or maximum possible distance.

### 5.3.2. Special protective equipment for fire-fighters

- Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

## 6. ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

#### 6.1.1 For non-emergency personnel

- Avoid contact with skin, eyes, and clothing.
- No action shall be taken involving any personal risk or without suitable training.
- Keep unnecessary and unprotected personnel from entering.
- Do not touch or walk through spilled material.
- Evacuate the accident area.
- In case of fire: Evacuate area.
- Keep unnecessary and unprotected personnel away from entering.
- Refer to protective measures listed in section 7 and 8.
- Wear appropriate personal protective equipment as described in section 8.

#### 6.1.2. For emergency responders

- Ventilate area of leak or spill.
- If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials.
- See also the information in "For non-emergency personnel".

### 6.2 Environmental precautions

- Do not empty into drains and sewers.
- Keep from entering to water and ground water systems.
- Spillages or uncontrolled discharges into watercourses must be alerted to the Environmental Agency or other appropriate regulatory body.

### 6.3 Methods and material for containment and cleaning up

#### 6.3.1 For containment

- Prevent entry into sewers, water courses, basements or confined areas.

#### 6.3.2 For cleaning up

- Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- Dispose of via a licensed waste disposal contractor.
- Place spilled material in a designated, labeled waste container.

#### 6.3.3 Other information

- Dispose of waste material according to local, state and federal regulations.





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### 6.4 Reference to other sections

- See Section 1 for emergency contact information.
- See Section 8 for information on appropriate personal protective equipment.
- See Section 13 for additional waste treatment information.

## 7. HANDLING AND STORAGE

### 7.1 Precautions for safe handling

#### 7.1.1 Protective measures

##### Personal preventions

- Wear personal protection equipment. Refer to chapter 8.
- Do not eat, drink, smoke or sneeze at the workplace.
- Always wash hands with soap and water after handling.
- Do not inhale gas/vapor/mist/spray of the product.
- Avoid contact with hand and eye.
- Provide adequate ventilation
- Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use.
- Keep away from clothing, incompatible materials and combustible materials.
- Working areas must be arranged in such a manner that they can be cleaned at all times.
- Take off all contaminated clothing immediately and never use before washing.
- Ensure adequate ventilation and, if necessary, exhaust ventilation when handling or transferring the product.

#### 7.1.2 Measures to Prevent Fire

- See section 5.
- Wear fire resistant clothing. Keep away from heat.

#### 7.1.3 Measures to Protect Environment

- Dispose of waste material according to local, state and federal regulations.

#### 7.1.4 Advice on general occupational hygiene

- Avoid direct contact of substance with skin/eyes.
- Use good occupational work practice.
- Do not wear contaminated clothing at home.
- Comply with the health and safety at work laws.
- Remove contaminated clothing and protective equipment before entering eating areas.

### 7.2 Conditions for safe storage, including any incompatibilities

- Store in accordance with local regulations.
- Store away from ignition sources, food and drink.
- Keep container tightly closed.
- Store in original containers.
- Store in a cool, dry, well-ventilated area.



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- Store under 25 °C temperature.
- Avoid contact with incompatible materials
- Avoid physical damage to containers.

### STORAGE INCOMPATIBILITY

- No data available

### Advice on common storage

- See also instructions on the label.
- Store in a cool, dry, well-ventilated area.
- Keep away from food, drink and animal feeding stuffs.
- Store away from incompatible materials and foodstuff containers.

### 7.3 Specific precautions on storage

- Self-life: 3 years

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### 8.1 Control parameters

Preventive industrial and medical examinations must be carried out according to the application area. 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.

Reference should be made to monitoring standards, such as the following: European

#### 8.1.1 Occupational exposure limits

No data available

### 8.2 Exposure controls

Adequate ventilation should be used during processing.

Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

#### 8.2.1 Appropriate engineering controls:

Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective threshold limit value.

Ensure that eyewash stations and safety showers are proximal to the work-station location.

If user operations generate dust, fumes, gas, vapour or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

Keep away from food, drink and animal feeding stuffs.

Use personal protective equipment according to EN<sup>6</sup> standards.

See Section 7





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### 8.2.2 Individual protection measures, such as personal protective equipment

#### 8.2.2.1 Eye / Face protection:

- Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. (NIOSH (USA) or EN (EU))
- If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles and/or face shield.



#### 8.2.2.2 Skin protection

##### Hand protection

- Use protective gloves.



##### Body protection

- Choose body protection according to the amount and concentration of the dangerous substance at the work place.

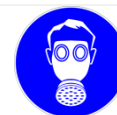


##### Other protection

- Handle in accordance with good industrial hygiene and safety practice.
- Eye wash
- Body wash

#### 8.2.2.3 Respiratory protection

- No protection is required under normal conditions.
- Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator. (NIOSH (USA) or EN (EU))



#### 8.2.3 Environmental exposure controls

- Legislation for the protection of the environment must be met in full.
- Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Form/Physical state	Powder
Color	White
Odor	Parfum
pH at (20 °C)	8,2 -/+1
Melting Point (°C)	No data available
Flash point (°C)	No data available
Density (g/cm <sup>3</sup> ) (20°C)	0,95
Flammable properties	Product Is not self-igniting



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Oxidising Properties	No data available
Explosive properties	Product does not present an exposure hazard
Explosion limits, %	No data available
Vapor pressure, mmHg	No data available
Vapor density, (15, Air: 1)	No data available
Boiling Point (°C)	No data available
Decomposition Point (°C)	No data available
Viscosity Dynamic (20 °C) (mPas)	No data available
Solubility in / Miscibility with water	Fully miscible

### 9.2 Other Information

Other physical and chemical parameters

## 10. STABILITY AND REACTIVITY

### 10.1 Reactivity

- The product is stable in normal handling and storage conditions.

### 10.2 Chemical stability

- The product is stable in normal handling and storage conditions.

### 10.3 Possibility of hazardous reactions

- The product is stable.

### 10.4 Conditions to avoid:

- No specific data.

### 10.5 Incompatible materials:

- No specific data.

### 10.6 Hazardous decomposition products:

- Development of toxic decomposition gases possible in the event of fire.

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Based on our experience and the information available, adverse health effects are expected if not handled as recommended with suitable precautions for designated uses.

The product has not been tested in animal experiments.

### 11.2 Acute toxicity

- LD50 (Oral, Rat): 2000-5000 mg/kg

### 11.3 Skin corrosion/irritation and Eye damage/irritation:

- Skin irritation: Irritant effect on skin. Irritant effect on mucous membrane prolong-exposure.
- Eye irritation: Irritant effect on skin



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### 11.4 CMR effects (Carcinogenity) :

- The product does not have carcinogenic effect.

### 11.5 CMR effects (Mutagenicity and Toxicity for reproduction) :

The product is not mutagenic or toxic for reproduction.

### 11.6 Other Toxicological Effects:

Allergic Effects	No data available
Effects on Repeated Doses Chronic Exposures	No data available
Sensitization	No data available
Developmental Toxicity (Teratogenicity)	No data available
Fertility	No data available

### 11.7 STOT-single/repeated exposures:

STOT-single exposure	The substance is not classified as a specific target organ toxicant.
STOT-repeated exposure	The substance is not classified as a specific target organ toxicant.

### 11.8 Symptoms related to the physical, chemical and toxicological characteristics:

In case of inhalation	It can cause inhalation irritation.
In case of skin contact	Causes skin and mucous membrane irritation in prolong exposure.
In case of eye contact	Causes serious eye irritation
In case of ingestion	Ingestion: It can cause ingestion irritation.

### 11.9 Additional Toxicological Information:

- Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of oesophagus and stomach.
- The special effects to health are considered by taking into account the information in section 3.

## 12. ECOLOGICAL INFORMATION

### 12.1 Toxicity:

There is no environmental hazard for this product. Do not dispose to environment.

### 12.2 Persistence and degradability

Abiotic degradation/Hydrolysis: No data available

Biodegradation: In accordance with the requirements of the RVO in the Act on Detergents and Cleansing Agents, tensides are biodegradable up to at least 90 %.

According to OECD-Confirmatory-Test N,N-bis(3-aminopropyl)-dodecylamine is biodegradable.





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### 12.3 Bioaccumulative potential

Partition coefficient n-octanol /water (log Kow): No data available  
Bioconcentration factor (BCF): No data available

### 12.4 Mobility in Soil

No data available

### 12.5 Results of PBT and vPvB assessment

According to Annex XIII of Regulation (EC) No.1907/2006 product is not fulfilling PBT (persistent/bioaccumulative/toxic)/vPvB (very persistent/very bioaccumulative) criteria

### 12.6 Other adverse effects

Water hazard class 2 (German Regulation) : Hazardous for water  
See the sections 6, 7, 13, 14 and 15.

## 13. DISPOSAL CONSIDERATIONS

### 13.1 Waste Treatment Methods

#### 13.1.1 Product / Packaging disposal

- The generation of waste should be avoided or minimized wherever possible.
- Note that properties of a material may change in use, and recycling or reuse may not always be appropriate
- When recycling of the product is not possible, disposal to landfill or incineration in accordance with all applicable government laws and regulations is recommended.
- Disposal according to local authority regulations.
- According to the European Waste Catalogue, waste codes are not product specific, but application specific. Waste codes should be assigned by the user.
- Contaminated packaging can be re-used after emptying and cleaning.

#### 13.1.2 Waste Treatment-Relevant Information

- None

#### 13.1.3 Sewage Disposal-Relevant Information

- None

#### 13.1.4 Other Disposal Recommendations

- Dispose of chemicals waste or in accordance with local regulations.
- The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.
- Follow all applicable local laws, rules and regulations regarding the proper disposal of this material.
- Dispose of waste according to applicable local, state, and federal regulations.
- 07 00 00 WASTES FROM ORGANIC CHEMICAL PROCESSES
- 07 06 00 wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics



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· 07 06 08 other still bottoms and reaction residues

### 14. TRANSPORT INFORMATION

	ADR <sup>7</sup> /RID <sup>8</sup>	ADNR <sup>9</sup>	IMDG <sup>10</sup>	ICAO <sup>11</sup> /IATA <sup>12</sup>
TRANSPORTATION	Road	River	Marine	Airways
14.1 UN No.	-	-	-	-
14.2 Un Proper Shipping Name	This product is not hazardous for transport			
Symbols	-	-	-	-
HIN No	-	-	-	-
Tunnel Restriction Code	-	-	-	-
Classification Code	-	-	-	-
EMS Code	-	-	-	-
14.3 Transport Hazard Class	-	-	-	-
14.4. Packaging Group	-	-	-	-
14.5 Environmental Hazards	-	-	-	-
14.6 Special Precautions For Users	Not Available			
14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code	Not Available			

### 15. REGULATORY INFORMATION

#### 15.1 Safety, Health And Environmental Regulations / Legislation Specific For The Substance or Mixture

EU Regulation (EC) No. 1907/2006 (REACH) Annex XIV - List of substances subject to authorization Substances of very high concern: None of the components are listed.

Not applicable.

Annex XVII – Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles: Not applicable

Other EU regulations

Europe inventory: This material is listed or exempted.

#### 15.1.1 HAZARD

CLP classification according to Annex VI of CLP (Regulation (EC) No 1272/2008)

#### INTERNATIONAL REGULATIONS

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006 (REACH) and ISO 11014:2009.





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This product is classified according to EU Directive GHS/CLP.  
European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR 2015)

### 15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance by the supplier.

## 16. OTHER INFORMATION

### 16.1 Other information

For additional information regarding products please contact the **Kuzey Sağlık Ürünleri ve Kimya Sanayi A.Ş.**

The above information complies with the 1907/2006 Directives and their amendments.

### 16.2 Related Person

- AYANSAN CHEMICAL CONSULTANCY PLASTIC INC. AND TRD. LTD. CO.
- Prepared by
- Chemical Safety and Regulatory Affairs Consultant: MSc Burak AYAN ([burakayan@ayansan.com](mailto:burakayan@ayansan.com))
- [www.ayansan.com](http://www.ayansan.com) [info@ayansan.com](mailto:info@ayansan.com) +90 (212) 485 50 59
- Kuzey Sağlık Ürünleri ve Kimya Sanayi A.Ş.
- Handan YAĞIŞ
- [handanyagis@bq-ilac.com](mailto:handanyagis@bq-ilac.com)

### 16.3 Revision Date, Version and SDS no

- Date : May 30, 2017
- Version : 2.0
- SDS No : 027012

### 16.4 Reason of re-issue

- Complying to English SDS

### 16.5 Relevant H- and EUH-phrases:

H302 Harmful if swallowed  
H315 Causes skin irritation  
H319 Causes serious eye irritation

### 16.6 Legal disclaimer

- The purpose of the above information is to describe the products only in terms of health and safety requirements.
- The information given should not, therefore, be construed as guaranteeing specific properties or as specification.
- Customers should satisfy themselves as to the suitability and completeness of such information for their own particular use.



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- The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication.
- The above information relates only to the specific material(s) designated herein and may not be valid for such material(s) used in combination with any other materials or in any process or if the material is altered or processed, unless specified in the text.
- The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. Due to the many factors outside our control when using this product, we cannot accept liability for any injury, accident, loss or damage caused through its use.

<sup>1</sup> SDS: Safety Data Sheet

<sup>2</sup> CLP: Classification Labelling and Packaging

<sup>3</sup> GHS: Global Harmonised System

<sup>4</sup> CAS : Chemical Abstract Service

<sup>5</sup> EC : European Community number

<sup>6</sup> EN Standards: Personal Protective Equipment Standards Determined by CEN (European Committee for Standardization)

<sup>7</sup> ADR: Accord Dangereux Routier (European regulations concerning the international transport of dangerous goods by road)

<sup>8</sup> RID: Regulations Concerning the International Transport of Dangerous Goods by Rail (European law)

<sup>9</sup> ADNR: Regulation for the Carriage of Dangerous Substances on the Rhine (EU)

<sup>10</sup> IMDG: International Maritime Dangerous Goods (United Nations)

<sup>11</sup> ICAO: International Civil Aviation Organization

<sup>12</sup> IATA: International Air Transport Association



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