



# SAFETY DATA SHEET

[In accordance with the criteria of Regulation No 1907/2006 (REACH) as amended]

## Section 1: Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier

**HYPOCHLOR 5,25 %**

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses: product for root canal rinsing.

Uses advised against: not determined.

### 1.3 Details of the supplier of the safety data sheet

Manufacturer: **P.F.O. VETOS – FARMA Sp. z o.o.**

Address: ul. Dzierżonowska 21, 58 – 260 Bielawa, Poland

Telephone/Fax number: +48 74 833 74 85-8; +48 74 833 56 69

E-mail address for a competent person responsible for SDS: [biuro@theta-doradztwo.pl](mailto:biuro@theta-doradztwo.pl)

### 1.4 Emergency telephone number

112

## Section 2: Hazards identification

### 2.1 Classification of the substance or mixture

**Skin Irrit. 2 H314, Eye Irrit. 2H318**

Causes skin irritation. Causes serious eye irritation.

### 2.2 Label elements

Hazard pictograms and signal words



**Warning**

Hazard statement

H314 Causes severe skin burns and eye damage.

H318 Causes serious eye damage.

Precautionary statement

P280 Wear protective gloves/protective clothing/eye protection.

P303+P361+P353 If on skin: Take off immediately all contaminated clothing. Rinse skin with water.

501 Dispose of contents/ container to special signed containers.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/ doctor.

### 2.3 Other hazards

Assessment of PBT and vPvB properties in accordance with Annex XIII of REACH Regulation was not conducted since sodium hypochlorite is an inorganic substance.

## Section 3: Composition/information on ingredients

### 3.1 Substances

Not applicable.



# SAFETY DATA SHEET

## 3.2 Mixtures

|                                                                                                                       |                                                                                                                              |         |
|-----------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|---------|
| CAS number: 7681-52-9<br>EC number: 231-668-3<br>Index number: 017-011-00-1<br>REACH number:<br>01-2119488154-34-XXXX | <u>sodium hypochlorite</u> <sup>1</sup><br>Met. Corr 1 H290, Skin Corr. 1B H314, STOT SE 3 H335, Aquatic Acute 1 H400 (M=10) | < 5,5 % |
| CAS number: 1310-73-2<br>EC number: 215-185-5<br>Index number: 011-002-00-6<br>REACH number:<br>01-2119457892-27-XXXX | <u>sodium hydroxide</u><br>Met. Corr. 1 H290, Skin Corr. 1A H314                                                             | < 1 %   |

<sup>1</sup> substance with occupational exposure limits defined on the Community level

Full text of each relevant H phrases is given in section 16 of SDS.

## Section 4: First aid measures

### 4.1 Description of first aid measures

Skin contact: take off contaminated clothing. Wash the contaminated skin thoroughly with water. Consult a doctor if disturbing symptoms occur.

Eye contact: protect non-irritated eye, remove contact lenses. Rinse contaminated eyes thoroughly with water for 10-15 minutes. Avoid powerful water stream – risk of cornea damage. Consult a doctor if disturbing symptoms occur.

Ingestion: do not induce vomiting. Rinse mouth with water. Never give anything by mouth to an unconscious person. Consult a doctor immediately, show packaging or label.

Inhalation: remove casualty to fresh air, keep the victim warm and calm. Consult a doctor if disturbing symptoms occur.

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

Skin contact: possible redness, irritation.

Eye contact: possible redness, burning sensation, irritation.

Ingestion: irritation of digestive tract.

Inhalation: irritation of airways, coughing, breathing difficulties.

### 4.3 Indication of any immediate medical attention and special treatment needed

Physician makes a decision regarding further medical treatment after thoroughly examination of the injured.

## Section 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media: extinguishing foam, extinguishing powder, carbon dioxide, water spray. Adjust firefighting measures to the surrounding materials.

Unsuitable extinguishing media: water jet – risk of the propagation of the flame.

### 5.2 Special hazards arising from the substance or mixture

During the combustion, the product may produce hazardous fumes containing e.g. oxygen, chlorine, chlorine dioxide. Do not inhale combustion products, they can be dangerous for human health.

### 5.3 Advice for firefighters

Personal protection typical in case of fire. Do not stay in the fire zone without self-contained breathing apparatus and protective clothing resistant to chemicals. Do not let the extinguishing water reach the drainage system, surface of ground water. In case of fire, cool endangered containers with water spray. Product decomposes at high temperature with release of chlorine, which may cause bursting of the container.



# SAFETY DATA SHEET

## Section 6: Accidental release measures

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

Limit the access of the outsiders to the breakdown area until suitable cleaning operations are completed. Ensure that only trained personnel can remove the effects of the accident. In case of large release, isolate the exposed area. Avoid skin and eye contact. Do not inhale vapors. Use personal protective equipment. Ensure adequate ventilation.

### 6.2 Environmental precautions

Do not enter to the drainage system, surface or ground water. In case of large release, prevent the mixture from spreading into the environment. Notify relevant emergency services.

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

Place damaged container in an emergency packaging. Cover the spillages with liquid-binding material (eg. sand, earth) and place them in labeled containers. Clean and ventilate the contaminated area.

### 6.4 Reference to other sections

Appropriate conduct with waste product – section 13. Personal protective equipment – section 8.

## Section 7: Handling and storage

### 7.1 Precautions for safe handling

Handle in accordance with good occupational hygiene and safety practices. Use only in well-ventilated rooms. Avoid eye and skin contact. Do not inhale vapours. Do not eat, drink or smoke when handling the product. Do not let the product reach the mouth. Ensure adequate ventilation.

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

Store only in tightly closed containers. Keep away from flammable substances and heaters. Keep out of the reach of unauthorized persons. If the product is stored in original containers in refrigerator at 2-8 °C, it is stable for 1 year.

### 7.3 Specific end use(s)

No information about other uses than those mentioned in subsection 1.2.

## Section 8: Exposure controls/personal protection

### 8.1 Control parameters

| Specification            | TWA 8 hour | STEL 15 min           |
|--------------------------|------------|-----------------------|
| chlorine [CAS 7782-50-5] | -          | 1,5 mg/m <sup>3</sup> |

Please check any national occupational exposure limit values in your country.

Legal Basis: Commission Directive 2006/15/EC, 2000/39/EC, 2009/161/EC

#### Recommended control procedures

Procedures concerning the control over the dangerous components concentrations in the air and control over the air quality in the workplace – if they are available and justified for the position – in accordance with the European Standards, with the conditions within the exposure place and a proper test methodology adapted to the working conditions.

#### DNEL values for sodium hypochlorite

| Route of exposure | Workers               |                       |                         |                        |
|-------------------|-----------------------|-----------------------|-------------------------|------------------------|
|                   | acute, local          | acute, systemic       | chronic, local          | chronic, systemic      |
| oral              | —                     | —                     | —                       | —                      |
| inhalation        | 3,1 mg/m <sup>3</sup> | 3,1 mg/m <sup>3</sup> | 1,55 mg/m <sup>3</sup>  | 1,55 mg/m <sup>3</sup> |
| dermal            | —                     | —                     | 0,5 % m/m<br>in mixture | —                      |



# SAFETY DATA SHEET

| Route of exposure | Consumers             |                       |                         |                        |
|-------------------|-----------------------|-----------------------|-------------------------|------------------------|
|                   | acute, local          | acute, systemic       | chronic, local          | chronic, systemic      |
| oral              | —                     | —                     | —                       | 0,26 mg/kg bw          |
| inhalation        | 3,1 mg/m <sup>3</sup> | 3,1 mg/m <sup>3</sup> | 1,55 mg/m <sup>3</sup>  | 1,55 mg/m <sup>3</sup> |
| dermal            | —                     | —                     | 0,5 % m/m<br>in mixture | —                      |

## **PNEC values for sodium hypochlorite**

|                                           |                    |
|-------------------------------------------|--------------------|
| Ecosystem of fresh water                  | 0,21 µg/l          |
| Ecosystem of fresh water sludge           | —                  |
| Ecosystem of marine water                 | 0,042 µg/l         |
| Ecosystem of marine water sludge          | —                  |
| Ecosystem of intermittent release         | 0,26 µg/l          |
| Wastewater treatment plant microorganisms | 0,03 mg/l          |
| Top predators                             | 11,1 mg/kg in food |

## **8.2 Exposure controls**

Use the product in accordance with good occupational hygiene and safety practices. Do not eat, drink or smoke when handling the product. Before break and after work wash hands carefully. Avoid eyes and skin contact. Ensure adequate ventilation.

### Hand and skin protection

Use protective gloves, e.g. made of PVC, butyl rubber, neoprene, Viton. Use clothing resistant to product. In case of a short contact, use protective gloves with effectiveness level  $\geq 2$  (breakthrough time > 30 min.). In case of a prolonged contact, use protective gloves with effectiveness level 6 (breakthrough time > 480 min.).

The material that the gloves are made of must be impenetrable and resistant to the product's effects. The selection of material must be performed with consideration of breakthrough time, penetration speed and degradation. Moreover, the selection of proper gloves depends not only on the material, but also on other quality features and changes depending on the manufacturer. The producer should provide detailed information regarding the exact breakthrough time. This information should be followed.

### Eye protection

Tightly fitting safety goggles or face protection.

### Respiratory protection

In case of insufficient ventilation use appropriate respiratory protection

Applied personal protective equipment must comply with the requirements of the Directive 89/686/EC. The employer is obliged to provide protective equipment relevant to performed activities and in accordance with all quality requirements, including its maintenance and cleaning.

### Environmental exposure controls

Avoid releases to the environment, do not empty into drains. Possible emissions from the ventilation systems and processing equipment should be controlled in order to determinate their compatibility with environmental protection regulations.

## **Section 9: Physical and chemical properties**

### **9.1 Information on basic physical and chemical properties**

|                                          |                                                               |
|------------------------------------------|---------------------------------------------------------------|
| physical state:                          | liquid                                                        |
| colour:                                  | light yellow                                                  |
| odour:                                   | light smell of chlorine                                       |
| odour threshold:                         | not determined                                                |
| pH:                                      | not determined                                                |
| melting point/freezing point:            | not determined                                                |
| initial boiling point and boiling range: | not applicable, decomposition occurs before the boiling point |



# SAFETY DATA SHEET

|                                               |                                  |
|-----------------------------------------------|----------------------------------|
| flash point:                                  | is reached (sodium hypochlorite) |
| evaporation rate:                             | not applicable                   |
| flammability (solid, gas):                    | not determined                   |
| upper/lower flammability or explosive limits: | not applicable                   |
| vapour pressure (20°C):                       | not determined                   |
| vapour density:                               | not determined                   |
| density:                                      | 0,988-1,092 g/cm <sup>3</sup>    |
| solubility(ies):                              | fully soluble in water           |
| partition coefficient: n-octanol/water:       | -3,42 (sodium hypochlorite)      |
| auto-ignition temperature:                    | not determined                   |
| decomposition temperature:                    | > 30 °C (sodium hypochlorite)    |
| explosive properties:                         | not display                      |
| oxidising properties:                         | not display                      |
| dynamic viscosity:                            | not determined                   |

## 9.2 Other information

No additional test results.

## Section 10: Stability and reactivity

### 10.1 Reactivity

Product is reactive. It does not undergo a violent polymerization. See subsection 10.3-10.5.

### 10.2 Chemical stability

The product is stable under normal conditions of storage and use. Decomposition temperature  $\geq 25$  °C.

### 10.3 Possibility of hazardous reactions

Reacts explosively with hydroxen, metal powders and many organic substances. Reacts exothermically with acid with release of chlorine.

### 10.4 Conditions to avoid

Avoid temeptrature over 25 °C, heating, sunlight.

### 10.5 Incompatible materials

Flammable materials, strong acids, reductors, oxidizers, organic compounds, amines, ammonium salts, cellulose, metals.

### 10.6 Hazardous decomposition products

Chlorine (at 35 °C), chlorine dioxide (at 100 °C).

## Section 11: Toxicological information

### 11.1 Information on toxicological effects

#### Toxicity of a component

##### sodium hypochlorite

Substance reacts violently with organic molecules, cells and tissues with release of chlorinated organic compounds. There is a very little data on penetration of the skin and respiratory system. Due to considerable popularity of the substance, only slight skin absorption is assumed. Exposure through the respiratory system is limited due to low vapor pressure above the aqueous solution. Animal studies have shown that by oral exposition HOCl form is absorbed and excreted as chlorine in urine (app. 40% of the administered dose after 96h).



# SAFETY DATA SHEET

|                                          |                                                                                                               |
|------------------------------------------|---------------------------------------------------------------------------------------------------------------|
| LD <sub>50</sub> (rat, oral)             | 1 100 mg/kg bw calculated as active chlorine (estimated dose at substance concentration of 12,5%) – OECD 401  |
| LD <sub>50</sub> (albino rabbit, dermal) | 20 000 mg/kg bw calculated as active chlorine (estimated dose at substance concentration of 12,5%) – OECD 403 |
| LC <sub>50</sub> (rat, inhalation)       | 1050 mg/m <sup>3</sup>                                                                                        |

## Toxicity of the mixture

### Acute toxicity

Based on available data, the classification criteria are not met.

### Skin corrosion/irritation

Causes skin irritation.

### Serious eye damage/irritation

Causes serious eye irritation.

### Respiratory or skin sensitisation

Based on available data, the classification criteria are not met.

### Germ cell mutagenicity

Based on available data, the classification criteria are not met.

### Carcinogenicity

Based on available data, the classification criteria are not met.

### Reproductive toxicity

Based on available data, the classification criteria are not met.

### STOT-single exposure

Based on available data, the classification criteria are not met.

### STOT-repeated exposure

Based on available data, the classification criteria are not met.

### Aspiration hazard

Based on available data, the classification criteria are not met.

## Section 12: Ecological information

### 12.1 Toxicity

#### Toxicity of a component

##### sodium hypochlorite

|                                              |                   |                                                 |
|----------------------------------------------|-------------------|-------------------------------------------------|
| Acute toxicity for fish                      | LC <sub>50</sub>  | 0,06 mg/l/96h ( <i>Lepomis macrochirus</i> )    |
| Acute toxicity for fish                      | LC <sub>50</sub>  | 0,0032 mg/l/96h ( <i>Oncorhynchus kisutch</i> ) |
| Acute toxicity for invertebrates             | EC <sub>50</sub>  | 0,141 mg/l/48h ( <i>Daphnia magna</i> )         |
| Acute toxicity for invertebrates             | EC <sub>50</sub>  | 0,035 mg/l/48h ( <i>Ceriodaphnia dubia</i> )    |
| Acute toxicity for algae population growth   | ErC <sub>50</sub> | 0,1-0,4 mg/4 days                               |
| Chronic toxicity for algae population growth | NOEC              | 0,02 mg/l/4 days                                |
| Chronic toxicity for fish                    | NOEC              | 0,04 mg/l/28 days ( <i>Menidia peninsulae</i> ) |
| Chronic toxicity for invertebrates           | NOEC              | 0,0021 mg/l/ 7 days                             |

#### Toxicity of the mixture

Mixture is not classified as hazardous for aquatic environment.

### 12.2 Persistence and degradability

Sodium hypochlorite contained in the product is hydrolyzed in water. It is not possible to determine its biodegradation coefficient in soil and sediment because it is an inorganic substance. Decomposition in the air is primarily a result of photolysis and oxidation.



# SAFETY DATA SHEET

## 12.3 Bioaccumulative potential

sodium hypochlorite: log Po/w= -3,42

## 12.4 Mobility in soil

Product is mobile in soil and aquatic environment.

## 12.5 Results of PBT and vPvB assessment

Criteria are not met.

## 12.6 Other adverse effects

This product has no influence on the global warming or the ozone layer depletion.

## Section 13: Disposal considerations

### 13.1 Waste treatment methods

Disposal methods for the mixture: dispose in accordance with local legislation. Prevent from entering to surface or ground waters or soil. Do not empty to the drainage system. The waste product should be incinerated only in authorized waste disposal sites. Substance fulfill the criteria for hazardous wastes.

Disposal methods for used packing: reuse/recycle/eliminate empty containers in accordance with the local legislation. Only completely empty containers can be recycled.

Legal basis: Directive 2008/98/EC, 94/62/EC.

Please check national legislation.

## Section 14: Transport information

### 14.1 UN number

Not applicable, product is not classified as dangerous during transport by land, sea or air.

### 14.2 UN proper shipping name

Not applicable.

### 14.3 Transport hazard class(es)

Not applicable.

### 14.4 Packing group

Not applicable.

### 14.5 Environmental hazards

Mixture is not classified as dangerous for the environment in accordance with the criteria of transport legislation.

### 14.6 Special precautions for user

Not applicable.

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable.

## Section 15: Regulatory information

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

**Regulation (EC) No 1907/2006** of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC as amended.



# SAFETY DATA SHEET

**Regulation (EC) No 1272/2008** of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance) as amended.

**Commission Regulation (EU) No 2015/830** of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance) as amended.

**Directive 2008/98/EC** of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives as amended.

**European Parliament and Council Directive 94/62/EC** of 20 December 1994 on packaging and packaging waste as amended.

## 15.2 Chemical safety assessment

Chemical Safety Assessment for a mixture is not required.

## Section 16: Other information

### Full text of H phrases from section 3

|        |                                          |
|--------|------------------------------------------|
| H290   | May be corrosive to metals.              |
| H314   | Causes severe skin burns and eye damage. |
| H318   | Causes serious eye damage.               |
| H400   | Very toxic to aquatic life.              |
| EUH031 | Contact with acids liberates toxic gas.  |

### Clarification of aberrations and acronyms

|                   |                                                      |
|-------------------|------------------------------------------------------|
| PBT               | Persistent, Bioaccumulative and Toxic substance      |
| vPvB              | very Persistent, very Bioaccumulative substance      |
| Aquatic Acute 1   | Hazardous to the aquatic environment, category 1     |
| Eye Dam. 1        | Serious eye damage, category 1                       |
| Met. Corr. 1      | Substance or mixture corrosive to metals, category 1 |
| Skin Corr. 1A, 1B | Skin corrosion, category 1A, 1B                      |

### Trainings

Before commencing working with the product, the user should learn the Health & Safety regulations, regarding handling chemicals, and in particular, undergo a proper workplace training. Personnel related with the transport of hazardous substances in accordance with the ADR agreement should be trained and should obtain proper certification in a range of their obligations (general training, workplace training, safety training).

### Other data

Safety Data Sheet made by: **PFO VETOS-FARMA Ltd.**

The information above is based on a current available data concerning the product, but also on the experience and knowledge in this field of the producer. They are neither a quality description of the product nor a guarantee of particular features. They are to be treated as aid to safety in transport, storage and usage of the product. That does not free the user from the responsibility of improper usage of the information above and also of improper compliance with the law norms in the field.