PPH CERKAMED
TCAdent Product Data Sheet

1. Product and company identification

Product trade name: **TCAdent**

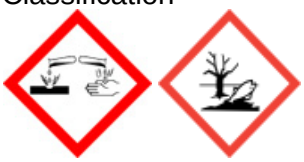
Usage: A product for local cauterisation of pathological changes and slight bleeding in the oral cavity

Manufacturer: PPH CERKAMED Wojciech Pawłowski
[manufacturing and trading company]
37-450 Stalowa Wola
ul. Kwiatkowskiego 1
Tel. 015 / 842 35 85

Toxicological Information (0-22) 618 77 10,
The National Toxological Information Centre (0-42) 631 47 24
The person responsible for drawing up the product data sheet: katarzyna.motyka@cerkamed.pl
The date of drawing up the product data sheet 29.04.2016

2. Threat identification
The product is corrosive and may cause burns.

GHS Classification



NOTE

Threat:	GHS03, GHS05, GHS07 DANGER H314 Causes severe skin burns and eye damage H410 Very toxic to aquatic life with long-lasting effects.
Prevention:	P270 Do not eat, drink or smoke when using this product. P273 Avoid release to the environment. P280 Wear protective gloves/protective clothing/eye protection/face protection. P303+361+353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. P305+351+338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
Storage:	P405 Store locked up.

3. Composition/ingredients information

	Substance name	CAS No.	EC No.	H-statements	Concentration % (of mass)
1.	Trichloroacetic acid	76-03-9	200-927-2	H314. H410	>35

The full wording of H-statements and symbols can be found in Point 16 of this sheet.

4. First aid

General remarks:
Do not administer any substances orally to an unconscious person.
In the event of exposure through the respiratory system
Ensure the access of fresh air. Call a doctor.
In the event of eye contamination: Immediately rinse the eyes with a large amount of water for at least 15 minutes. Avoid strong jets of water, considering the risk of mechanical cornea damage. Consult a doctor if the irritation symptoms continue.
In the event of skin contamination: Take off contaminated clothing. Rinse the skin with a large amount of water. Consult a doctor in the case of skin irritation.
In the event of swallowing: Do not cause vomiting. Serve a lot of water. Call a doctor.

5. Measures to be taken in the case of fire

A non-flammable substance. In the case of fire, dangerous vapours or gases are released, including: HCl, CO, phosgene.
Adequate extinguishing agents: depending on the materials stored nearby.
Special protective equipment for fire-fighters: Do not stay in the fire compartment zone without the oxygen breathing apparatus and protective clothing. Put down the vapours by spraying water. Do not let the water for fire-fighting enter the surface water or groundwater.

6. Measures to be taken in the case of unintentional release to the environment

Individual precautions:
Avoid contact with eyes and skin. Ensure air exchange (ventilation).
Comply with the H&S regulations concerning chemical substances. Use personal protection equipment, as indicated in Point 8.

Precautions regarding environmental protection:
In the case of failure, avoid release to the environment. Secure the product against release to the sewage system, groundwater and soil.

Cleaning methods:
Use absorbents, e.g. sprinkle sand, collect the product carefully and place it in the appropriate, properly-marked waste container. Rinse the contaminated surface with water.

7. Product handling and storage

Product handling: Handle the product in line with the principles of good professional practice and comply with the H&S regulations. Do not eat, drink or smoke when using the product, avoid contact with eyes and skin, and use personal protection equipment (as specified in Point 8).

Protection against fire and explosion: A non-flammable product.

Storage: Store in sealed packaging, in a dry, cool and well-ventilated storage area.

8. Exposure control and personal protection equipment

Harmful substances and the maximum permissible concentrations that must be controlled:

Substance name	NDS	NDSCh
Trichloroacetic acid [CAS: 76-03-9]	2 mg/m^3	4 mg/m^3

Legal basis
Regulation of the Minister of Labour and Social Policy of 6 June 2014 on Maximum Permissible Concentration and Intensity of Agents Harmful to Health in the Working Environment

Concentration determination in workplace air
Not determined.

Biological monitoring:
Non-applicable

Respiratory system protection:
Respiratory system protection is not required provided that the product is properly handled.

Eye protection:
When using the product protective glasses or face protection, e.g. a protective dental visor model, must be used.

Skin protection:
When using the product, protective gloves and adequate protective clothing, e.g. an apron, must be used.

Other information:
When using the product, avoid eye and skin exposure, and do not eat, drink or smoke.

9. Physical and chemical properties

Physical form, colour, smell:	a straw-coloured liquid
Boiling point:	not determined
Melting point	not determined
Vapour pressure	not determined
Solubility in water	good
Density	1.18 g/ml
Flash point	not determined
pH	1
Decomposition point	not determined

10. Stability and reactivity

Stability:
Stable under normal application and storage conditions.

Materials and conditions to be avoided:
The product reacts exothermically with alkali, alkali hydroxides, amines, dimethyl sulfoxide, strong oxidants, sulfoxides and copper.

Dangerous decomposition products
Carbon oxides, phosgene, hydrogen chloride.

11. Toxicological information

Respiratory system:
Not determined.

Alimentary system:
Chronic toxicity
Trichloroacetic acid (CAS 76-03-9) LD50 (rats orally) 3 320 mg/kg
Swallowing can cause irritations of the oral mucosa, throat and oesophagus.

Skin contact:
The product can cause skin burns.

Eye contact:
Avoid contact with eyes. The product can cause eye burns.

Other information
None of the product ingredients has been classified as carcinogenic, mutagenic or having an adverse impact on fertility, in accordance with the Regulation of the Minister of Health of 3 August 2012 on Chemical Substances and Mixtures as well as Carcinogenic or Mutagenic Factors and Technological Processes in the Working Environment.

12. Ecological information

Ecotoxicity:
Harmful to aquatic life:
Trichloroacetic acid EC50 2000 mg/l/48 h (Daphnia magma). Avoid release to potable water intakes, soil and waste.

Bioaccumulation:
Do not expect considerable bioaccumulation.

Biodegradation:
Not easily biodegradable.
Biodegradability: 59%/20 days.

Other information:
Secure the product against release to groundwater and soil.

13. Waste handling

Used product
Avoid surface water and groundwater contamination. Do not discard together with municipal waste.
Used products should be handed in to an authorised waste collector. *(Journal of Laws 2013 item 888 of 13 June 2013)*
Waste code: 07 05 80* *(Regulation of the Minister of Environment of 9 December 2014 on Waste Catalogue).*

Packaging
Uncontaminated packaging should be handed in for recycling.
Contaminated packaging, once emptied and washed, should be handed in for recycling.
Waste code: 15 01 02 (*Act of 13 June 2013 on Packaging and Packaging Waste)*

14. Transport information

The product is not subject to regulations regarding transportation of dangerous materials.
Road transport (ADR/RID) – not classified
Sea transport (IMDG) – not classified
Air transport (ICAO/IATA) – not classified

15. Information on legal regulations

The product must be marked.

H314 Causes severe skin burns and eye damage.
H410 Very toxic to aquatic life with long-lasting effects.



NOTE

Other information:
The product is intended to be used only by the qualified medical staff, in the mode recommended by the manufacturer.

European Community regulations:
COMMISSION REGULATION (EU) No. 453/2010 of 20 May 2010 amending Regulation (EC) No. 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (EC) No. 1272/2008
of 16 December 2008 on Classification, Labelling and Packaging of Substances and Mixtures, Amending and Repealing Directive 67/548/ECC and 1999/45/EC and Amending Regulation (EC) No. 1907/2006

National regulations:
ACT of 25 February 2011 on Chemical Substances and Mixtures (Journal of Laws 2011 No. 63, item 322)

REGULATION OF THE MINISTER OF HEALTH of 20 April 2012 on Labelling of Packaging of Hazardous Substances and Mixtures as well as Some Preparations (Journal of Laws 2012 No. 0, item 445, as amended).

REGULATION OF THE MINISTER OF HEALTH of 24 July 2012 on Chemical Substances and

Mixtures, as well as Carcinogenic or Mutagenic Factors and Technological Processes in the Working Environment (Journal of Laws 2012 No. 0, item 890, as amended)

Regulation of the Minister of Labour and Social Policy of 6 June 2014 on Maximum Permissible Concentration and Intensity of Agents Harmful to Health in the Working Environment

Regulation of the Minister of Economy of 21 December 2005 Concerning Essential Requirements for Personal Protection Equipment (Journal of Laws No. 259, item 2173, 2005)

Government Statement of 26 March 2015 on Entry into Force of Amendments to Appendices A and B to the European Agreement on International Road Transport of Dangerous Waste (ADR) (Journal of Laws of 2015, item 882)

Regulation of the Minister of Health of 16 January 2003 on Preservatives, Sweeteners, Colours and Antioxidants that May Be Included in Medicinal Products

16. Other information

Explanation of symbols and statements used in Point 3:
H314 Causes severe skin burns and eye damage.
H410 Very toxic to aquatic life with long-lasting effects.

Other sources of basic data used for drawing up the data sheet:

- Data sheets provided by manufacturers of individual product ingredients
- EINECS 2005 database
- IUCLID Data Bank
- ESIS – The European Chemical Substances Information System

All the data are consistent with the current state of our knowledge. Information included in the data sheet is aimed at characterising the product in terms of safety requirements.

The user is in charge of ensuring adequate conditions for the safe use of the product and assumes responsibility for any consequences resulting from an improper use of this product.