Medical devices

Development of a new disinfection device using Pernitric acid solution

Principal **Investigator** Center for Atomic and Molecular Technologies, Graduate School of Engineering, Osaka University

Associate Professor Katsuhisa KITANO

Project Outline

Sterilization by Peroxynitric acid (PNA)



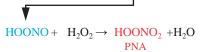
Name	Peroxynitric acid (PNA)	
Formula	HNO ₄ (HOONO ₂)	
CAS number	26404-66-0	

Sterilization method, preparation for sterilization, and device for producing bactericidal liquid Patented in Japan, US, UK, Germany, Italy, France, Spain

[1] S. Ikawa, A. Tani, Y. Nakashima, K. Kitano, Journal of Physics D: Applied Physics, 405401(2016).

Chemical synthesis

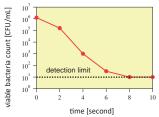
 $HNO_2 + H_2O_2 \rightarrow HOONO + H_2O$ peroxynitrite



[2] F. Raschig, Angewandte Chemie, 17, 1419 (1904).

Sterilization of spore

6.5mM PNA



D value (time to reduce the bacteria count by one digit) is 1.1 seconds, which is

Concentration of PNA

There is a need for disinfectants to be used at lower concentrations than can be harmful. Hydrogen peroxide at 3% is used as oxydol in disinfectants, but at concentrations on the order of 10% it can cause chemical burns, and at concentrations on the order of 90% there is a risk of explosion.

	PNA conc.	equivalent H ₂ O ₂	
		conc.	
undiluted solution	1,000 mM	10,000 %	
Medical device sterilization	~10 mM	100 %	
Disinfection	~2 mM	20 %	

For fungicides, the ratio of fungicidal power to toxicity is important.

Safety studies with animals

	Acute oral toxicity test	Skin irritation test	
animal	rat	rabbit	
guideline	OECD TG420	OECD TG404	
photo			

lization level of disinfection can be applied to living organism oblem with 100 mM PNA (1,000% H₂O₂

Material compatibility test

Endurance testing with various materials Sterilization, washing and drying process ~1000 times

No damage to SUS, O-rings, medical device parts, etc.

Comparison with other bactericides

using spore solution

	PNA 1M HOONO ₂	Oxydol 3% H ₂ O ₂	Antiformin 6% NaCIO	Peracetic acid 6% CH ₃ COO ₂ H
relative bactericidal activity	3300	1	9.6	400
cost [JPY/L]	1100	1200	28000	27000
cost [JPY/L/bactericidal activity]	0.33	1200	2900	68

PNA solution is odorless

Disinfection of a skin contamination model (pig skin)

Sterilization of vegetative cells (Staphylococcus aureus) was simple. Spray iet of PNA solution was applied to pig skin contaminated with spores (Bacillus subtilis).



The evaluation criteria for disinfectant efficacy are ~2LogR

he world's first successful sterilization of spores on skin contamination nodels to the detection limit using disinfectants at concentrations that

The world's first disinfectant, PNA has an excellent ratio of safety and disinfecting power, and can be applied to various fields from biological disinfection to medical equipment sterilization. The basic patent has been granted in Japan and overseas. Currently, we are building a consortium for research and development of PNA application (http://www.ppl.eng.osaka-u.ac.jp/pna/), in which several companies are participating, and we are looking for new companies to join us.