

## **Notice of Results of Human Coronavirus (OC43) Inactivation Performance Test by Humidification Using Ionless™ Hypochlorous Acid Water CL Fine®**

Nipro Corporation (Headquarters: Kita-ku, Osaka, Japan; President & Representative Director: Yoshihiko Sano; hereafter, “Nipro”) hereby announces that the test results demonstrated that the Ionless™ hypochlorous acid water CL Fine® (hereinafter CL Fine®) reduced the beta coronavirus (OC43),\* which is the same type as the novel coronavirus (SARS-CoV-2), to the detection limit (99.78%) when the space where the viruses were floating was humidified with CL Fine® so that the effective chlorine concentration was approximately 0.02 ppm.

As stated in the press release dated January 29, 2021,\* CL Fine® is slightly acidic electrolyzed water prepared by removing impurity ions from hypochlorous acid water (conforming to JIS B8701: 2017) using our unique electrolysis and purification technologies. In addition to the results of the reduction of coliphage MS2, a type of virus, and *Staphylococcus aureus*, a type of bacterium, which were revealed in the spatial spray test of CL Fine® conducted by a third-party organization, we have also confirmed the results of reduction of the novel coronavirus (SARS-CoV-2) by suspension test using CL Fine®.

We recently observed the environmental bacteria in the space of indoor swimming pools\* and found that there were fewer environmental bacteria compared to the general environment (Table 1). We also found that the effective spatial chlorine concentration of indoor swimming pools was 0.02 to 0.03 ppm (Table 2). Pool water is slightly alkaline (around pH8) and becomes weakly acidic (pH6 to 7) when spontaneously evaporated (Table 3). It can be inferred that this is the result of the spontaneous evaporation of sodium hypochlorite in water (1 ppm or less) with sodium ions remained in the water. Since the total amount of ions of CL Fine®, including sodium ions, is less than one tenth of the average amount of tap water, the total ion concentration when CL Fine® is humidified, is considered to be close to that of the aerial component of indoor swimming pools.

As a result of reproducing the effective spatial chlorine concentration of indoor swimming pools (0.02 to 0.03 ppm) in the general environment by humidifying the space using CL Fine®, we succeeded in creating a clean space by reducing the airborne bacteria / viruses and adhered bacteria / viruses (Figure 1).

- (1) When the chlorine concentration in the space was 0.02 ppm, human coronavirus (OC43) decreased by 99.78% or more in 60 minutes.
- (2) When the chlorine concentration in the space was 0.02 ppm, *Staphylococcus aureus* decreased by 99% or more in 60 minutes.
- (3) When the chlorine concentration in the space was 0.02 ppm, *Staphylococcus aureus* on and under the table decreased by 99% or more in 4 hours.

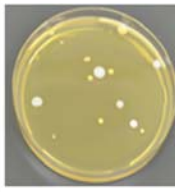

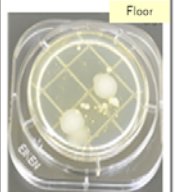
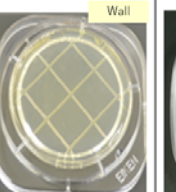
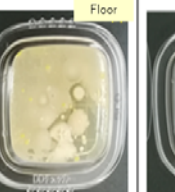

In addition, as announced in the press release dated January 29, 2021, a decrease in the novel coronavirus (SARS-CoV-2) and influenza virus type A (H1N1) was confirmed by suspension test using CL Fine<sup>®</sup> (Table 4).

Based on these results, we believe that CL Fine<sup>®</sup> can also be used as an infection control agent.

When using tap water for humidification, it is necessary to consider the risk of contamination by *Legionella* spp. and bacterial infectious diseases, and pay sufficient attention to daily water exchange and hygiene management in the humidifier. On the other hand, it has been confirmed that CL Fine<sup>®</sup> can disinfect *Legionella* spp. by 99.9% or more when the effective chlorine concentration is 1 ppm or more (Table 5). In addition, when using humidifiers that were not protected against bacterial growth, bacterial growth was observed in tap water even if they were replaced daily, but no bacterial growth was observed in CL Fine<sup>®</sup> even if they were not replaced (Table 6). This indicates that the risk of bacterial infections caused by *Legionella* spp. by humidifying the space using CL Fine<sup>®</sup> is extremely low.

Nipro will continue to conduct further studies and provide CL Fine<sup>®</sup> in order to help prevent the spread of various infectious diseases.

(Table 1) Environmental bacteria in general environments and indoor swimming pools

Measured Object	Colony count		Measured Object	Colony count			
	Indoor swimming pool	General environment		Indoor swimming pool		General environment	
Airborne bacteria			Airborne bacteria	Floor 	Wall 	Floor 	Wall 
	14	≥250		46	0	≥250	≥250

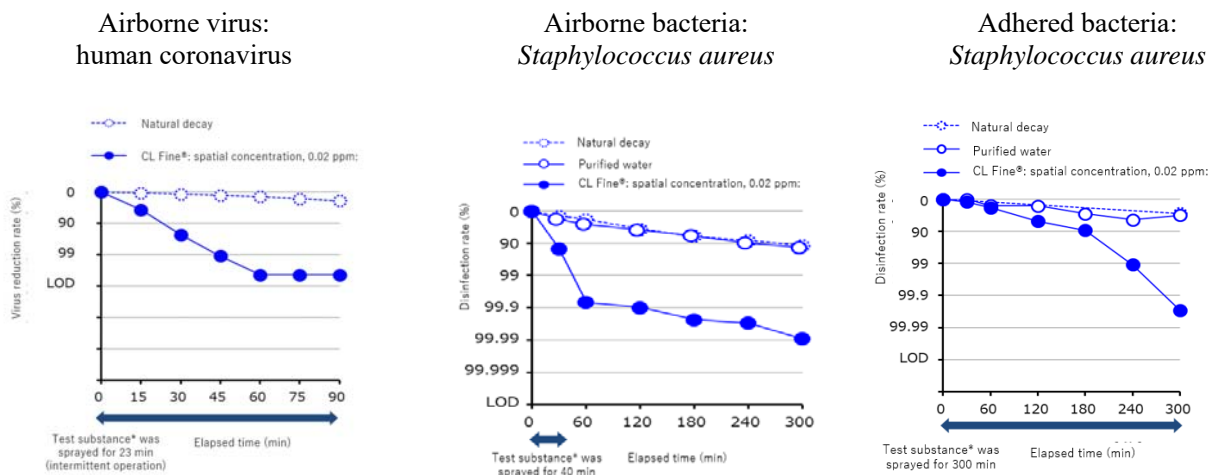
(Table 2) Effective spatial chlorine concentration of indoor swimming pools

Facility	Environmental conditions		Effective spatial chlorine concentration (ppm)	
	Water temperature	Room temperature	Theoretical value	Actual measurement value (n = 4, Mean ± SD)
Indoor swimming pools (3 facilities)	30°C	30 to 31°C	0.026 to 0.028	0.028 ± 0.004 to 0.030 ± 0.004

(Table 3) Comparison of pH between humidifier mist and spontaneous evaporation

Sample			pH value of collected sample	
Compound	Concentration	pH	Humidifier mist	Spontaneous evaporation
Indoor swimming pool water (2 facilities) (Sodium hypochlorite)	0.2 to 0.3 ppm	7.99 to 8.16	-	-
Hypochlorous acid	1 ppm	6.12	5.88 ± 0.02	6.03
Sodium hypochlorite	1 ppm	7.69	7.42 ± 0.05	6.01

(Figure 1) Inactivation test on *Staphylococcus aureus* and human coronavirus (HCoV-OC43) by humidification



LOD: limit of detection

\*: CL Fine® / purified water was sprayed into the space where bacteria / viruses are floating / adhering.

(Table 4) *In vitro* virus sterilization performance test

Bacteria / virus	Duration of action			
	20 seconds	1 minute	5 minutes	30 minutes
Novel coronavirus (SARS-CoV-2)	≥0.3 ppm	≥0.3 ppm	≥0.3 ppm	≥0.3 ppm
Influenza virus type A (H1N1)	≥1 ppm	≥0.3 ppm	≥0.3 ppm	≥0.3 ppm














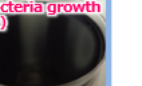
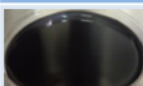

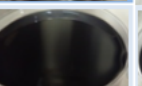


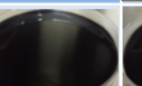
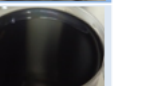


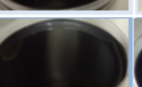

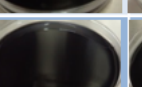
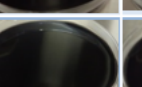
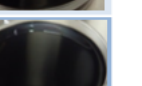
Hypochlorous acid (HOCl) concentration where reduction of 3 log or more viruses (= reduction rate: 99.9% or higher) was observed

(Table 5) Sterilization performance test against *Legionella* spp.

Test substance	Effective chlorine concentration	Disinfection rate of <i>Legionella</i> spp. (%)
CL Fine®	10 ppm	>99.9
	1 ppm	>99.9
	0.1 ppm	89.1
Tap water	(0.16 ppm)	3.8

Mixing ratio of the bacterial solution and test substance: 1:98, mixing time: 5 min

(Table 6) Bacterial growth in humidifiers

Group(Test solution)	Day1	Day2	Day3	Day4	Day5	Day6	Day7
<b>1. Tap water</b> without water exchange							
<b>2. Tap water</b> with water exchange							
<b>3. CLFine</b> without water exchange							
<b>4. CLFine</b> with water exchange							

Humidified for 7days (1 hour / day)

Sales of Ionless™ Hypochlorous Acid Water “CL Fine®”

Sales area: nationwide

Sales target: health institutions, nursing care facilities, pharmacies, etc.

Reference price (excluding tax): 20,000 yen (10 liters)

Category: Miscellaneous \*This product is not a medical product.

Ingredients: Hypochlorous acid (40 ± 10 ppm), sodium chloride (10 mg/L or less)

Nipro will continue to strive to develop and provide products that not only improve the quality of life (QOL) of patients but also are safer and meet the needs of society.

\*Human coronavirus (HCoV-OC43):

One of four common cold viruses (HCoV-229E, HCoV-OC43, HCoV-NL63, and HCoV-HKU1) that spread among humans.

\*Environmental bacteria:

Bacteria that live in the natural environment.

\*CL Fine® is a trademark of Nipro Corporation.