



VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



DECON-CLEAN®

**Residue Remover and Cleaner
Pharmaceutical Cleanroom Formula**

Product Description

DECON-CLEAN is designed for and processed to meet the standards required by pharmaceutical, biotechnology, healthcare, and lab animal research operations that demand a cleaning agent to remove residues left behind from disinfecting agents. **DECON-CLEAN** is an effective one-step residue remover when diluted at 1:128 (1 oz. per 1 gallon) of hard or soft water (400 ppm hard as CaCO₃). Due to **DECON-CLEAN**'s formulation it is an excellent cleaner designed for all washable, non-porous environmental surfaces. Using **DECON-CLEAN**, one can assure that noticeable and unnoticeable residues are removed, thus returning the surface to its original form. Residues left behind from disinfectants, sanitizers, and sporicidies, including Sodium Hypochlorite can be easily removed using **DECON-CLEAN**. Returning the surface to its original form assures that future decontamination will be able to penetrate to the surface.

DECON-CLEAN is filled in ISO 5 (Grade A/B, Former Class 100), filtered, and then subsequently terminally sterilized to 10⁻⁶ sterility assurance level. Each lot of **DECON-CLEAN** is sterility tested according to current USP Compendium, is completely traceable, and has been completely validated for sterility and shelf life. **DECON-CLEAN** is delivered each time with a lot specific Certificate of Analysis, Certificate of Sterility, and Certificate of Irradiation.

DECON-CLEAN is available in multiple container sizes including a 1 gallon, 16 oz trigger spray, unit dose, and a 200 L drum. **DECON-CLEAN** 1 gallon, 16 oz, and 200 L containers come in our one-step, ready-to-use SimpleMix® System that allows for exact and fresh formulations each and every time without handling the concentrate. Each sterile container of **DECON-CLEAN** is individually double bagged and packaged in two liner bags using the ABCD Cleanroom Introduction System®.

Please consult the end of this document for use to remove representative disinfecting agents.

Quality and Manufacturing

- Filled in an ISO 5 (Grade A/B, Former Class 100) operation
- Filtered
- Components are air washed with 0.2 micron filtered air before assembly
- Gamma irradiated at a 10⁻⁶ SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

DECON-CLEAN – Residue Remover and Cleaner	
Certificate of Analysis	Result
Appearance:	Clear free of suspended matter
Solubility in Water:	Completely
% Nonvolatile Matter:	$\leq 20.0\%$
pH of Concentrate:	9.0-11.0
Specific Gravity @20 degrees:	1.010-1.040
Expiration Period:	2 years

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Uses

DECON-CLEAN is designed for use in aseptic filling suites to controlled corridors and can be used for all washable, non-porous, environmental surfaces in order to return the surface to its original form after being disinfected. Examples include on aseptic connections, process lines, walls, floors, and ceilings, counter tops, and stainless steel items.

Features and Benefits

- Each sterile container is double bagged in easy tear bags
- Packaged quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with Certificate of Sterility, Certificate of Irradiation, and Certificate of Analysis
- Available in our convenient, one-step, ready-to-use, SimpleMix System
- Removes residues from sanitizers, disinfectants, and sporicidies
- Excellent cleaning characteristics
- Multiple convenient container sizes – unit dose, 16 oz, 1 gallon, 200 L
- Available in either sterile or non-sterile



ABCD Cleanroom Introduction System®

The ABCD Cleanroom Introduction System is a packaging system that allows operators/users to take the package through each level of classified areas by simply removing one bag at a time. Each bag acts as barrier protecting the finished product from becoming a carrier of viable and non-viable contamination. This prevents the need to decontaminate each outer bag prior to entering a cleaner area. In this packaging system, sterilized groups of containers are contained in two outer bags and after each are removed individual containers are each additionally contained in two easy tear bags.

The SimpleMix® System Technology Alternative

Veltek Associates, Inc. has developed the patented SimpleMix System Technology to eliminate measuring and additional containers. It provides for the transfer of the sterile concentrated disinfectant or sporicide and sterile water in a sealed container to the aseptic area. The system container is double bag packaged for easy transfer and eliminates all internal and external sterility concerns. The patented SimpleMix System Gallon, 16 oz, and 200 L systems provide a sealed multi-chamber container that when activated mixes the solution to the correct use dilution. The opening on the top of the gallon size contains the concentrate and the bottom reservoir contains the VAI WFI Quality Water. The 16 oz side container houses the concentrate and the bottom reservoir houses the VAI WFI Quality Water. Just open the small chamber cap, push the plunger container completely down until the bottom pops open and the bellows are compressed. 200 L SimpleMix systems are activated through a hose and valve system connecting the cubicontainer of concentrate to the VAI WFI Quality Water. The solution and water mix together. The system design permits the easy transfer of the product to the aseptic manufacturing area without concern for the transfer of contamination.

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Ordering Information

DECON-CLEAN – Residue Remover and Cleaner		
Part number	Description	Qty/cs
DC-01	DECON-CLEAN, 1 Gallon, Concentrate, Non-Sterile	4
DC-02	DECON-CLEAN, 1 Gallon, Concentrate, Sterile	4
DC-03-4Z	DECON-CLEAN, 4 oz ,Unit Dose, Sterile	24
DCWFI-SP-11Z	DECON-CLEAN, 11 oz, Aerosol Spray Mist, Sterile	24
DC-06-16Z-01	DECON-CLEAN, 16 oz SimpleMix, Attached Trigger, Sterile	12
DC-07-16Z-01	DECON-CLEAN, 16 oz SimpleMix, Attached Trigger, Non-Sterile	12
DC-04-1Z	DECON-CLEAN, 1 Gallon SimpleMix, Sterile	4
DC-05-1Z	DECON-CLEAN, 1 Gallon SimpleMix, Non-Sterile	4
DC-100-200L-CI	DECON-CLEAN, 200L, SimpleMix Drum, Sterile	1



DC-01



DC-03-4Z



DC-06-16Z-01

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VAI's Product Label Colors

Product Name	Bottle/Can Color	Label Background Color	Bar & User Info Color	Text Color
DECON-AHOL WFI FORMULA 70% AEROSOL	COOL GREY	PRINTED CAN COOL GREY		
DECON-AHOL WFI FORMULA 70% TRIGGER SPRAY, 1 & 5 GALLON	WHITE	COOL GREY		
DECON-AHOL WFI FORMULA 70% SQUEEZE BOTTLE	WHITE SEMI-TRANSPARENT	COOL GREY		
DECON-AHOL WFI FORMULA 70% ASEPTI-CLEANSE BOTTLE	WHITE SEMI-TRANSPARENT	COOL GREY		
DECON-AHOL WFI FORMULA 60%	WHITE	WHITE		
DECON-AHOL WFI FORMULA 91%	WHITE	WHITE		
DECON-AHOL FORMULA 99%	WHITE	WHITE		
STER-AHOL WFI AEROSOL	WHITE	PRINTED CAN WHITE		
STER-AHOL WFI TRIGGER SPRAY, 1 & 5 GALLON	WHITE	WHITE		
DECON-HAND STERILE	WHITE SEMI-TRANSPARENT	PRINTED BOTTLE		
DECON-HAND NON-STERILE	CLEAR	PRINTED BOTTLE		
DECON-HAND ASEPTI-CLEANSE BOTTLE	WHITE SEMI-TRANSPARENT	WHITE		
STERI-OIL	WHITE	WHITE		
STERI-BUFFER	CLEAR	WHITE		
DECON-PHENE	WHITE	WHITE		
DECON-CYCLE	WHITE	WHITE		
DECON-CLEAN	WHITE	WHITE		
DECON-QUAT 100	WHITE	WHITE		
DECON-QUAT 200C	WHITE	WHITE		
DECON-QUAT 200V	WHITE	WHITE		
HYPO-CHLOR 0.25%	WHITE	WHITE		
HYPO-CHLOR 0.52%	WHITE	WHITE		
HYPO-CHLOR 5.25%	WHITE	WHITE		
STERI-PEROX 3%	WHITE	WHITE		
STERI-PEROX 6%	WHITE	WHITE		
DECON-SPORE 200 PLUS (SPORICIDE)	WHITE SEMI-TRANSPARENT	WHITE		
DECON-SPORE 200 PLUS (DISINFECTANT)	WHITE SEMI-TRANSPARENT	WHITE		
STEEL-BRIGHT	WHITE	WHITE		
STERI-SILICON	WHITE	BLACK		
DECON-GLASS	WHITE	WHITE		
VAI WFI QUALITY WATER	WHITE	WHITE		
STERI-WATER	WHITE	WHITE		

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PRODUCT LABELING

DECON-CLEAN® Residue Remover and Cleaner Pharmaceutical Cleanroom Formula

(Any specific product label is available upon request.)



DECON-CLEAN Family of Products

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DECON-CLEAN® Residue Remover and Cleaner Pharmaceutical Cleanroom Formula

Active Ingredients:

Water	87.5%
Potassium Tall Oil Soap.....	7.5%
Alcohols, C9-11, ethoxylated.....	3.0%
*Other ingredients	2.0%
Total.....	100.0%

(*elemental phosphate less than 0.2% by weight of concentrate before use dilution)

Container and Product Sterilized and Distributed by:
Veltek Associates, Inc.
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610-644-8335

Residue Remove
Fragrance Free

WARNING. Causes eye irritation

PRECAUTIONARY STATEMENTS

Do not get in eyes, on skin, or on clothing. Wash hands, forearms and face thoroughly after handling. If swallowed: Call a doctor if you feel unwell. Store in a closed container. Dispose of contents/container to an authorized waste collection point.

FIRST AID

EYES: Rinse immediately with plenty of water for 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center or doctor/physician.

SKIN: Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. If irritation persists, consult a doctor.

INGESTION: Rinse mouth. Drink plenty of water. DO NOT induce vomiting. Immediately call a poison center or doctor/physician.

INHILATION: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.

Emergency Response: 1-866-928-0789 (toll free USA), 1-800-579-7451 (toll free Canada), 1-215-207-0061 (Americas).

SDS No: DC-01-98
For Industrial Use Only

RECOMMENDATIONS FOR USE - Concentrate

Mix 1 ounce of **DECON-CLEAN** with 1 gallon of water (1:128) or mix all 4 ounces with 4 gallons of water. Apply product generously to wet entire surface and use mechanical action to loosen residue. Squeegee off, wipe dry or rinse with clean water and dry.

DIRECTIONS FOR USE - SimpleMix

Prepare use solution by following SimpleMix System Container Instructions:

Trigger Spray Bottle:

1. To prepare use solution, open cap.
2. Peel off inner seal by grasping tab at far edge and pulling off.
3. Firmly push small, inner container completely down.
4. Replace cap and tighten.
5. Slowly swirl for 15 seconds.
6. Move spray nozzle to open position.

Gallon Size Bottle:

1. To prepare use solution, open cap.
2. Peel off inner seal by grasping far edge and pulling off.
3. Firmly push small, inner container completely down.
4. Replace cap and tighten.
5. Slowly swirl for 15 seconds.
6. Open small side spout and peel off inner seal, as above.
7. Pour solution from small side spout onto surfaces to be treated or alternate containers.

200 Liter Drum:

(note: To be used with a Veltek Associates, Inc. pump)

1. Close all valves.
2. Uncoil hoses.
3. Connect center hose to pump between X and Y.
4. Open valve 1, then valve 2, then valve 4.
5. START pump to empty cubic container.
6. When cubic container is empty, turn pump OFF.
7. Close valve 1 and valve 2.
8. Open valve 6 and valve 5.
9. Re-start pump and mix 15 minutes
10. STOP pump.
11. Close valve 4.
12. To dispense – Open valves 3 and 7. Run pump only when dispensing.

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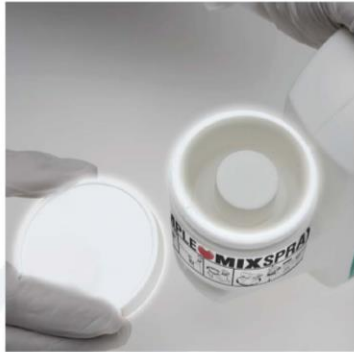
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SIMPLEMIX® 16 oz/473 mL Aseptic Mixing System
For the Exact Formulation of 16 oz/473 mL Disinfectants and Sporicides
Ready-to-Use Mixing Instructions

- 1) To prepare use solution, open cap.
2) Peel off inner seal by grasping tab at far edge and pulling off.



- 3) Firmly push small, inner container all the way down.



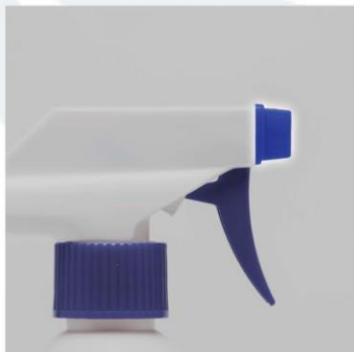
- 4) Replace cap and tighten.



- 5) Slowly swirl for 15 seconds.



- 6) Move spray nozzle to open position.



- 7) Follow directions for use on label.



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SIMPLEMIX® 1 Gallon/3.79 L Aseptic Mixing System
For the Exact Formulation of 1 Gallon/3.79 L Size Disinfectants and Sporicides
Ready-to-Use Mixing Instructions

1) To prepare use solution, open cap.
2) Peel off inner seal by grasping tab at far edge and pulling off.



3) Firmly push small, inner container all the way down.



4) Replace cap and tighten.



5) Slowly swirl for 15 seconds.



6) Open small side spout and peel off inner seal, as above.



7) Pour solution from small side spout onto surfaces to be treated or alternate containers.



8) Follow directions for use on label.

Veltek Associates, Inc.

SIMPLEMIX® 200 L Aseptic Mixing System
 For Large Scale Aseptic Manufacturing Environments
Ready-to-Use Mixing Instructions

Remove drum from double-bag packaging.



Remove cubic container from top of drum. 1) Close all valves. 2) Uncoil hoses.



3) Connect center hose to pump between X and Y.



4) Open valve 1, then valve 2, then valve 4.



5) START pump to empty cubic container. 6) When cubic container is empty, turn pump OFF.



7) Close valve 1 and valve 2.



8) Open valve 6 and valve 5.



9) Re-start pump and mix 15 minutes. 10) Stop pump.



11) Close valve 4. 12) To dispense- Open valves 3 and 7. Run pump only when dispensing.



13) Follow directions for use on label.

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Testing Summary

DECON-CLEAN

Residue Remover and Cleaner for Hard Surfaces
Sterile Pharmaceutical Clean Room Formula

Surface Evaluation for Determining the Residual Levels of VAI Sterile Chemicals and Disinfectants

Discussion and Purpose of Testing

The aim of this study was to evaluate the cleaning efficiency of the new environmentally friendly and biodegradable **DECON-CLEAN** formula. In accordance with recent EPA regulations (Significant New Use Rule, 25 Sep 2014) the **DECON-CLEAN** formula was updated and the alkyphenol based detergent was replaced with environmentally friendly ethoxylated alcohol surfactant.

Chemical residues can be quantified and appropriate operating procedures can be developed to reduce their existence on surfaces. VAI developed **DECON-CLEAN** residue remover to assure the removal of existing chemical residues. By removing these residues, a class 100 aseptic facility is less likely to transfer existing residues from their initial location to critical manufacturing sites.

Particulate Impurities

Particulate impurities can cause contamination problems and may provide a nutrient source for existing organisms in the aseptic manufacturing area. Particulate impurities can be removed from solution by filtration. All VAI sterile chemicals and disinfectants receive a level of filtration.

Chemical Ingredient Residues

Chemical ingredient residues pose a complicated problem associated with both buildup and cross-contamination. The removal of such residues should be considered as a standard practice to eliminate the possibility of these concerns.

DECON-CLEAN as a Residue Remover

DECON-CLEAN has been developed to cope with the removal of residues within the ISO 5 (Grade A/Class 100) aseptic manufacturing operation. The patented formula assures the breakdown of VAI's **DECON-AHOL®**, **STER-AHOL®**, **DECON-PHENE®**, **DECON-CYCLE®**, **DECON-QUAT 100®**, **HYPO-CHLOR®**, **STERI-PEROX®**, **DECON-QUAT 200**, **Cage2Wash®**, **Process2Clean®** and **DECON-SPORE 200® Plus** products. Once broken down, these residues or remnants of chemicals may be mopped, sponged, wiped or rinsed free from the surface.

DECON-CLEAN's Effectiveness Test Procedure:

DECON-CLEAN was tested against the following chemicals for effectiveness of residue removal and was found extremely effective in the control of residual levels.

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DECON-AHOL® (70% and 91% RTU)
 DECON-PHENE® (1:128 Use Dilution)
 DECON-CYCLE® (1:256 Use Dilution)
 HYPO-CHLOR® (5.25%, 0.52%, and 0.25%)

STER-AHOL® (70% RTU)
 DECON-SPORE® 200 Plus (5%)
 DECON-QUAT® 100 (2:128 Use Dilution)
 STERI-PEROX® (3% and 6%)

Test Procedure

1. Residue and residue removal were determined gravimetrically.
2. Stainless steel coupons (316L) were used as the test surface.
3. Testing was conducted in a Class 100 laminar flow hood.
4. All appropriate safety precautions were taken. All safety precautions are to be taken referencing safety. This includes gowning, gloves and a NIOSH approved chemical mask.
5. 5 ml of each chemical was prepared and applied to separate stainless steel coupons.
6. The chemicals were permitted to air dry.
7. The chemical residue was determined gravimetrically.
8. Cleaning was performed with **DECON-CLEAN** by two separate methods; spray rinse only and mechanical cleaning.
9. Residue after cleaning was determined gravimetrically.

Chemical Residue after Drying

Chemical Tested	Results
DECON-AHOL® 70% (RTU)	ppm of isopropyl alcohol = 0 ppm*
DECON-AHOL 91% (RTU)	ppm of isopropyl alcohol = 0 ppm*
STER-AHOL® 70% (RTU)	ppm of ethanol = 0 ppm*
DECON-PHENE® II (1:128 Use Dilution)	ppm of Phenols and Chlorophenols = 2 ppm
DECON-CYCLE® II (1:256 Use Dilution)	ppm of Phenols and Chlorophenols = 3 ppm
DECON-QUAT® 100 (2:128 Use Dilution)	ppm of Ammonium Chloride = 3 ppm
HYPO-CHLOR® 5.25%	ppm of Sodium Chloride = 252 ppm
HYPO-CHLOR 0.52%	ppm of Sodium Chloride = 30 ppm
HYPO-CHLOR 0.25%	ppm of Sodium Chloride = 18 ppm
STERI-PEROX® 3%	ppm Hydrogen Peroxide = 1 ppm*
STERI-PEROX 6%	ppm Hydrogen Peroxide = 1 ppm*
DECON-SPORE® 200 Plus (5%)	ppm Peroxyacetic acid = 3 ppm

* No residue detectable gravimetrically

Testing Residue Removal Ability of DECON-CLEAN as a SPRAY RINSE ONLY

After the chemical residue was established on the surface, the surface was cleaned with a RINSE ONLY of **DECON-CLEAN** at a use dilution of 1:128.

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Chemical Tested	Results
DECON-AHOL® 70% (RTU)	ppm of isopropyl alcohol = 0 ppm
DECON-AHOL 91% (RTU)	ppm of isopropyl alcohol = 0 ppm
STER-AHOL® 70% (RTU)	ppm of ethanol = 0 ppm**
DECON-PHENE® II (1:128 Use Dilution)	ppm of Phenols and Chlorophenols = 0 ppm
DECON-CYCLE® II (1:256 Use Dilution)	ppm of Phenols and Chlorophenols = 0 ppm
DECON-QUAT® 100 (2:128 Use Dilution)	ppm of Ammonium Chloride = 0 ppm
HYPO-CHLOR® 5.25%	ppm of Sodium Chloride = 1 ppm
HYPO-CHLOR 0.52%	ppm of Sodium Chloride = 0 ppm
HYPO-CHLOR 0.25%	ppm of Sodium Chloride = 0 ppm
STERI-PEROX® 3%	ppm Hydrogen Peroxide = 0 ppm**
STERI-PEROX 6%	ppm Hydrogen Peroxide = 0 ppm**
DECON-SPORE® 200 Plus (5%)	ppm Peroxyacetic acid = 0 ppm

* Visual residue spots, not detectable gravimetrically

Testing Residue Removal Ability of DECON-CLEAN USING MECHANICAL CLEANING

After the chemical residue was established on the surface, the surface was cleaned with a **DECON-CLEAN** application at a use dilution of 1:128 and using a VEL8-12X12 Dry Wiper with a circular mechanical cleaning action.

Chemical Tested	Results
DECON-AHOL® 70% (RTU)	ppm of isopropyl alcohol = 0 ppm
DECON-AHOL 91% (RTU)	ppm of isopropyl alcohol = 0 ppm
STER-AHOL® 70% (RTU)	ppm of ethanol = 0 ppm**
DECON-PHENE® II (1:128 Use Dilution)	ppm of Phenols and Chlorophenols = 0 ppm
DECON-CYCLE® II (1:256 Use Dilution)	ppm of Phenols and Chlorophenols = 0 ppm
DECON-QUAT® 100 (2:128 Use Dilution)	ppm of Ammonium Chloride = 0 ppm
HYPO-CHLOR® 5.25%	ppm of Sodium Chloride = 0 ppm
HYPO-CHLOR 0.52%	ppm of Sodium Chloride = 0 ppm
HYPO-CHLOR 0.25%	ppm of Sodium Chloride = 0 ppm
STERI-PEROX® 3%	ppm Hydrogen Peroxide = 0 ppm**
STERI-PEROX 6%	ppm Hydrogen Peroxide = 0 ppm**
DECON-SPORE® 200 Plus (5%)	ppm Peroxyacetic acid = 0 ppm*

* No visual residue spots

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Conclusion

It is concluded from the testing performed that the use of **DECON-CLEAN** is extremely effective as a chemical residue remover. Furthermore, the incorporation of mechanical cleaning further reduces the levels of residues as well as any visual, but gravimetrically undetectable, residue spots.

Written By: Boris Polanuyer Date: 05Oct2015

Approved By: Kelly Rocco Date: 05Oct2015

Additional Documentation

Upon request, the following additional documentation is available:

- Specific product testing reports
- Safety Data Sheets SDS# DC-01-98
- Product validation
- In-use validation
- Sample lot specific documentation packages including Certificate of Sterility, Certificate of Irradiation, Certificate of Analysis



VAI's Sterile Chemical Manufacturing Division - SCMD manufactures a complete range of cleaning agents and disinfectants that are used daily in cleanroom operations. Overall, VAI's capabilities for manufacturing products include the ability to fill aerosol, bulk, and unitdose packages in ISO 5 (Grade A/B).

Our aseptic filling operations are coupled with the validated and proven ability to irradiate a final product. Assurances are taken in every aspect of SCMD concerning sterility and particulate removal. VAI's operations mirror current GMP's and enforces the adherence to USP specifications. VAI is an EPA and FDA registered facility. To learn more about our division capabilities please visit www.sterile.com.

Patents: www.sterile.com/patents

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