



Manufacturing Forward

AIR FILTRATION SOLUTIONS FOR PHARMACEUTICAL INDUSTRY

www.mikropor.com


mikropor

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Mikropor began its journey in 1987 with a passion to create “Tomorrow’s Technology” and has become one of the leading manufacturers of atmospheric air filtration solutions and compressed air treatment systems for a variety of industries.

By closely following the latest developments in technology, Mikropor’s “Best in Class” products and solutions are appreciated by customers in more than 140 countries.

The company’s sustainable growth has been provided by its passion for innovation and commitment to quality, as well as its dedication to technology. Mikropor is an environmentally conscious company that values people, while developing products that extend the needs and expectations of customers.

With this mission, Mikropor continues to become one of the most recognized brands in the world by expanding its global penetration in the field of technological filtration and contributes to a healthier planet.

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LEADER IN AIR FILTRATION SOLUTIONS

Choosing the right filter for a pharmaceutical application is extremely critical. From the AHU (Air Handling Unit) to the final output, the filtration system plays a crucial role in keeping pharmaceutical grade air free from airborne contaminants, bacteria, viruses and hazardous gases.

Mikropor offers a wide variety of solutions including high efficient EPA, HEPA & ULPA filters and leakage free hood and box variations. Mikropor guarantees the performance and impermeability (leakproof) by using the EN 1822 test standard. Each of the HEPA filters are individually scan tested before packaging. All EPA, HEPA & ULPA class filters are delivered with test certificates.

Mikropor is a global leader in air filtration solutions for the pharmaceutical & life science industry and works closely with several of the largest pharma manufacturers worldwide.





Indoor Air Quality plays a significant role in the protection of personal health. Healthcare facilities pay particular attention to reduced particle counts and the elimination of bacteria and airborne molecular contaminants. Mikropor provides a wide array of filter options to meet the critical needs of all areas of concern related to HVAC Systems in healthcare institutions.

Industries requiring pure, clean air;

- Pharmaceutical Industry
- Biotechnology
- Hospitals
- Food & Beverage
- Nanotechnology

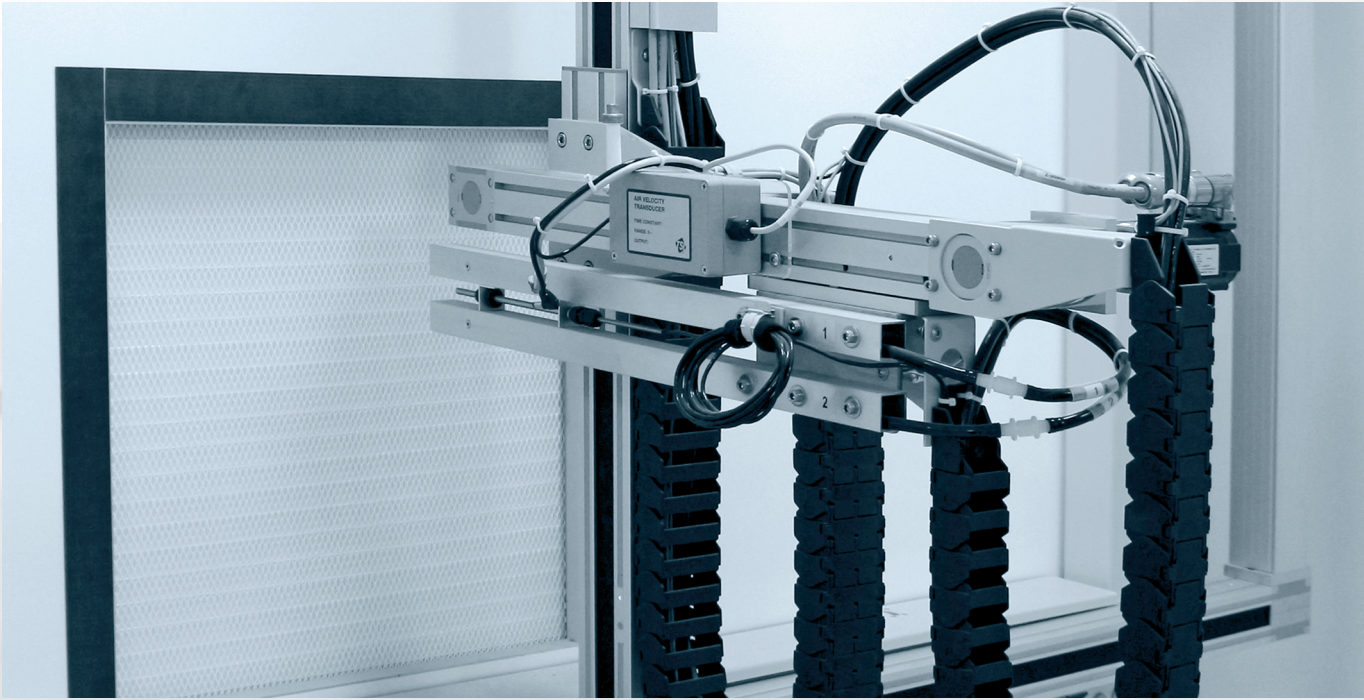


FILTER CLASSIFICATION: EN 1822

Contaminants in air differ in size and affect different areas in a pharmaceutical process so classification of filters take a critical role. EPA, HEPA and ULPA filters are the main filter types for classification according to EN 1822 for filtration efficiency in Europe. HEPA and ULPA filters are also subject to individual tests. The international standard ISO 29463 is based on European standard EN 1822 and will probably replace this standard in the future. Both standards are based on the latest particle counting methods. The EN 1822 Standard involves efficient, high-efficient and ultra-low permeability air filters (EPA, HEPA, ULPA) used in ventilating and air-conditioning, cleanroom technologies or applications in nuclear and pharmaceutical industries. Their classification is based on the measuring of the size of particles (MPPS) passing to the clean side at a specific air speed.

FILTER CLASSIFICATION	EFFICIENCY (%) @MPPS		PENETRATION (%) @MPPS	
	Overall Value	Local Value	Overall Penetration	Local Penetration
EN 1822				
E10	85	-	15	-
E11	95	-	5	-
E12	99.50	-	0.5	-
H13	99.95	99.75	0.05	0.25
H14	99.995	99.975	0.005	0.025
U15	99.9995	99.9975	0.0005	0.0025
U16	99.99995	99.99975	0.00005	0.00025
U17	99.999995	99.9999	0.000005	0.0001

EN 1822 reports must show average and local efficiency at the stated flow rate, initial pressure drop and class of the filter.



CLEANROOM CLASSIFICATION: ISO 14644

Reduction of microbial contamination is vital in the design of a cleanroom. Mikropor follows ISO 14644, US 209E and EU GMP Directive 2017/1572 for classification and monitoring of cleanrooms where the contamination and particles need to be controlled.

A lower classification number means a higher level of cleanliness.

STANDARDS			PARTICLE COUNT			
US 209E 1992	ISO 14644 1996	BS 5295 1989	0,1 micron (per m ³)	0,3 micron (per m ³)	0,5 micron (per m ³)	0,5 micron (per ft ³)
-	SINIF 1	-	10	-	-	-
-	SINIF 2	-	100	10	-	-
1	SINIF 3	C	1000	102	35	1
10	SINIF 4	D	10000	1020	353	10
100	SINIF 5	E/F	100000	10200	3530	100
1000	SINIF 6	G/H	1000000	102000	35300	1000
10000	SINIF 7	J	-	-	353000	10000
100000	SINIF 8	K	-	-	3530000	100000

CLEANROOM STANDARD		MAXIMUM PERMITTED NUMBER OF PARTICLES /M ³				EXAMPLES OF OPERATIONS FOR TERMINALLY STERILISED PRODUCTS	EXAMPLES OF OPERATIONS FOR ASEPTIC PREPARATIONS
EU GMP Grade	ISO EN 14644-1	At Rest ≥0.5µm	At Rest ≥5.0µm	In Operation ≥0.5µm	In Operation ≥5.0µm		
A	5	3.520	20	3.520	20	Filling products, when unusually at risk	Aseptic preparation and filling
B	5	3.520	29	352.000	2.900		
C	7	352.000	2.900	3.520.000	29.000	Preparation of solutions, when unusually at risk. Filling of products	Preparation of solutions to be filtered
D	8	3.520.000	29.000	Not defined	Not defined	Preparation of solutions and components for subsequent filling	Handling of components after washing

A FILTER YOU CAN TRUST

Air Quality is critical in injectable and infusion production zones: these areas must remain free of contaminants. A leak free EPA, HEPA or ULPA filter of high efficiency plays an important role in fulfilling the hygienic requirements and help optimize the differential pressure between zones.

How can you check a high quality manufactured HEPA filter before installation and during operation?

KURULUM


- Doğru ve sağlam paketlenme
- İzlenebilirlik açısından bir seri numarasının bulunduğu uygun bir etiket
- Her filtre için EN1822-4 standardına uygun bir test raporu
- Mevcut HEPA kutusu için uygun conta veya tavan detayı
- Filtre materyalinde, çerçevesinde veya contasında herhangi bir görsel hasar olmaması

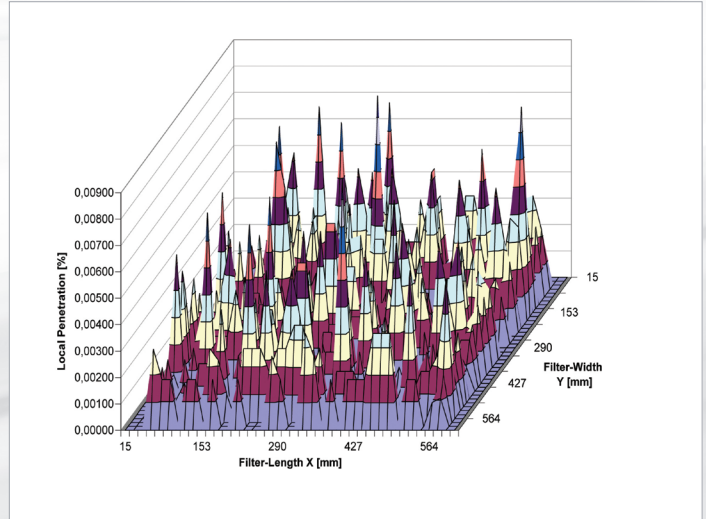
OPERASYON

- Başarılı filtre tarama testi ve bütünlük sonucu
- Başlangıç basınç düşümünün talep edilen spesifikasyonlar ile uyuşması

PERFORMANS

- Zamandan bağımsız tutarlı partikül verimliliği sağlanması
- Zamandan bağımsız filtre materyali ve contanın sızdırmazlık performansının devamlılığı

TOPAS 				Rücksetzen / Reset / RAZ			
Prüfbericht nach EN 1822-4							
Test report according to EN 1822-4							
Rapport de test selon EN1822-4							
Filterdaten / Filter data / Filtre techniques							
Besuchennummer Production lot Numero de production		Filtrenummer Filter no. Numero de filtre		Mediencharge Medium lot no. Numero de lot du medium		Prüfdatum Date of test Date du test	
HFN-610/61070-13PD				1259		2009-02-25	
						op	
Filtrabmessung (B x L x T) Filter dimensions (W x L x D) Dimensions du filtre (L x l x P)				Nennvolumenstrom Nominal flow rate Débit d'air nominal		Anfangsdruckdifferenz Initial pressure drop Perte de charge initiale	
610 x 610 x 70mm				800		Filtrklasse Filter class Classe de filtration	
Minimale integrale Abschnegegrad Minimum integral efficiency Minimum efficacité intégrale				Minimale lokale Abschnegegrad Minimum local efficiency Minimum efficacité locale		HEPA H13	
						MPPS	
99.95000%				99.75000%		0.20µm	
Prüfbedingungen / Test Conditions / Conditions de test							
Prüfstromstrom Test flow rate Débit de test		Prüfmedium Test aerosol Aérosol de test		Partikelgröße Particle size Taille de particule		Luftgaskonzentration Loadstream concentration Concentration amount	
799.8m³/h		DEHS		0.10 - 0.50µm		Temperatur Temperature Température	
						8.02E+2#/cm³	
						16.1°C	
						37.9%	
Prüfergebnisse / Test Results / Résultats de test							
Integrierte Abschnegegrad Integral efficiency Valeur intégrale d'efficacité		Minimale Abschnegegrad Minimum efficiency Minimum valeur d'efficacité		Druckdifferenz Pressure drop Perte de charge		Klassifizierung gemäß Testergebnis Classification to test result Classification selon résultat de test	
99.99870%		99.99865%		196Pa		HEPA H13	
Anzahl der gefundenen Leckstellen Number of leaks detected Nombre de fuites détectées		Lecktest gemäß EN1822-4 Leakage test to EN 1822-4 Test de fuite selon EN 1822-4					
0		bestanden / passed / accepté					
Lecksignal / Leak signal / Signal du fuite:				171			
Signalabstand / Signal difference / Signal difference:				99			



BEST HEPA FILTERS ALSO NEED GOOD PRE-FILTRATION

Correct combination of filtration stages reduces overall air flow resistance and keeps pressure drops lower for longer. This reduces the energy consumption of fans and leads to a more energy efficient system.

Typically, three stage filtration: a G4 panel filter, an M class 2nd stage and a fine filter is used as pre filtration of a high efficient HEPA filter. A rigid type MPR pocket filter can be used as a pre filter instead of a G4 panel and an M class filter combination. MPR filters offer optimum combination of high dust holding capacity, coarse & fine dust arrestance, low pressure drop and long life time. Mikropor recommends MPG or MVEE type fine filters for pharmaceutical applications in order to make additional energy savings.



With its energy efficient filters, Mikropor protects your health and the environment while allowing you to save money.

MICAM

With customer demands and long-term cost reductions in mind, **MIKROPOR CLEAN AIR MANAGEMENT (MICAM)**, the total filter management system focused on long term cost reduction, filter life cycle optimization and improved air quality, was created.

MICAM STEPS

FULL SITE AUDIT



REPORTING & OPTIMIZATION



ON SITE TECHNICIAN



MIKROPOR SOLUTIONS

With more than 20 years of Global Filtration experience as a World Class Manufacturer utilizing state of the art technologies and equipment, Mikropor understands its customers' demands and thus is the preferred partner of pharmaceutical manufacturers worldwide.

MSKPN SERIES

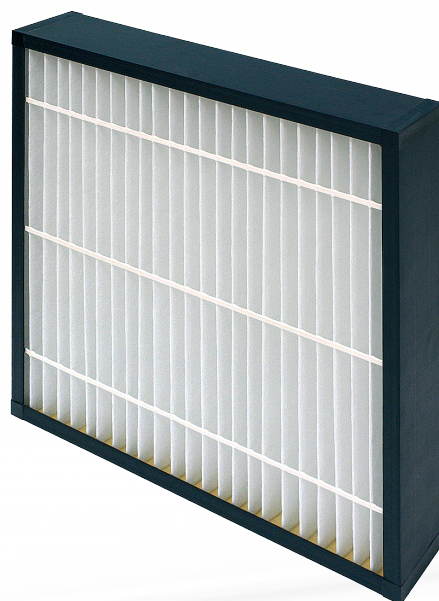
Media	Synthetic
Frame	Plastic (ABS), Galvanized Steel, Stainless Steel
Final Pressure Drop	250 Pa
Operating Temperature	80°C
Filter Efficiency*	G4
Filter Class**	ISO Coarse
Sealant	Polyurethane
Separators	Thermoplastic Adhesive
Gasket	Optional

Applications

- Primary filtration

Advantages

- Tidy pleat spacing
- Light and rigid filter
- Leakage free



MPG SERIES

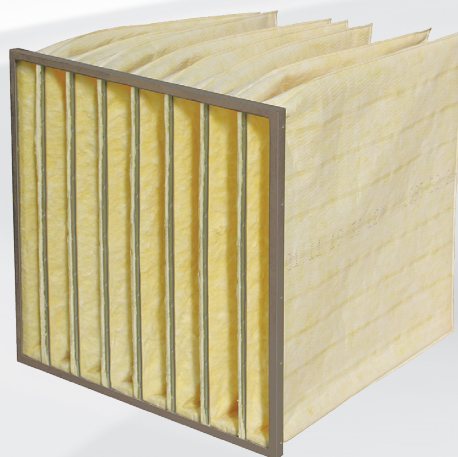
Media	Glassfiber
Frame	Galvanized Steel
Final Pressure Drop	450 Pa
Operating Temperature	80°C
Filter Efficiency*	M5-M6-F7-F8
Filter Class**	ISO ePM10 / ISO ePM1
Media Color	M5: White / M6: Green / F7: Pink F8: Yellow
Fiber Assembly Type	Sewn

Applications

- HVAC
- Pre-filter of absolute filters

Advantages

- Low initial pressure drop
- Low energy use



* According to EN 779:2012 ** According to ISO 16890

MPR SERIES

Media	Synthetic
Frame	Molded Plastic Frame
Final Pressure Drop	450 Pa
Operating Temperature	80°C
Filter Efficiency*	G4-M5-M6
Filter Class**	ISO Coarse - ISO ePM10

Applications

- Automotive industry
- Gas turbine air intake systems
- General ventilation and air conditioning for office buildings, industrial environments, food processing facilities and laboratories

Advantages

- High dust holding capacity
- Low initial pressure drop
- Rigid self-supporting pocket filter
- Incinerable



MVEE SERIES

Media	Microglass Fiber
Frame	PS
Final Pressure Drop	450 Pa
Operating Temperature	80°C
Filter Efficiency*	F7-F8-F9
Filter Class**	ISO ePM1
Gasket	Optional
Sealant	Polyurethane
Separators	Hot Melt
Header Thickness	20 mm, 25 mm

Applications

- HVAC
- Cleanroom applications

Advantages

- A Energy saver
- High surface area
- High efficiency



* According to EN 779:2012 ** According to ISO 16890 *** According to Eurovent 4/21-2014

MVHHT SERIES

Media	Micro Glass Fiber
Separators	Micro Glass Fiber
Frame	Stainless Steel or Galvanized Steel
Sealant	Silicone
Temperature Max	250°C
Final Pressure Drop	600 Pa

Applications

- Air conditioning systems
- Industrial processes



 **250°C**

HFN SERIES ALUMINIUM PROFILE 70 mm

Media	Microglass Fiber
Frame	Extruded Anodized Aluminium
Final Pressure Drop	600 Pa
Operating Temperature	80°C
Filter Efficiency****	E10-U15
Gasket	Half Round Endless Polyurethane
Protection Grids	Painted Aluminium on Both Sides
Separators	Hotmelt

Applications

- Air conditioning systems (Hospitals, Laboratories, Museums)
- Industrial processes (Pharmaceutical, Food, Microelectronics)



70 mm Aluminium Profile View

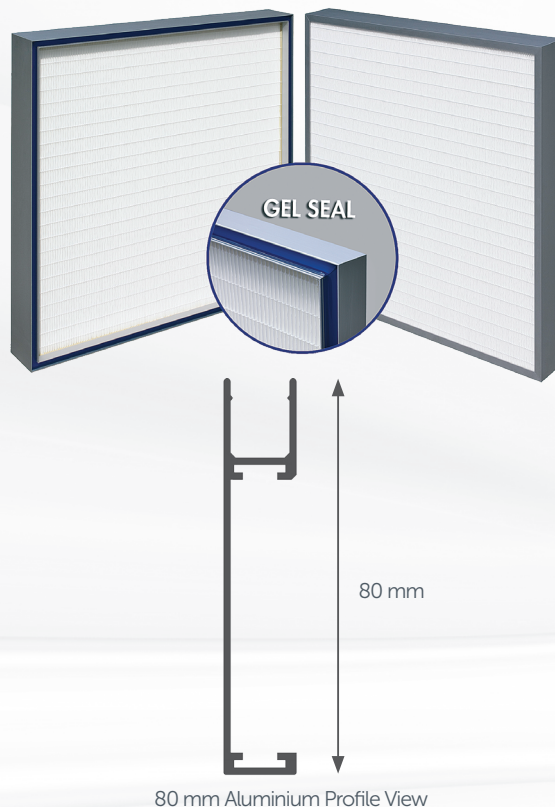
**** According to EN 1822

HFN SERIES GEL SEAL 80 mm

Media	Microglass Fiber
Frame	Extruded Anodized Aluminium
Final Pressure Drop	600 Pa
Operating Temperature	80°C
Filter Efficiency****	E10-U15
Gasket	Gel
Protection Grids	Painted Aluminium on Both Sides
Separators	Hotmelt

Applications

- Air conditioning systems (Hospitals, Laboratories, Museums)
- Industrial processes (Pharmaceutical, Food, Microelectronics)



MVH SERIES METAL FRAME MAX. FLOW 292 mm

Media	Microglass Fiber
Frame	Galvanized Steel, Aluminium, Stainless Steel
Final Pressure Drop	600 Pa
Operating Temperature	80°C
Filter Efficiency****	E10-H14
Gasket	Flat Neoprene or Half Round Endless Polyurethane
Protection Grids	Optional
Separators	Hotmelt

Applications

- Air conditioning systems (Hospitals, Laboratories, Museums)
- Industrial processes (Pharmaceutical, Food, Microelectronics)

Advantages

- Strong frame
- High flow applications



**** According to EN 1822

MHH SERIES MICRO HOOD FILTER 150 mm

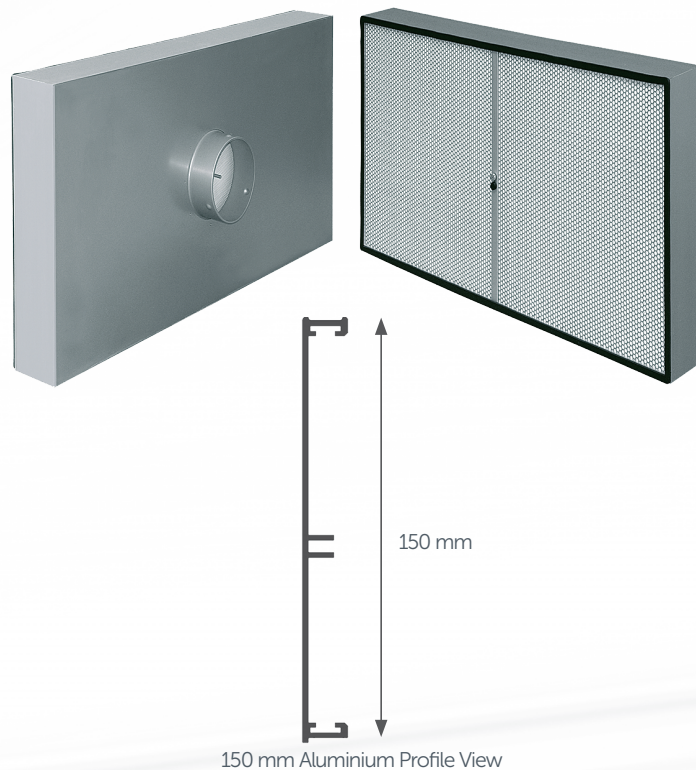
Media	Microglass Fiber
Frame	Extruded Anodized Aluminium
Final Pressure Drop	600 Pa
Operating Temperature	80°C
Filter Efficiency****	E10-U15
Collar Dimensions	150 mm, 200 mm, 250 mm, 300 mm, 400 mm
Collar Height	65 mm
Protection Grids	Painted Aluminium on Downstream Side
Separators	Hotmelt

Applications

- Cleanroom applications
- Laminar flow cabins

Advantages

- Adjustable air flow

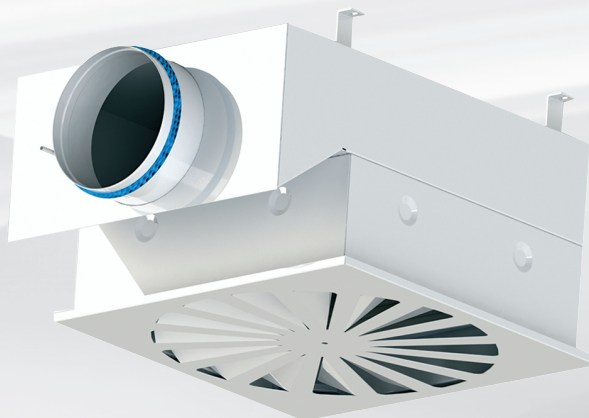


H-BOX LSC SERIES

Applications

- Ceiling diffusers for terminal filtration
- Cleanroom applications

LSC	Low side ceiling
DSW	Swirl diffusers
D4D	4-direction diffusers
DP	Perforated diffusers
Collar Dimensions	Ø150 mm, Ø200 mm, Ø250 mm



**** According to EN 1822

AIR FILTRATION SOLUTIONS FOR PHARMACEUTICAL INDUSTRY



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