Navigating Personal Protective Equipment Selection in the pharmaceutical industry

A guide to regulations and equipment selection

RESPIREX™

Selecting PPE for Pharmaceutical Development & Manufacturing

The pharmaceutical sector presents a plethora of occupational hazards that can pose significant threats to the well-being of workers. These risks emanate from the frequent interaction with chemical substances, biological agents, and potent drugs, collectively referred to as Active Pharmaceutical Ingredients (APIs).

Active Pharmaceutical Ingredients (APIs) are broadly categorised into two types – Synthetic APIs and Natural APIs. Synthetic chemical APIs, also known as small molecules, constitute the largest part of the pharmaceutical market, with many small molecule drugs commercially available on the market. Natural APIs are used in making biologics, which are increasingly becoming the top-selling drugs on the market. Despite the growing demand, biologics are currently significantly fewer in number compared to small molecule drugs.

Ensuring the safety of pharmaceutical personnel is paramount; however, it is equally crucial to safeguard pharmaceutical products and processes from contaminants, including chemicals, particles, and micro-organisms. Personal Protective Equipment (PPE) plays a vital role in this context, contributing to the maintenance of hygiene standards, contamination control, and worker safety.

Personal Protective Equipment (PPE) in the pharmaceutical industry in Europe is influenced by a variety of regulations and official guidelines. The most important of these are shown opposite.

These regulations and guidelines collectively provide a framework for the selection of PPE in the pharmaceutical industry in Europe. Individual organizations also typically have their own internal guidelines that must also be followed.

1. The Personal Protective Equipment Regulation (EU) 2016/425: This European Union regulation sets forth basic health and safety requirements for PPE, which includes equipment designed to be worn or held by a worker to protect against one or more risks to his or her health or safety.

2. Good Manufacturing Practice (GMP): While not a law or regulation per se, GMP is a set of guidelines developed by regulatory authorities to ensure that products are consistently produced and controlled according to quality standards. It includes guidelines on personnel hygiene and clothing that must be followed in the pharmaceutical industry.

3. ISO 45001:2018 - Occupational Health and Safety Management Systems: This standard, while not specific to the pharmaceutical industry, provides guidance on how to establish, implement, and maintain an occupational health and safety (OHS) management system, including guidelines on the use of PPE.

4. The European Agency for Safety and Health at Work (EU-OSHA) regulations: This agency produces a variety of guides and regulations on safety at work, including "Guidance for the safe management of hazardous medicinal products at work".

5. The Workplace (Health, Safety and Welfare) Regulations 1992: This is UK-specific regulation but it sets forth requirements for health and safety in the workplace, including the use of PPE.

6. Biological Agents Directive (2000/54/EC): In pharmaceutical settings, there may be exposure to biological agents. In such cases, the appropriate PPE must be used as dictated by this directive.

7. The Control of Substances Hazardous to Health Regulations 2002 (COSHH): Again, UK-specific, but COSHH outlines how to protect employees from harm caused by hazardous substances, including guidelines for using PPE.

8. Regulation (EC) No 1907/2006 (REACH): This European Union regulation addresses the production and use of chemical substances and their potential impacts on both human health and the environment.

Levels of Protection

AIR-FED SUITS

A one-piece suit fed with breathable air from an external supply (e.g. compressor) by an air line. Air-fed suits provide a high degree of protection, and are comparatively easy to don & doff.
Assigned Protection Factor (APF): **200**

ISOLATOR SUITS

Similar to air-fed suits above, but a half-suit (from the waist up) fitted into a sealed enclosure with an air tight seal between the suit and the enclosure.
Assigned Protection Factor (APF): **200**

POWERED AIR SUITS

A one-piece suit with filtered breathing air supplied to the wearer via a powered respirator fitted to the suit with external filters.
Assigned Protection Factor (APF) [TH3]: **40**

AIR-FED HOODS & BLOUSES

An air supplied hood or blouse with a clear visor worn over the top of other suitable PPE (e.g. coverall, gloves and safety boots)
Assigned Protection Factor (APF) [Class 4A]: **40**

COVERALLS, RESPIRATOR OR HALF MASK AND GOGGLES

A flexible option as the type of respiratory protection can be altered, but provides the lowest level of protection.
Assigned Protection Factor (APF): **4** [P1 filter] to **20** [P3 filter]

The level of protection required by workers should be determined by a risk assessment of the working environment, the substances to which workers could be exposed, their occupational exposure limits and the potential routes to exposure (e.g., skin contact, inhalation etc). The risk of contamination to product also needs to be taken into account in the risk assessment and selection process.

The provision of adequate facilities for safe donning and doffing also needs to be considered, not only to ensure that workers can safely and effectively don and doff Personal Protective Equipment (PPE), but also to eliminate the risk of contamination or cross contamination of product through effective controls, hygiene and training.

To determine the level of respiratory protection required you need to establish the concentration of the hazardous substance in the working environment and the occupational exposure limit for the substance (this can usually be found in the Safety Data Sheet [SDS]). The protection factor the wearer requires can be calculated by dividing the airborne concentration by the workplace exposure limit, simply select respirator protective equipment with an Assigned Protection Factor (APF) higher than this number. For hazardous substances that are classed as carcinogens or mutagens, or are a potential cause of occupational asthma, exposure needs to be reduced to as low a level as is reasonably practicable.

The Assigned Protection Factor (APF) for Respiratory Protective Equipment (RPE) is a number rating that indicates how much protection that RPE is capable of providing; e.g. equipment with an APF of 10 will reduce the wearer's exposure by at least a factor of 10 if used properly.

The APF's quoted in the chart are generic equipment type values taken from the UK Health & Safety Executive's 'Respiratory protective equipment at work' guide - HSG53:2013 .

Air-Fed Suits

Air-Fed protective suits (sometimes referred to as positive pressure suits) provide a high level of protection for wearers and are suitable for use with substances with low occupational exposure limits. These suits provide several advantages, especially in contexts where high levels of cleanliness and protection are necessary.

The key benefits in pharmaceutical manufacturing are:

Easy to use; Simpler to don and doff safely than separate PPE items, one-piece suits ensure that all parts of the wearer are equally protected, from the head and face down to the feet.

Greater wearer comfort, The constant supply of filtered air provides a more comfortable environment for the wearer, especially in warm conditions. This can reduce heat stress and allow workers to perform their tasks more efficiently.

Enhanced Protection; Air-fed suits provide a high level of protection against airborne contaminants, including fine powders, chemicals, and biological agents. The positive pressure inside the suit prevents contaminants from entering, even if there's a small breach or tear.

Communication; Suits allow the use of headset communication systems, allowing workers to communicate easily and the constant flow of air prevents the visor or face shield from fogging up, which aids non-verbal communication and ensures accuracy in tasks that require precision

ActiveAir API

SINGLE-USE, FULLY DISPOSABLE SUIT

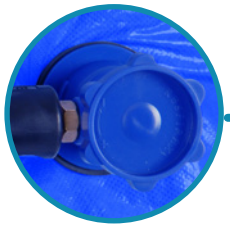
The ActiveAir API suit is a single-use **Type 3** (liquid-tight), one-piece suit with an **integral breathing and cooling air system** that provides the highest level of protection against particulate and liquid chemical hazards.

- Front entry design with zip across chest and two protective cover flaps with double sided tape
- Internal cooling system for arms & legs with comfort air-flow adjuster
- Airflow: 410 - 620 ltr/min with internal low-flow warning whistle
- Antistatic construction (EN 1149-5:2018)

Material:

Manufactured in **Chemprotex™ 300**, a lightweight, flexible 5-layer chemical barrier laminate fabric that incorporates a soft spun-bonded internal lining

For full details on the ActiveAir API suit scan the QR code, or visit respirex.com



External comfort air-flow adjuster

GLOVE OPTIONS:

Kemblok™ chemical barrier inner glove with conductive strip on the palm and an elasticated outer sleeve,

Butyl anti-static glove permanently attached to the sleeve with a ring.

FOOT OPTIONS:

Sock Foot with outer splash-guard leg for use with boots worn on the outside of the suit (e.g. Solestar ESD)

Boot Foot with elasticated ankle and slip resistant sole, for use with shoes worn inside the suit.

ActiveAir AutoFlow

SINGLE-USE SUIT WITH REUSABLE AIR SYSTEM

The ActiveAir AutoFlow suit is a single-use **Type 3** (liquid-tight), one-piece suit with a **reusable**, **removable air system** that provides the highest level of protection against particulate and liquid chemical hazards.

- Front entry design with zip across chest and two protective cover flaps with double sided tape
- Reusable AutoFlow 2-9 regulator, with a short air-line 'trunk' in the rear of the suit to feed through the air supply hose
- Cooling airflow; air is delivered into the hood and passes through a permeable neck seal to the body
- Antistatic construction (EN 1149-5:2018)
- Airflow: 210-400 ltr/min

Material:

Manufactured in **Chemprotex™ 300**, a lightweight, flexible 5-layer chemical barrier laminate fabric that incorporates a soft spun-bonded internal lining

For full details on the ActiveAir AutoFlow suit scan the QR code, or visit respirex.com

Belt-mounted regulator with integral warning whistle is easily removed for re-use

GLOVE OPTIONS:

Kemblok™ chemical barrier inner glove with conductive strip on the palm and an elasticated outer sleeve,

Butyl anti-static glove permanently attached to the sleeve with a ring.

FOOT OPTIONS:

Sock Foot with outer splash-guard leg for use with boots worn on the outside of the suit (e.g. Solestar ESD)

Boot Foot with elasticated ankle and slip resistant sole, for use with shoes worn inside the suit.

Simplair AE

REUSABLE SUIT & AIR SYSTEM

A reusable air-fed **Type 2** 'non-gas tight' suit with integral cooling available in a range of chemical resistant fabrics and with a range of customisation options allowing the suit to be tailored to a specific application or process.

- Internal air system providing breathing and cooling air to the user
- Three-point hanging system helps prevent distortion during storage
- Horizontal zip across the chest covered by a zip flap
- Internal low-flow warning whistle indicates if airflow into the suit drops below the required level

Material:

Available in green or yellow **PVC** as standard, but a range of other chemically resistant fabrics are available

For full details on the Simplair AE suit scan the QR code, or visit respirex.com

Gloves attached with a gas-tight locking cuff and cone system for easy glove changes

Wear with washable chemical safety boots, e.g. Hazmax™ ESD

Flexible transparent PVC hood providing 360° vision as standard, but a hood with rigid visor and outer protective cover also available

Double elasticated legs with stirrup on inner leg as standard, but other options including attached boots are available

Isolator Half-Suit

REUSABLE HALF SUIT & AIR SYSTEM

Our isolator half suits have been developed by Respirex in cooperation with leading pharmaceutical manufacturers for use within a positive or negative pressure chamber.

- Twin layer body and upper arms provides comfort and flexibility and prevents the suit from collapsing against the wearer in a positive pressure chamber
- Padded neck and shoulder support to reduce garment cling whilst balancing the hood
- Robust hood and arm hanging support system for ease of donning and doffing
- Air system brings breathing and cooling air up the back of the suit to the sleeves and hood

Material:

Available in yellow or green **PVC** as standard, but a range of other chemically resistant fabrics are available

For full details on the Isolator Half-Suit scan the QR code, or visit respirex.com

Clear, flexible **360° hood with a replaceable inner visor** for excellent all round vision

- Hood will not collapse when used in a positive pressure chamber

Areas liable to high physical wear are **reinforced**

Twin recessed glove connectors allowing easy initial glove fitting and in-use glove replacement during work activity (locking cuff also available)

Air-Fed Hoods

Air-Fed protective hoods provide a high level of respiratory protection in an item that is quick and easy to don and that allows users to wear glasses or radio communication headsets. These hoods provide several advantages, especially in contexts where high levels of cleanliness and protection are necessary.

The key benefits in pharmaceutical manufacturing are:

Quick & Easy; Simple to don and doff safely, hoods can be quickly fitted over the top of protective coveralls etc and can be worn by users with beards or glasses

Greater wearer comfort, The constant supply of filtered air provides a more comfortable environment for the wearer, particularly when compared to respirators or facemasks

Effective Protection; Air-fed hoods provide a high level of protection against airborne contaminants, including fine powders, chemicals, and biological agents. The hood and cape provide protection from liquid splashes to the face and upper body.

Communication; Hoods allow the use of headset communication systems, allowing workers to communicate easily and the large visor aids non-verbal communication and ensures accuracy in tasks that require precision

ActiveAir AutoFlow Hood

SINGLE-USE HOOD WITH REUSABLE AIR SYSTEM

The ActiveAir AutoFlow hood is a single-use **Type PB [4]** (partial body, spray-tight), hood with a **reusable**, **removable air system** that provides protects against particulate and liquid chemical respiratory hazards.

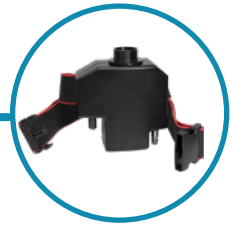
- Front & rear cape panels provide protection to the wearer's chest area
- Clear rigid visor with wide field of vision
- Reusable belt mounted AutoFlow 2-9 regulator
- Airflow: 210-400 ltr/min

Material:

Manufactured in **Chemprotex™ 300**, a lightweight, flexible 5-layer chemical barrier laminate fabric that incorporates a soft spun-bonded internal lining

For full details on the ActiveAir AutoFlow hood scan the QR code, or visit respirex.com

Soft, air-permeable neck seal for wearer comfort



Belt-mounted regulator with integral warning whistle is easily removed for re-use

Simplair AE Hood

REUSABLE HOOD & AIR SYSTEM

A reusable air-fed chemically protective **Type PB [4]** (partial body, spray-tight) hood available in a range of chemical resistant fabrics and with a choice of visor styles.

- Attached air system provides breathing air to the user and the Internal low-flow warning whistle indicates if airflow into the hood drops below the required level
- Front & rear cape panels provide protection to the wearer's chest area
- Three-point hanging system helps prevent distortion during storage
- Adjustable waist belt with a foam back pad comfortably supports the air system

Material:

Available in green or yellow **PVC** as standard, but a range of other chemically resistant fabrics are available

For full details on the Simplair AE hood scan the QR code, or visit respirex.com

Also available as a blouse with gloves attached via locking cuff system

Flexible transparent PVC hood providing 360° vision as standard, but a hood with rigid visor and outer protective cover also available

POWERED AIR

Powered respirator suits combine a high level of protection for wearers with untethered freedom of movement. These suits provide several advantages, especially in contexts where high levels of cleanliness and protection are necessary.

The key benefits in pharmaceutical manufacturing are:

Freedom; With no air-line connection, wearers are free to work where needed and a four hour batter life ensures that they can comfortably get through a shift.

Comfort; The constant supply of filtered air provides a more comfortable environment for the wearer, especially in warm conditions. This can reduce heat stress and allow workers to perform their tasks more efficiently.

Effective Filtration; Powered respirator suits provide excellent protection against airborne contaminants, including fine powders and chemical vapours, with a wide range of filter options available to suit your particular requirement.

Communication; Powered air suits allow the use of headset communication systems, allowing workers to communicate easily and the large visor aids non-verbal communication and ensures accuracy in tasks that require precision

RJS

SINGLE-USE POWERED RESPIRATOR SUIT

A one piece **Type 3** liquid-tight chemical protective suit designed for industrial handling of chemicals and API's. The reusable CleanAir® Chemical 2F powered respirator allows the wearer greater freedom of movement than air-fed suits.

- Front entry design with zip across chest and two protective cover flaps with hook and loop fastener
- Filtered air enters the hood and passes through a permeable neck seal over the body before exiting at the legs. This movement of air helps keep the wearer cool.
- Heads-up display in the hood and warning buzzer provide visual and audible indication of the respirators performance

Material:

Manufactured in **Chemprotex™ 300**, a lightweight, flexible 5-layer chemical barrier laminate fabric that incorporates a soft spun-bonded internal lining

For full details on the RJS suit scan the QR code, or visit respirex.com

Reusable chemical respirator with twin filters

Kemblok™ chemical barrier inner glove with an elasticated outer sleeve, Neoprene outer gloves are provided for mechanical protection

FOOT OPTIONS:

Sock Foot with outer splash-guard leg for use with boots worn on the outside of the suit

Boot Foot with elasticated ankle and slip resistant sole, for use with shoes worn inside the suit.

Coveralls & Accessories

Coveralls provide a quick and easy to wear solution for protection against lower level hazards and can be worn with either a respirator and goggles, a full facemask or an air supplied hood.

The key benefits in pharmaceutical manufacturing are:

Flexibility; Coveralls can be used in a range of different applications and in combination with a variety of other PPE.

Cost effective, Coveralls are often the most cost effective PPE option, particularly if reusable (launderable) coveralls can be used.

In addition to suits, coveralls and hoods, Respirex manufacture a range of protective footwear, chemical and chemical barrier gloves and can assist in providing ancillary equipment including hoses, hose reels and breathing air filtration systems. We have included a selection of these items in this brochure, but please contact our sales team to discuss your particular requirements.

Splashmaster™

SINGLE-USE COVERALLS

A lightweight, **Type 3** liquid-tight, single-use hooded coverall, designed for use with a full face mask and filter or appropriate facial and respiratory protection

- Integral hood with elastic face seal for a comfortable fit around a full or half mask respirator
- Nylon zip fitted at the front with double external zip flaps with hook and loop fastening
- Elasticated wrists and ankles for use with appropriate gloves and safety boots
- Antistatic (EN 1149-5:2018)

Material:

Manufactured in **Chemprotex™ 300**, a lightweight, flexible 5-layer chemical barrier laminate fabric that incorporates a soft spun-bonded internal lining

For full details on the Splashmaster coverall scan the QR code, or visit respirex.com

Elasticated wrists with thumb loop

Elasticated hood with adjustable throat flap provide an excellent seal around the base of full facemask respirators

Wear with washable ESD chemical safety boots, e.g. Hazmax™ ESD

COMB Coverall

REUSABLE COVERALLS

Reusable one-piece **Type 3** (liquid-tight) suits are available in a wide range of fabrics to provide the best possible protection in numerous industries. Our reusable coveralls are designed to be laundered in commercial washing machines, ensuring a lower lifetime cost of ownership than the equivalent number of single use garments.

- Suits feature nylon coarse tooth zips and a choice of hook and loop fastener or press stud fastening zip flaps.
- Zip can be central or from thigh to collar
- Separate jacket and trousers also available

Material:

Available in green or yellow **PVC** as standard, but a range of other chemically resistant fabrics are available

For full details on the COMB Suit scan the QR code, or visit respirex.com

GLOVE OPTIONS:

Liquid-tight push fit cuff and cone

Gas-tight locking cuff and cone system

Wear with washable chemical safety boots, e.g. Hazmax™ ESD

Choice of elasticated hood or collar

Range of reusable aprons with or without sleeves and cuffs also available

Double elasticated legs with stirrup on inner leg as standard, but other options are available

Kemblok™ Gloves

HIGH-PERFORMANCE CHEMICAL BARRIER GLOVE

Manufactured using a seven-layer chemical barrier laminate material, Kemblok™ gloves provide excellent protection against a wide range of chemicals, viruses and micro-organisms.

The gloves thin, lightweight construction makes it ideal for use as a chemically protective under-glove worn underneath gloves providing mechanical protection or enhanced grip.

Solestar ESD Boots

COST-EFFECTIVE SAFETY BOOT FOR STATIC SENSITIVE AREAS

A high performance Electro-Static Discharge safety boot; conforming to the latest European standards the Solestar ESD incorporates a steel toecap and midsole together with an oil resistant non-marking sole and is available in sizes 3 to 15 (UK).

- **ESD** properties meet the requirements of EN 61340-5-1:2016 (0.1MΩ to 100MΩ) and EN 61340-5-1:2007 (0.1MΩ to 35MΩ)
- **Antistatic** - Electrical resistance meets the requirements of EN ISO 20345:2011 A (0.1MΩ to 1,000MΩ)
- Slip resistant moulded sole

Hazmax™ ESD Boots

CHEMICAL RESISTANT BOOT FOR STATIC SENSITIVE AREAS

A chemically protective Electro-Static Discharge (ESD) boot with an integral steel toe cap and vulcanized rubber sole for superior slip resistance.

- Chemically resistant boot certified to EN 13832-3:2018 (footwear protecting against chemicals)
- **ESD** properties meet the requirements of EN 61340-5-1:2016 (0.1MΩ to 100MΩ) and EN 61340-5-1:2007 (0.1MΩ to 35MΩ)
- **Antistatic** - Electrical resistance meets the requirements of EN ISO 20345:2011 A (0.1MΩ to 1,000MΩ)
- Vulcanized rubber sole for improved slip resistance (SRC)

AutoFlow Regulator

AUTO-ADJUSTING REGULATOR FOR USE WITH ACTIVEAIR AUTOFLOW SUITS & HOODS

A reusable belt mounted breathing air regulator which operates from a working inlet pressure between 2 and 9 bar (29 to 130 psi) and maintains a comfortable airflow into the suit or hood, while minimising noise.

The regulator includes a low-flow warning whistle, to alert the wearer if the inlet pressure drops below the Manufacturers Minimum Design Flow (MMDF) and is mounted to a waist belt. The waist belt can be easily detached from the regulator and laundered.

CleanAir Chemical PAPR

POWERED RESPIRATOR & FILTERS FOR USE WITH THE RJS SUIT

The Chemical 2F powered respirator combines sophisticated electronics with a durable easy-clean construction. The auto-closing inlets prevent contamination entering the suit while the filters are being changed, while the smart flow control system maintains a constant airflow regardless of filter loading or battery charge.

The rechargeable battery gives up to 4 hours run time and a remote audio and visual alarm fitted in the suit hood indicates when safe working time has elapsed or if there is an issue with the respirator.

A range of filters is available with protection ranging from P3 all the way up to A3B2E2K2P3.

Air-Line Equipment

ACCESSORIES FOR AIR-FED SUITS AND HOODS

Respirex supply a range of accessories to assist with the deployment of our air-fed suits and hoods, including:

- Air hoses & couplings
- Automatic rewind hose reels
- Portable breathing-air filtration system

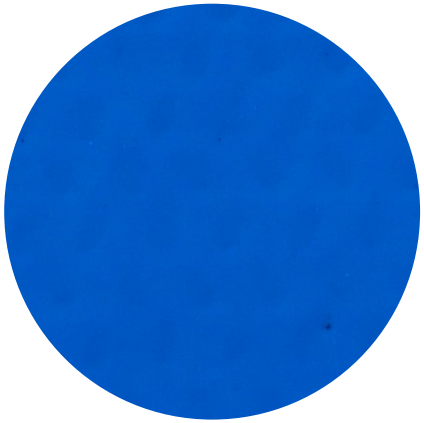
In addition a range of general cleaning and maintenance products for reusable suits & hoods are available including:

- Suit cleaning and sanitising agents
- Suit hangers
- Patch kits

Materials

Respirex produce garments in a range of chemically resistant materials, with differing mechanical and chemical properties. Our single-use garments are manufactured from Chemprotex 300, while our reusable suits are available in a choice of materials; for pharmaceutical applications PVC is the most commonly selected. A summary of the mechanical properties of the materials is given below, for chemical permeation data and information on our other materials please visit respirex.com.

Chemprotex™ 300

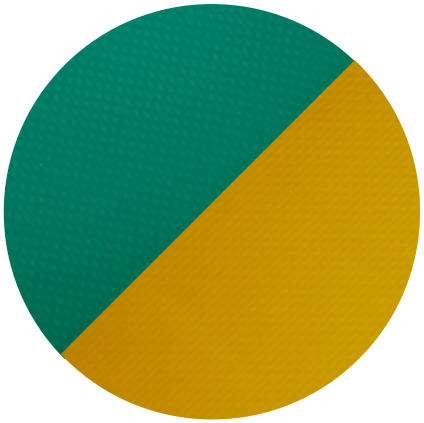


A high-performance, lightweight non-woven, chemical barrier fabric designed for single-use garments. It incorporates a 5-layer chemical barrier film, with a protective polyethylene top layer and spun bonded non-woven inner. This combination provides excellent chemical protection in a comfortable lightweight fabric. The material is halogen free and can be recycled as mixed polyolefin where facilities exist.

Chemprotex™ 300 is compatible with the **PermaSure® risk assessment modelling app** which calculates the ingress of toxic liquids and gasses through a garment and suggests a maximum safe exposure time based on the working environment (visit respirex.com/permasure for full details).

Abrasion	Flex	Tear	Tensile	Puncture	Ignition
6/6	1/6	3/6	2/6	2/6	✓

PVC



A robust reusable suit material comprising a polyester base layer coated on both sides with either green or yellow PVC. This material is suitable for light mechanical washing at up to 30°C.

Abrasion	Flex	Tear	Tensile	Puncture	Ignition
6/6	4/6	3/6	6/6	3/6	✓

RESPIREX™

Living + Breathing Personal Protection

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