Ansell

TIPS FOR SELECTING HAND PROTECTION WHEREVER BIOLOGICAL HAZARDS EXIST

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Researchers interact with biological agents across the spectrum of life sciences applications. From streaking agar plates to conducting DNA research, from growing cell cultures and developing new vaccines to working with infected animals – conducting microbial practices can pose health and safety risks. While many biological agents are harmless, many more are infective and can cause short-term illness, long-term harm or even fatal disease.

REGULATORY FRAMEWORK FOR PROTECTION AGAINST BIOLOGICAL HAZARDS

To prevent researchers and the environment from unnecessary exposure to harmful microorganisms, the European Union provides guidance in Directive 2000/54/EEC – biological agents at work. This directive refers to biological agents including those which have been genetically modified, cell cultures and human endoparasites, which may be able to provoke any infection, allergy or toxicity. Although toxicity and allergenicity are included in the definition of biological agents, the directive's four risk groups are based on the level of risk of infection.[1] (See figure 1)

European classification of infectious biological agents by risk group[2]

Risk Group 1	Biological agent is unlikely to cause sickness in humans
Risk Group 2	Biological agent could cause sickness in humans and represents a danger to employees; substance dispersal amongst the population is unlikely; effective preventative measures are used
Risk Group 3	Biological agent can cause severe illness in humans and represents a serious risk for employees; a risk of dispersal amongst the population may occur but effective preventive measures or treatment are normally possible
Risk Group 4	Biological agent causes severe illness in humans and represents a serious risk for employees; the risk of dispersal among the population is high under some circumstances; effective preventive measures or treatment are not normally possible.
Task Type A	Routine inspection = no contact with contaminated material or objects
Task Type B	Handling and disposal of possibly contaminated material, objects or animals
Task Type C	Tasks require application of cleaning and disinfecting chemicals

Figure 1

REGULATORY FRAMEWORK FOR PROTECTION AGAINST BIOLOGICAL HAZARDS

U.S. Centers for Disease Control and Prevention – Biosafety Levels[6]

Biosafety Level	BSL-1	BSL-2	BSL-3	BSL-4
Description	• No containment • Defined organisms unlikely to cause disease	• Containment • Moderate risk • Disease of varying severity	• High containment • Aerosol transmission • Serious/ potentially lethal disease	• Max containment • Exotic, high-risk agents • Life-threatening disease
Sample organisms	E.coli	Influenza, HIV, Lyme disease	Tuberculosis	Ebola virus
Pathogen type	Agents that present minimal potential hazard to personnel and the environment	Agents associated with human disease and pose moderate hazards to personnel and the environment	Indegenous or exotic agents, agents that present a potential aerosol transmission, and agents causing serious or potentially lethal disease	Dangerous and exotic agents that pose a high risk of aerosol-transmitted laboratory infection and life-threatening disease

Figure 2

Similarly, in the U.S. four biological safety levels (BSLs) are specified by the Centers for Disease Control and Prevention[3]. Each BSL defines the required controls for containment of microorganisms based on factors including infectivity, severity of disease, transmissibility, and the nature of work conducted.[4] The levels are organized in ascending order by degree of protection necessary for personnel, the environment, and the community.[5] (See figure 2)

Whether infective or not, laboratory personnel require protection from biological agents — and they deserve the confidence that their personal protective equipment (PPE) will stand up to whatever hazards they face. But with so many options in materials, performance, fit, and function, making the right selection can seem daunting. This paper looks at key considerations in hand and body protection to help employers and researchers alike make appropriate, informed and safe decisions for every application in which biological agents are present.

A CLOSE LOOK AT HAND PROTECTION

Because we rely on our hands to conduct the majority of laboratory tasks (i.e. handling vials and pipettes to manipulate, transfer and apply agents), they are among the most likely sites to make contact with microbes. Therefore, it is vital that the hands be properly protected at all times. Single-use gloves deliver a barrier between the skin and agents that blocks microorganisms from passing through — but not all gloves are created equal or designed for every application.

Recognizing the importance of effective hand protection among biological agents, two globally recognized safety standards address testing criteria and recommended use for gloves in laboratory settings. In Europe the recently developed EN ISO 374-5:2016 standard addresses criteria for gloves that protect against microorganisms, and includes bacterial, fungal and viral penetration testing.[6] In the U.S. ANSI/ISEA 105-2016, the American National Standard for Hand Protection Selection Criteria, provides end-users with guidance for selecting appropriate gloves for identifiable workplace hazards.[7] It also sets performance-based testing criteria used by manufacturers in assigning the product's protective classification.

Whether made of Nitrile, Neoprene or Latex, a single-use glove is comprised of a tightknit network of polymer chains that are connected at the molecular level by crosslinks. This structure forms a tight film that must remain flexible enough to stretch, but not break, while worn. The right combination of key components in the glove formulation helps determine the glove's properties and barrier performance. A manufacturer's unique formulation in conjunction with strict manufacturing process controls is its proprietary recipe for delivering reliable protection and performance.
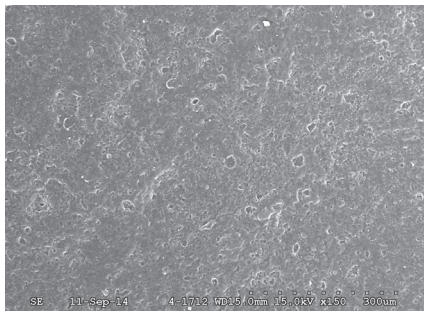
Electron microscope photograph of nitrile glove surface (0 degr tilt)
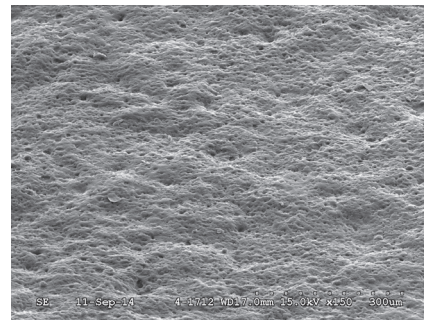
Electron microscope photograph of nitrile glove surface (60 degr tilt)

Due to the tightknit molecular structure of the polymer material, single-use gloves will protect the wearer against microorganisms and biological agents as long as their material is not compromised. That's because microorganisms (generally no smaller than 27 nanometers) are too large to fit through the film. The quality of glove material is key to keeping such agents out, though. In lesser quality materials, the higher instance of pinholes as well as the more rapid formation of microscopic cracks that develop during regular wear create gateways for microbes to reach the hands. Therefore, a glove's performance is determined by its unique formula – which must deliver strength, integrity and flexibility, attributes that can be delivered only when the manufacturer is committed to delivering the highest standard of quality.

PERMEATION VS. PENETRATION

A common misconception is that protection from biological agents can be measured by glove thickness. This is not the case, however, as microorganisms cannot permeate the film. Permeation occurs when a chemical migrates through the glove on a molecular level — without needing a breach or pinhole. Remember, microorganisms cannot permeate a glove because they are too large to pass through the film's tightknit structure. In fact, rather than enhance protection thicker gloves can actually be detrimental when handling biological agents.

Beware, the thicker the glove the less dexterity is afforded to the wearer, jeopardizing fine motor skills and increasing the chance of accidents. Alternatively, thinner gloves allow for increased tactility and dexterity, supporting controlled and precise handling.

The only way for microorganisms to reach the hand is penetration via a pinhole or defect. Such a breach affords a physical gateway through which the agent can travel to the hand and cause infection. Therefore the glove that affords the greatest protection is one with the least likelihood of defects, pinholes or damage.

KEY PROPERTIES OF AN EFFECTIVE GLOVE

To ensure protection from biological agents, it is vital that a glove's formulation and design:

- **Provide a reliable barrier with the lowest number of allowable defects or pinholes (low AQL)**
- **Stretch and flex without breaking (superior elongation and strength)**

ACCEPTABLE QUALITY LEVEL (AQL)
The absence of pinholes or defects is among the most critical protective measures of a glove.
AQL is a statistical sampling process used for evaluating glove quality based on the amount of allowable defects in any given batch of products. ISO 2859-1:1999 defines AQL as "the worst tolerable process average when a continuing series of lots is submitted for acceptance sampling." [8] Process average is the typical percentage of defective gloves in the lots/batches sampled.

A low AQL represents a glove with a lower probability of pinholes while a high AQL signifies a greater probability of pinholes — as well as researcher contamination. A glove's AQL is one of the most direct indicators of its quality, and a direct reflection of the manufacturer's quality and process standards.

When selecting single-use gloves, look for a manufacturer who minimizes defects by:

- **Employing rigorous quality standards throughout production processes,**
- **Maintaining reliable sources of supply, and**
- **Undergoing frequent audits by external parties to maintain ISO quality management system certification.**

PERMEATION VS. PENETRATION

At Ansell, we deliver products with AQLs far below industry standards. While the ANSI 105-2011 standard called for PPE gloves to meet 2.5 AQL or better, gloves used among biological risks should meet 0.65 AQL or 1.5 AQL. Ansell solutions feature AQLs as low as 0.65 and now even 0.4 with the new Microflex® 93-850.

Acceptable quality levels this low can only be delivered by Ansell's stringent in-house testing and control processes. Gloves coming from our production line undergo pinhole AQL testing every hour to ensure they meet industry-leading standards. Gloves are tested again after they come off the former and yet again during pre-shipping inspections. This commitment to frequent and rigorous product testing ensures the highest level of product integrity – and end-user confidence.

ELONGATION

A glove's ability to stretch and flex (elongate) without breaking is equally as important as its AQL. A glove exhibiting excellent elongation is less prone to cracking while worn, thereby ensuring reliable, long-term protection. It is also typically more comfortable to wear, as elongation supports a softer, more flexible and less rigid feel.

Elastomeric properties that lend to elongation are gained when the polymer formula is comprised of less crystallized structure and more flexible amorphous material, held together with strong crosslinking bonds. The goal is to formulate a sturdy, yet soft and flexible, film that doesn't disintegrate during wear and stands up to exposure to biological or other types of agents.

Elongation is expressed as a percentage, and a high elongation rating indicates the glove material's ability to stretch instead of tear when snagged. Elongation ratings can typically be found on a manufacturer's product data sheet.

While latex glove formulations can deliver good AQL and elongation properties, they are also a common source of skin allergies and irritation, and do not provide good chemical resistance. For most life sciences applications, nitrile and neoprene materials are preferred. Ansell offers a wide variety of specially formulated solutions ideally suited for use among biological agents. Whether nitrile or neoprene, Ansell gloves deliver exceptional, soft comfort with outstanding elongation properties. Elongation data is found on hand protection product data sheets or on product packaging for at-a-glance comparisons.

ADDITIONAL GLOVE SELECTION CRITERIA

Cuff length
The shorter the protective cuff, the greater the risk of exposure to the forearm. Cuff length ranging between 14" to 16" is recommended in biological applications.

BSL-3 and BSL-4 applications
In high-risk environments, double donning is typically required to ensure redundant protection and further reduce risk of exposure.

Sterile or clean applications
In applications where sterile or clean protection is required, look for gloves with the same high standards of quality mentioned above, that also meet sterile or clean specifications.

SOLUTIONS

All Ansell Microflex® and TouchNTuff® products are expertly designed and developed by Ansell's technical teams. Our systems are assessed and certified to ensure the highest standards of quality are met in every product released, ensuring end-users the highest degree of confidence in their protective equipment.

While many gloves and coveralls within the Ansell portfolio can be used when working with biological agents, below are some excellent choices:

Microflex® 93-833
- Our thin and very comfortable nitrile glove made with ERGOFORM® Technology and a 0.65 AQL

Microflex® 93-850
- Delivers comfort, durability, and the highest barrier quality and consistency for exceptional chemical protection with a 0.40 AQL

Microflex® 93-243
- Extra-long cuff (395mm) for improved forearm protection and a 1.50 AQL

Microflex® 93-853
- A sturdy nitrile glove with an extended cuff (295mm) and exceptional chemical resistance and a 0.65 AQL

To find out more about how Ansell's range of Hand Protection Solutions for Laboratories can help protect both workers and products or to request a sample, visit www.ansell.com/lifesciences.

1. Belgian Biosafety Server, "International classification schemes for micro-organisms based on their biological risks," http://www.biosafety.be/RA/Class/ClassINT.html
2. Directive 2000/54EC of 18 September 2000 (O.J. L 262, 17.10.2000, p.21)
3. Centers for Disease Control and Prevention, "Biosafety Lab Levels," https://www.cdc.gov/phpr/infographics/biosafety.htm
4. CDC, "Recognizing the Biosafety Levels," https://www.cdc.gov/training/quicklearns/biosafety/
5. CDC, "Biosafety Publication," https://www.cdc.gov/biosafety/publications/bmbl5/bmbl5_sect_iv.pdf
6. International Organization for Standardization, ISO 374-1:2016 https://www.iso.org/standard/66421.html
7. American National Standards Institute, ANSI/ISEA 105-2016, https://webstore.ansi.org/RecordDetail.aspx?sku=ANSI%2FISEA+105-2016

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