

BIODEGRADABLE NITRILE EXAM GLOVES

93% of plastic waste end up in landfills or oceans.



BACKGROUND

The world currently produces over 300 million tonnes of plastic each year (APCO 2018; Emadian et al. 2017; Rujnić-Sokele et al. 2017), and creates over 30 million tonnes in plastic waste with 93% of it ending up in landfill or oceans (Emadian et al. 2017). Single use plastics are the single major contributor to plastic waste in terrestrial and marine environments, posing a serious threat to wildlife in these environments and general public health (Emadian et al. 2017; Narancic et al. 2018).

The long period of accumulation and persistence in the environment of non-biodegradable plastics allows them to enter the food chain, as well as release large amounts of carbon dioxide emissions into the atmosphere (Emadian et al. 2017).

With the majority of medical consumables and packaging ending up in landfill, new solutions are needed to reduce the impacts of this waste (Kale et al. 2007).

The switch to bioplastics represents a real opportunity for the health sector to help with this problem.

WHAT ARE BIOPLASTICS?

What is a bioplastic?

The term bioplastic is used to describe plastics that are either:

- derived from renewable materials like plant oil, starch and cellulose (also known as bio-based plastics) or;
- plastics that are biodegradable including conventional (fossil fuel) or bio-based.

Examples of bioplastics include biobased polyethylene (PE), polylactic acid (PLA), and polycaprolactone (PCL).

Bioplastics currently make up about 1% of the total production of plastics in the world (APCO 2018; Rujnić-Sokele et al. 2017)

What is biodegradable plastic?

Biodegradable plastics are plastics that **degrade through interactions with microorganisms** such as bacteria, fungi and algae and are converted back into carbon dioxide and water over a period of months or years as opposed to decades or centuries.

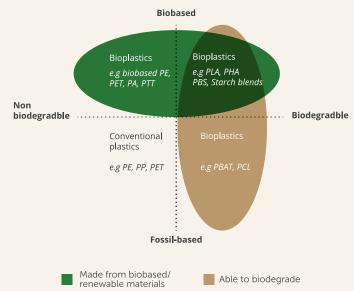


'Biobased' does not equal biodegradable'

It's important to know that not all bio-based plastics are biodegradable, while some conventional plastics are. The key factor for biodegradation to occur is related to a material's molecular structure (also known as a polymer) rather than the material itself (European Bioplastics 2020).

The graph on the right illustrates the four possible groups that plastics can fit into, with the vertical axis showing whether the material has come from renewable or petrochemical sources, and the horizontal axis showing whether the material is biodegradable or not.





TYPES OF PLASTIC

Non-biodegradable plastics from renewable resources

While made from renewable resources, their polymers don't allow for biodegradation. They are often derived from biofuels like bioethanol, which is produced from sugar cane fermentation. Some examples include polyethylene (bio-PE), polyvinyl chloride (bio-PVC), polyethylene terephthalate (bio-PET) or polypropylene (bio-PVC, bio-PET, bio-PP). Plastics in this group can also be a blend of renewable and fossil fuel resources which restricts their ability to biodegrade (Rujnić-Sokele et al. 2017).

Biodegradable plastics from renewable resources

Plastics that are made from biomass feedstock material and show the property of biodegradation. The examples in this group include starch blends made from thermo-plastically modified starch and other biodegradable polymers, and polyesters such as polylactic acid (PLA) or polyhydroxyalkanoate (PHA) (Rujnić-Sokele et al. 2017).

Non-biodegradable plastics from fossil-based resources

These are plastics that are made from fossil fuels and are not biodegradable. This group has what is known as conventional plastics such as polyethylene (PE), polystyrene (PS) or polyvinyl chloride (PVC) (Rujnić-Sokele et al. 2017).

Biodegradable plastics from fossil-based resources

This small group of plastics mainly consists of conventional plastics containing a chemical additive that attracts microbes which break down the material's polymers (Rujnić-Sokele et al. 2017).









WHAT IS THE DIFFERENCE BETWEEN (OXO)DEGRADABLE, BIODEGRADABLE, CONVENTIONAL PLASTIC?

Degradable / Oxo-degradable

Degradable plastic, also known as oxo-degradable plastic, is a type of conventional plastic (e.g. PE, PP, PET) that contains a heavy metal additive to help it break down faster into smaller pieces **in the presence of UV light and air** (Rujnić-Sokele et al. 2017; Sonkkila, 2019).

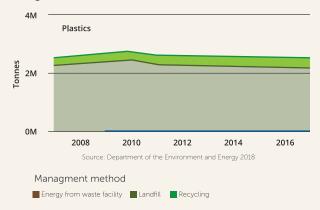
Biodegradable

A biodegradable plastic is one that degrades through **microbial activity** to break it down into carbon dioxide and water over a period of months or years. This is different from conventional plastics which typically take decades or centuries to degrade (Selke et al. 2015).

Confusingly, biodegradable plastics can sometimes be referred to as bioplastics, which is an umbrella term for plastics that are either biodegradable, made from biobased materials, or both (Iwata 2015; Rujnić-Sokele et al. 2017).

Conventional

Trends in the generation and management of key catagories, Australia 2006-07 to 2016-17



Conventional plastics come from fossil fuel sources and are extremely persistent in the environment. They tend to undergo a very slow process of degradation where it may take centuries for them to fragment into small particles through **biological**, **physical and photodegradation processes** (Kubowicz et al. 2017), and eventually turn into micron sized particles called microplastics which can pose a threat to local and regional ecosystems.

While recycling is a great way to redirect plastic waste from landfill and reduce the need to extract new raw materials, recycling rates in Australia and across the globe remain quite low (Narancic et al. 2018).



While these "pro-degradants" speed up the first stage of degradation to turn plastic items into tiny fragments, the resulting microplastics will still take decades, if not centuries, to completely biodegrade (Kubowicz et al. 2017). In this form, microplastics present a threat to the surrounding environment and food chain through infiltration and ingestion with animals.

This means that not all biobased plastics, those made from renewable materials, are biodegradable. What really matters for biodegradation is the material's chemical structure, also known as their polymer, as this needs to be friendly to allow microbes to consume it as food for growth and reproduction (Emadian et al. 2017; Pathak et al. 2014; Rujnić-Sokele et al. 2017; Selke et al. 2015).

It also means that the environment in which the plastic is placed is important as well, to ensure the right microbes are present for biodegradation (Narancic et al. 2018).



Disposing of conventional plastic in landfill leads to the production of greenhouse gases especially methane, which is 25 times more potent than carbon dioxide in warming the planet (Emadian et al. 2017; Sonkkila 2019).

It can also lead to toxins leaching from the ground and into ground water supplies. With the vast majority of plastic waste disposed of in landfill, the need for new initiatives on plastic waste are badly needed.

GLOVEON AVALON BIODEGRADABLE TECHNOLOGY

Temperature, moisture, pH levels and oxygen content are all important environmental factors to consider when looking at the biodegradation of plastics (Emadian et al. 2017). GloveOn Avalon has been specially formulated to include an organic additive which attracts microbes found exclusively in landfill and anaerobic digester environments that break down their polymers naturally through mineralisation.

GloveOn Avalon

gloves biodegrade up to **30% in <7 months** in landfill conditions.

GloveOn Avalon gloves biodegrade up to 90% in <1.5 years in anaerobic digesters.



When microbes identify a food source, they send out chemical signals to other microbes which then colonize on the glove and begin to consume it. Over time, the glove is consumed through a natural process called mineralisation, leaving behind organic material such as inert humus, CO_2 and methane gas.

90% biodegradation rate in 490 days.*

*Tested based on ASTM D5511.

| Standard | Test | Result |
|------------|---|------------------------------------|
| ASTM D5526 | To determine the degree and rate of anaerobic biodegradation of materials in accelerated landfill conditions. This is a long-term test that replicates the landfill environment of low heat, high pressure, limited oxygen, no light and low moisture. | 30% biodegradation in 202 days. |
| ASTM D5511 | To determine the degree and rate of anaerobic biodegradation of materials in high-solids anaerobic digestion conditions, which replicates the anaerobic digester or landfill bioreactor environment. | 90% biodegradation in 490 days. |



GloveOn Avalon gloves will not biodegrade prior to disposal. Our unique formulation has been created so that the biodegradation process only begins once the gloves are surrounded by microbes present in landfill environments. This ensures GloveOn Avalon gloves have a shelf life of up to 3 years. GloveOn Avalon has also been created and tested to well exceed international standards for tensile strength and force at break, making them versatile for a range of applications. They have also been certified for food handling and proven to be non-irrritating and non-sensitising on skin.



GloveOn Avalon Real-Time Shelf Life Results Compared to ASTM & EN Requirements

GloveOn Avalon gloves not only pass but exceed **ASTM standards** for tensile strength and **EN standards** for force at break, as well as AQL 1.5 for pinhole.

ASTM Requirement: Tensile Strength: 16.0 MPa after ageing

EN Requirement: Force at Break: 6.0 N after ageing

| Standard | Test | Result | Compliance |
|--------------|-------------------------|------------------------------|--------------|
| ISO 10993-5 | Cytotoxicity Test | Non-cytotoxic at 10% extract | ~ |
| ISO 10993-10 | Primary Skin Irritation | Non-irritating | \checkmark |
| ISO 10993-10 | Dermal Sensitisation | Non-sensitising | ~ |
| Food Contact | 21 CFR 177.2600 | Pass | ~ |
| Food Contact | Japan Sanitation Law | Pass | \checkmark |









glove@n Avalon

BIODEGRADABLE NITRILE EXAM GLOVES

Powder Free, Standard Cuff

| | e CE |
|--|------|
|--|------|

| | GloveOn® Avalon | | |
|----------------------------------|------------------|--------------|--|
| Length (mm) | | | |
| | 2 | <u>≥</u> 230 | |
| Thickness Measurements (mm) | | | |
| Palm (centre of Palm) | 0.07 | 0.07 ± 0.02 | |
| Finger (13mm \pm 3mm from tip) | 0.10 | 0.10 ± 0.02 | |
| Physical Properties | Before Ageing | After Ageing | |
| Tensile Strength (MPa) | ≥ 18 | ≥ 16 | |
| Elongation (%) | ≥ 500 | ≥ 400 | |
| Inspection Levels & AQL | Inspection Level | AQL | |
| Watertightness | G1 | 1.5 | |
| Physical Dimensions | S2 | 4.0 | |
| Tensile Strength | S2 | 4.0 | |
| Visual Inspection (Major) | S4 | 2.5 | |
| Visual Inspection (Minor) | S4 | 4.0 | |
| Particulate Residue | N = 5 | ≤ 2mg/glove | |

| Chemotherapy Drugs and Concentration (Tested for Resistance to Permeation by Chemotherapy Drugs as per ASTM D6978-05-Test Report PN 151891B - Rev 1) | Minimum Breakthrough Detection Time (minutes) |
|--|--|
| Carmustine (BCNU), 3.3mg/ml (3,300 ppm) | 22.2 Minutes |
| Cisplatin, 1.0mg/ml (1,000 ppm) | >240 minutes |
| Cyclophosphamide (Cytoxan), 20.0mg/ml (20,000 ppm) | >240 minutes |
| Dacarbazine (DTIC), 10.0mg/ml (10,000 ppm) | >240 minutes |
| Doxorubicin Hydrochloride, 2.0mg/ml (2,000 ppm) | >240 minutes |
| Etoposide (Toposar), 20.00mg/ml (20,000 ppm) | >240 minutes |
| Fluorouracil, 50.0mg/ml (50,000 ppm) | >240 minutes |
| Methotrexate, 25.0mg/ml (25,000 ppm) | >240 minutes |
| Mitomycin C, 0.5mg/ml (500 ppm) | >240 minutes |
| Paclitaxel (Taxol), 6.0mg/ml (6,000 ppm) | >240 minutes |
| Thiotepa, 10.0mg/ml (10,000 ppm) | 66.1 Minutes |
| Vincristine Sulfate, 1.0mg/ml (1,000 ppm) | >240 minutes |
| | |

WARNING: Carmustine and Thiotepa, at the tested concentration, degraded Avalon nitrile glove at 22.2 minutes and 66.1 minutes, respectively. The safe use of gloves in chemotherapy treatment is solely the decision of clinicians authorised to make such decision.

REORDER CODE

| BDG33XS | X-SMALL |
|---------|---------|
| BDG33SS | SMALL |
| BDG33MM | MEDIUM |
| BDG33LL | LARGE |
| BDG33XL | X-LARGE |

FEATURES

- Fingertip textured
- Powder free
- Not made with natural rubber latex
- Chemo drugs tested
- Lab chemical tested
- Ambidextrous
- Standard cuff
- Violet blue colour

PACKAGING

200 gloves per box for XS to L 180 gloves per box for XL 10 boxes per carton

REGULATORY COMPLIANCE

ARTG 164563, FDA 510(k), MDR 2017/745, REACH, ROHS Directive 2002/95/EC, EU 10/2011, EC 1935/2004, EU 2016/425

STANDARDS

ASTM D6319, ASTM D5151, ASTM D6124, ASTM D6978, ASTM D5526, ASTM D5511, EN ISO 374-1 (Type C), EN 374 part 2, 4 & 5, EN 16523-1, EN 420, EN 455 part 1, 2, 3 & 4, EN 1186, EN 13130, CEN/TS 14234, ISO 10993 part 5 & 10

MANUFACTURING ACCREDITATIONS ISO 9001, ISO 13485, EN ISO 13485





FAQs



The organic additive in GloveOn Avalon attracts microorganisms present in landfills onto the glove and facilitates the production of enzymes which together with the microbes metabolise the glove. This mineralisation process converts nutrients (i.e. carbon) in the glove into CO_2 , H_2O , CH_4 (methane) and other inorganics.

2. Where is the organic additive applied to the glove?

As the additive has been incorporated into the formulation of GloveOn Avalon, it is present throughout the entire glove. This ensures that microorganisms are attracted to mineralise all parts of the glove, not just the outer layer, which would be the case if the additive was only applied to the surface.

3. How is the biodegradation process measured?

Using the international standards ASTM D5511 and ASTM D5526, the conversion of carbon within the glove into biogas is used to measure the rate of biodegradation. ASTM D5511 shows the level at which the biodegradation process would happen in ideal anaerobic conditions. ASTM D5526 shows the biodegradation level in more real-world circumstances (i.e. landfill). As microbes will use carbon for growth and reproduction, the biodegradation rates shown in tests for both standards will not reach 100%, even though the material is fully biodegraded.

4. Does Gloveon Avalon have a shorter shelf life?

No, GloveOn Avalon has the same shelf life as other conventional nitrile gloves. These gloves will only start to biodegrade in an active microbial landfill environment.

5. What's the best way to dispose of Gloveon Avalon when I've finished using them?

When using GloveOn Avalon for a clinical purpose, these gloves should be disposed of with all other clinical waste. If you have used them for any other purpose, they should be put in with the general waste stream.

6. Can they be composted?

8

As GloveOn Avalon is still made from synthetic polymer (nitrile), they are not able to be composted at home or in an industrial composter. Like recycling, if they are placed in a compost bin they will act as a contaminant to the end product (compost).





7. Are they safe?

Yes! GloveOn Avalon has been tested for safe use in clinical and non-clinical environments. It is also safer for the environment as no toxic residue is left after the biodegradation process.

8. What is mineralisation?

This process decomposes organic compounds to release nutrients (i.e. carbon) in the glove into CO_2 , H_2O , and other inorganics.

9. What are the determinants for a faster or slower biodegradation?

Actual rate of biodegradation will vary dependent upon environmental conditions and the biological activity of microorganisms surrounding the synthetic polymer.

10. Are these gloves safe to use?

Yes, GloveOn Avalon has passed a number of biocompatibility tests to show they are safe for use against various contacts such as skin and oral.

11. Will these gloves breakdown while in stock?

No, GloveOn Avalon has been designed to only attract microbes from an active microbial environment (such as a landfill) for biodegradation. Warehouses, offices and store shelves are not considered such environments.

12. Do synthetic polymers biodegrade?

Although carbon is a great nutrient source for microorganisms, the long chains in synthetic polymers make it difficult for them to be metabolised by microorganisms. Biodegradation of these polymers can be accelerated through the use of organic additives which attract certain microbes in landfill environments.

13. What is the difference between biodegradable plastic, compostable plastic and degradable plastic?

Biodegradable Plastic: When plastic (or any other material) degrades from the action of naturally occurring microorganisms, such as bacteria, fungi and algae. Biodegradation can occur in either aerobic (with oxygen) or anaerobic (without oxygen) environments.

Compostable Plastic: Capable of undergoing biological decomposition in an industrial compost environment to the point that the plastic is not visually distinguishable and breaks down to carbon dioxide, water, inorganic compounds, and biomass in a time frame similar to other organic materials.

Degradable Plastic: A plastic designed to undergo a significant change in its chemical structure under specific environmental conditions resulting in a loss of physical properties. This degradation can be initiated by oxygen, ultra-violet light or heat. In many cases these products begin to degrade the moment they are manufactured which leads to a shortened useful life.







9

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