Manufacturing Focus Group On Sustainability

Whitepaper

SureScreen Diagnostics

Sustainable Alternative Materials for Biodegradable Sars-Cov-2 Rapid Lateral Flow Tests

Synopsis

Single-use plastic in healthcare produces the equivalent carbon-footprint of 514 coal fired power plants. Countries around the world are committing to reducing plastic pollution, and SureScreen believe this should be a key area of focus for healthcare products going forward. In the UK there is ongoing work to develop a 'circular economy' in which products are made from bio-resources which degrade naturally after use to return back to nature.(1)

SureScreen believe making lateral flow devices more sustainable is of great importance to the planet, especially given the increasing quantity of devices currently being used around the world and the potential future applications of the technology in home and professional testing.

Ongoing internal research has demonstrated that alternative materials can be used to provide more sustainable solutions for lateral flow tests, and we are committed to adopting more sustainable materials going forward wherever possible.

It is hoped that this white paper including some of our recent work on suitable materials for lateral flow tests will be useful for other test and medical product manufacturers in a bid to introduce more sustainable materials across all lateral flow tests and other medical applications. SureScreen are happy to share any research in this area and welcome collaboration with other manufacturers to ensure kits across the world are being manufactured in a more sustainable way.

Introduction

Currently, the majority of plastic cassettes used for SARS-CoV-2 lateral flow test (LFT) kits around the world are non-biodegradable polystyrene made from petrochemicals. Billions of tests are being disposed of by incineration or placed in landfill sites. Medical waste contributes 4.4% of global carbon emissions (2), and we believe single-use medical plastics should be a focus in reducing pollution. The House of Commons Research Briefing 'Plastic Waste' (1) states that plastic waste often does not decompose and can last centuries in landfill, polluting soils, rivers and oceans, and harming the creatures that inhabit them.

This white paper focuses on SureScreen's actions to switch our Lateral Flow Tests (LFT's) to biodegradable alternatives, providing the circular economy, in which materials are derived from natural materials and are naturally biodegradable. The report focuses on two elements of the kit: the LFT test cassette and the waste bag, but also discusses wider appeal. The report summarises the suitability of the materials being used, their environmental impact compared to 'traditional' plastics, and the sustainability of the materials (3,4).

Summary Of Traditional Materials.

LFT Test Cassettes

Cassettes used to house LFT's are almost exclusively made from high-density polystyrene (HIPS), derived from petrochemical products, polymerised with benzoyl peroxide which acts as the catalyst in a reactor that requires a large amount electricity/fuel, resulting in a significant carbon footprint.

Most of the polystyrene used for lateral flow test cassettes are disposed of in general waste and most will end up in landfill. Polystyrene is classified as non-biodegradable and may persist in landfill for centuries. The smaller proportion used clinically may be incinerated resulting in significant carbon emissions. Furthermore, due to the slow disintegration process in landfill, microplastics build up in the earth and leach out and enter the seas over time, exacerbating the environmental impact of plastic disposal. In a study from 2015, microplastics (including polystyrene), were found in 20% of individual shellfish and the gastrointestinal (GI) tracts of commonly eaten fish[5].

Polystyrene recycling via mechanical, chemical and thermal methods is possible[6], but only for simple, single-polymer, uncontaminated waste, and assembled rapid test cassettes are not suitable for recycling. Most medical waste, even that which is not clinically contaminated, including gloves and masks, is a major challenge to recycle. For LFT cassettes, therefore, an alternative disposal strategy is required, based on whole-cycle philosophy.

Waste Bags

The plastic (waste) bags incorporated into kits are made of polyethylene, the most popular plastic in the world with annual production of around 63 million tons. Polyethylene production from petrochemical products requires considerable heat, pressure, solvents, and a catalyst[7]. Although polyethylene presents fewer environmental hazards per se than other polymers, use of non-renewable resources and the energy-intensive nature of the production cycle itself together with the worldwide large-scale production of polyethylene and derivates make the environmental and human safety impact of polyethylene significant[8]. Moreover, polythene film and bags represent a relatively greater biohazard because they are far more likely to escape into the environment and may cause suffocation or death by ingestion in a wide variety of life forms.

The American Society for Testing and Materials classifies polyethylene as non-biodegradable, and along with polystyrene, numerous studies have concluded that although degradation does occur, through microorganisms and other environmental mechanisms, the process is extremely slow[9], and the average plastic bag may take up to 450 years to fully degrade. Landfill sites have become overfilled by plastic bags, leading to a drive towards more sustainable alternatives, such as biodegradable plastics, paper bags, and taxes for consumers for plastic bag use (‘plastic bag tax’.)

Chemical recycling of polyethylene is possible[10], but not a very common process, as it requires significant quantities of solvents and is a high-cost process. Most used plastic bags end up in landfill, causing significant environmental issues and build-up of microplastics in the earth and in the oceans[5].

Other areas of healthcare use a variety of other plastics, but generally, due to the huge quantities involved there is a significant opportunity and responsibility of manufacturers in the healthccare arena to reduce waste and plastic use across products.

Review Of Proposed Materials That Could Be Used For Cassettes

Cassettes are injection moulded, using plastics that have sufficient strength and rigidity to secure a LFT strip in place. There are many plastics suitable for moulding, the more popular, and two candidate alternatives are shown here.

PLASTIC	CODE	DEGRADABLE	COST	MOULDING SUITABILITY
Polyethylene	PE	No	Low	Easy
Polypropylene	PP	No	Low	Easy, but higher temp than PE
Polystyrene	PS	No	Low	Easy, predictable shrinkage
Acrylonitrile-Butadiene-Styrene	ABS	No	Medium	
Polyoxymethylene	POM	No	Medium	Fairly easy
Thermoelastomer	TPU	No	High	Easy
Nylon polyamide	PA	No	High	Difficult to mould, expensive
Polyurethane	TPU	No	High	Can be challenging
Polycarbonate	PC	No	High	Expensive to mould (high temp)
Acrylic	PMMA	No	High	Expensive
Polyetherether ketone	PEEK	No	Very High	Specialist mouldings
RECOMMENDED ALTERNATIVES				
Polybutylene-adipate terapthalate	PBA	Yes	Moderate, reducing	Not widely used currently, Easy, but requires experience
Polylactic acid	PLA	Yes	Moderate, reducing	Not widely used currently. Easy, but requires experience

None of the most popular materials are classified as biodegradable, so the search for suitable alternatives must be widened, and the two polymers at the bottom of the table are SureScreen's proposed material replacements.

Poly (butylene-adipate-co-terephthalate) (PBAT)

PBAT is formed by condensing three different chemical components (butanediol (BDO), adipic acid (AA), and terephthalic acid (PTA)) together via a metal catalyst and heat[11]. These components are by-products of petroleum processing but can also be derived through natural processes. The properties can be adjusted by using chemicals or additives to increase the hardness and stability. One of these 'blends' incorporates poly (lactic acid) (PLA), and starch. PLAS is discussed later.

PBAT manufacture employs similar processing machinery to other plastics, and its carbon footprint of manufacture is similar. Additionally, the chemicals used during synthesis and modification can also negatively impact the environment, though better environmental control can mitigate this issue. However, PBAT is classified as biodegradable after modification with aliphatic components into the aromatic polyester chains[11]. When left in soil, PBAT is degraded by microorganisms (bacteria and fungi), which use the degraded products as a carbon source. Rates of decomposition depend on temperature, but studies on the degradation rates in soil at 25˚C have shown that the carbon content from a PBAT/PLA blend after 4 months was 55% of the original content (12). Unblended PBAT polymer on its own also biodegraded rapidly, with 59.1% remaining after 4 months. This offers a major advantage over the previously mentioned non-biodegradable conventional plastics.

However, biodegradable plastics can increase discharge of microplastic particles into watercourses and the oceans. Several studies have compared the deposition of plastic microparticles (<25μm) from biodegradable and non-biodegradable plastics into fresh and seawater. In all these studies, the proportion of biodegradable microplastics found in the water samples was significantly higher than the non-biodegradable plastics[13]. In one study comparing PBAT to the non-biodegradable low-density polyethylene (LDPE), the percentage surface coverage of PBAT in fresh water was 11%, compared to 4.2% for LDPE[14]. Similar results can be observed in seawater, and the problem may be even greater in soil-borne organisms inhabiting land around waste dumps. This poses a major environmental issue, despite numerous methods proposed to prevent microplastic build-up in water sources.

It is important to remember that non-biodegradable plastics, including polyethylene and polystyrene, still pose a major issue with regards to microplastic pollution, and is not only reserved to biodegradable materials. However, concerns over increases in microplastic pollution from PBAT mitigate the benefit in its use for disposable medical devices. The trade-off between biodegradation rate (carbon emissions) and microplastic pollution is a key statistic that requires better waste management, but that is receiving much attention currently. In our opinion PBAT represents an ideal polymeric material for cassette manufacture and many other single use medical products that could be brought under circular economy management strategies.

Poly (Lactic Acid) (PLA)

PLA is synthesised by a simple reaction, where naturally forming lactic acid (a by-product or bacterial metabolism) is condensed to form PLA. Lactic acid exists as D- and L-enantiomers; most PLA products are the racemic mixture of the two, however, using either the D or L enantiomer alone gives the final PLA product different physicochemical properties[15,16]. Its development has largely been fuelled by the emerging technology of 3-D printing, but it has great promise in circular economics because it is made from bio-material, and is completely biodegradable. PLA is becoming popular in the food and drug industry as carrier polymers, because they are non-toxic and are rapidly broken down in the body.

In our opinion PLA is an option for the main component of the plastic waste bags, replacing the traditional polyethylene. To form biodegradable plastic bags, other compostable materials such as starch are added, and the PLA stretched to the desired shape and size. Since PLA is formed from naturally occurring sources (lactic acid from bacteria metabolism or plant sources) and doesn't use large amounts of energy for its synthesis, its carbon footprint is minimal compared to conventional plastics, for example one cradle to shelf study showed that PLA's life cycle generates as much as 75% less carbon as other plastics[17].

PLA is biodegradable, as many micro- and macro-organisms possess enzymes that break down lactic acid and its derivatives. However, it's biodegradation is dependent on many factors, such as the ambient temperature, species of bacteria/fungi present in the soil, and the type of PLA (D- and L-enantiomers). Several studies have investigated the biodegradation rate of PLA in different environments. In one study, PLA with different ratios of D- and L-isomer were found to be degraded between 20 and 75% in soil after 20 months[18]. Another study comparing PLA biodegradation by different bacteria species found that in perfect conditions, with certain species of bacteria, PLA could degrade as much as 90% in 8 days[19]. However, in colder conditions, with a low concentration of bacterial and poor biodiversity, PLA may degrade very slowly; nonetheless, PLA will biodegrade and in the right conditions, can fully biodegrade in months, offering a significant environmental advantage over conventional materials.

As with PBAT, PLA the issue of microplastics has been studied, looking at the ecological impact of PLA microplastics compared to non-biodegradable plastics. Care needs to be taken when disposing PLA, to prevent the build-up of microplastics in the environment during the biodegradation process, but since PLA is formed from natural sources, it is unlikely to have long-term toxic effects to organisms, although longer term ecological effects by altering the biomass balance in certain environments are currently being studied.

Biodegradable Vs. Non-Biodegradable Plastics

Considering the above information, the choice to switch to PBAT and PLA from their non-biodegradable counterparts rests on their overall environmental impact. This includes the carbon footprint generated by producing them, their biodegradation, and the microplastic pollution generated. In general, the overall carbon footprint generated by producing biodegradable plastics is very much less than traditional plastics, due to the monomer units being naturally derived. This is particularly the case for PLA as its starting material is entirely biological.

The major advantage for switching to biodegradable plastics is the rate at which they are broken down, which is a matter of months or years rather than centuries. Additionally, there is a growing wealth of evidence to suggest that microplastics from natural sources are a significantly smaller threat to our rivers and oceans than conventional plastics. Several studies have shown that biodegradable plastics, including PBAT, generate higher microplastic pollution in water sources than non-biodegradable plastics, but they are short-lived and may have decayed completely before they enter our oceans. Other studies have demonstrated similar levels of microplastics present in the soil and oceans from both biodegradable and non-biodegradable sources. Hence, emphasis still lies on water treatment options for the time being, although this is not a viable long-term option.

Overall, our focus group strongly recommends switching to biodegradable plastics as the better choice, as they are naturally sourced, rapidly biodegrade and generate a lower carbon footprint.

PBAT and PLA are readily formable, and have been validated at SureScreen to be suitable for mass manufacture. For other LFT manufacturers, the implementation of such materials may require some adjustments to manufacturing practice, however the benefits are clear, especially in the formulated blend of PBAT developed for SureScreen products.

Conclusion

The ecological and environmental benefits of biodegradable plastics far outweigh the disadvantages posed through microplastic pollution, which can be mitigated. Hence, switching to biodegradable plastics for the lateral flow test kits is by far the best choice environmentally.

SureScreen will continue to research and work in this area to improve the sustainability of the kits going forward, and hope we can help other manufacturers to do the same.

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