



Spotlight

Chemical innocuousness testing of PPE

Defining 'chemical innocuousness' and outlining the assessments that need to be made for successful certification of PPE products.



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Personal protective equipment (PPE) is essential for many industries to ensure that workers can perform potentially hazardous tasks with minimal risks to their safety and wellbeing. It is therefore vital that PPE is fit for purpose and does not cause any harm or detriment to the wearer. One aspect of this is to ensure that the materials used in PPE do not have harmful chemical properties (a quality known as 'innocuousness'). Assessment for innocuousness is mandatory for certification in accordance with the PPE Regulation (EU) 2016/425 and UK PPE regulations, so all PPE products placed on the market within the EU and UK must comply.

PPE Innocuousness

PPE encompasses a broad range of product types, from occupational wear to sports equipment. Because of the variety in the different risks against which the products are claimed to offer protection, many products have their own specification standards which detail the requirements they must meet, such as EN ISO 21420 for protective gloves and EN ISO 20345 for safety footwear.

There is also a more generic standard for protective clothing, EN ISO 13688, which is also referred to for a broad range of products, including motorcycle jackets and trousers and equestrian wear.

Product specification standards typically detail both the physical performance and chemical innocuousness requirements which products need to meet.

Assessments of physical properties tend to be quite varied, as these are largely determined by the end use and the risks against which the product is intended to protect. In contrast, the applicable innocuousness tests are dependent upon the materials present, meaning that the requirements are often similar across different types of articles.

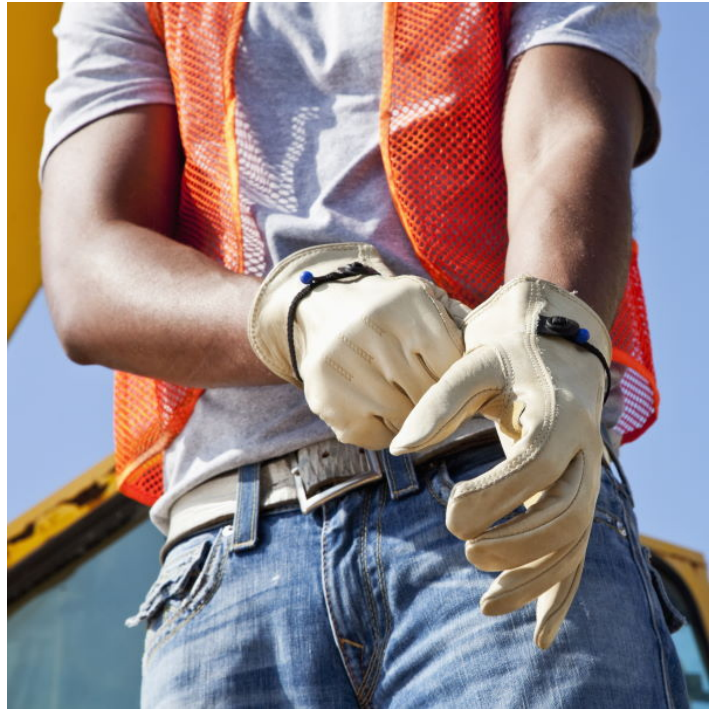
In most cases, innocuousness requirements are based upon REACH Regulation (EC) No 1907/2006 Annex XVII – the chemical compliance legislation for the EU. As REACH Annex XVII is periodically reviewed and updated with new substances, standards will not always specifically include the most recent chemical restrictions.

However, in addition to providing a list of specific substances that must be assessed, the majority of standards also include a statement explaining that the product must not adversely affect the health or hygiene of the user.

This is a somewhat subjective statement, which leaves the decision of compliance to be determined by the Conformity Assessment Body conducting the type-examination certification (a Notified Body for CE certification or an Approved Body in the case of UKCA certification). It is generally interpreted that products must meet applicable legal chemical restrictions, and so will require products to be fully compliant with REACH restrictions in order to be certified.

Hazardous substances

Boxes 1 to 4 in this article provide a summary of several product types, the product specification standards with which they must comply, and additional restricted substances that SATRA requires to be absent in order



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Many products have their own specification standards which detail the requirements they must meet, such as EN ISO 21420 for protective gloves



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EN ISO 13688 covers a broad range of products, including motorcycle jackets and trousers

for the product to be certified. The tests listed are all intended to assess for properties that could cause harm to the wearer.

Several of the chemicals listed are classified as carcinogens, meaning that exposure to them can increase the risk of developing cancer. Examples include certain azo colourants, which can be present in dyed leather and textiles, polycyclic aromatic hydrocarbons (PAHs), which arise as contaminants in plastics and rubbers, and dimethylformamide (DMFa), which is used in the manufacture of polyurethane (PU).

Box 1: Gloves

Product Specification: EN ISO 21420:2020+A1:2022

Specification requirements:

- pH value (all materials)
- chromium VI (leather)
- azo colourants (textiles and leather)
- PAHs (plastics and rubbers in contact with the skin)
- dimethyl formamide (PU)
- nickel (metal in contact with the skin)

Additional requirements:

- phthalates (plastics and synthetic rubbers)

Box 2: Footwear

Product specification: EN ISO 20345:2022

Specification requirements:

- pH value (leather)
- chromium VI (leather)
- requirements of ISO 16178 to be considered

Additional requirements:

- azo colourants (textiles and leather)
- PAHs (plastics and rubbers in contact with the skin)
- nickel (metal in contact with the skin)
- phthalates (plastics and synthetic rubbers)

Box 3: Protective clothing

Product specification: EN ISO 13688:2013

Specification requirements:

- pH value (all materials)
- chromium VI (leather)
- azo colourants (textiles and leather)
- nickel (metal in contact with the skin)

Additional requirements:

- PAHs (plastics and rubbers in contact with the skin)
- phthalates (plastics and synthetic rubbers)

Box 4: Mouthguards

Product specification: SATRA M33

Specification requirements:

- pH value (all materials)
- PAHs (plastics and rubbers)
- phthalates (plastics and synthetic rubbers)
- dimethyl formamide (PU)
- EN 71-3 'Migration of toxic elements' (all materials)
- overall migration in accordance with the requirements of Commission Regulation (EU) No. 10/2011
- specific migration in accordance with the requirements of Commission Regulation (EU) No. 10/2011

Another group of chemicals which raise concerns for long-term exposure is phthalates, which are used as plasticisers to increase the flexibility of polymers. These chemicals affect the endocrine system, and therefore can cause reproductive harm. Until recently, phthalates were only restricted under REACH in children's products, so were not included as part of innocuousness testing of PPE. However, in 2020, the scope of the REACH restriction expanded to include all consumer goods. Although many product standards have not yet been updated to take this into account, SATRA requires phthalates testing or declarations to be included in innocuousness assessments to demonstrate compliance with the legal requirements.

As well as protecting wearers from risks of long-term exposure, innocuousness also addresses unpleasant short-term effects, such as allergic reactions or irritation. There are several assessments used to identify if these effects are likely to occur, such as for pH value, which evaluates whether the materials are strongly acidic or alkaline, for chromium VI (a skin irritant and suspected carcinogen that can be present in leathers) and for nickel, a common allergen which can be present in metals.

The product standards for gloves and footwear provide very clear guidance on the innocuousness testing required. However, this is not the case for all types of PPE, many of which do not have specific standards. In such cases, the EN ISO 13688 general requirements standard for protective clothing would usually be applied

by SATRA, although – depending on the product – this does not always adequately address the risks. One example of this is mouthguards, which present additional risks due to their close ‘invasive’ contact with the oral cavity.

SATRA has therefore developed a protocol for this type of product – SATRA M33 – with which mouthguards must comply in order to gain SATRA certification. The requirements for this include pH value and evaluation for the presence of PAH, phthalates and DMFa (as are required for other PPE standards and under REACH), as well as additional requirements to address the risks of ingestion. These include EN 71-3, which assesses the migration of toxic elements, and overall and specific migration of substances based upon the requirements for materials in contact with food.

Innocuousness assessments

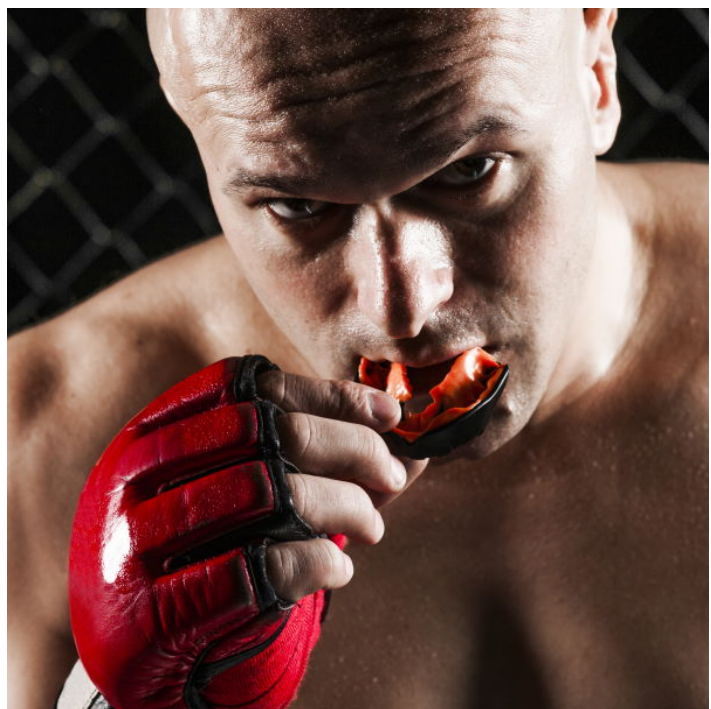
To conclude, it can often be difficult to determine the applicable innocuousness testing for different product types. There are a variety of different factors that must be considered, including the type of product, the materials used and the construction of the item. Furthermore, while most European PPE product standards provide detailed guidance on the tests required, this is not always sufficient to fully comply with legal requirements, as legislative requirements tend to be reviewed and updated more frequently than product specifications.

Notified Bodies may therefore require additional testing to ensure that products are fully compliant with legislation such as the PPE Regulation in order to certify the product. Because of this, it is always advisable to liaise with the Conformity Assessment Body as early as possible in the certification process in order to ascertain the requirements that must be met. As a PPE Conformity Assessment Body, SATRA is experienced in certifying products and performing assessments for the applicable innocuousness testing.



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'Innocuousness' also addresses unpleasant short-term effects, such as allergic reactions or irritation



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Mouthguards present additional risks due to their close 'invasive' contact with the oral cavity

How can we help?

15 PER CENT DISCOUNT ON FIRST SATRA TEST – please [click here](#).

Please contact SATRA (chemistry@satra.com) for chemical innocuousness testing of the PPE products mentioned in this article, as well as eyewear, hearing protection and head protection.