



Australian Government
Department of Health and Ageing

THERAPEUTIC GOODS ACT 1989
Section 10

THERAPEUTIC GOODS ORDER NO. XX - *Standards for human skin.*

I, Rohan Hammett, delegate of the Minister for Health and Ageing for the purposes of section 10 of the *Therapeutic Goods Act 1989* and acting under that section, having consulted with the Therapeutic Goods Committee in accordance with subsection 10(4) of that Act, HEREBY:

DETERMINE that the matters specified in this Order shall constitute a standard for human skin.

Dated this day of 2011

Rohan Hammett
Delegate of the Minister for Health and Ageing

1. Name of Order

This Order may be cited as Therapeutic Goods Order No. XX Standards for human skin.

2. Commencement

This Order commences on the day after the day it is registered on the Federal Register of Legislative Instruments.

3. Purpose of this Order

The purpose of this Order is to specify minimum technical requirements for the safety and quality assurance for a biological that is human skin.

4. Interpretation

(1) For the purpose of this Order, the presence of the term “must” in relation to a particular requirement in a provision set out in this Order means that the requirement is to be complied with at all times.

(2) In this Order:

allogeneic use means use of a biological that is removed from one person and applied to another.

antimicrobial means the ability of a substance to kill or inhibit growth of microorganisms.

aseptic technique means the technique that consists of measures used to prevent contamination by microorganisms.

autologous use means use of a biological that is removed from and applied to the same person.

bioburden has the same meaning as in “bioburden” in subsection 3(1) of the *Therapeutic Goods Act 1989*, as amended from time to time.

biological has the same meaning as “biological” in subsection 3(1) of the *Therapeutic Goods Act 1989* as amended from time to time.

Note that “biological” under the Act means:

- (1) Subject to subsection (3), a biological is a thing that:
 - (a) either:
 - (i) comprises, contains or is derived from human cells or human tissues; or
 - (ii) is specified under subsection (2); and
 - (b) is represented in any way to be, or that is, whether because of the way in which it is presented or for any other reason, likely to be taken to be:

- (i) for use in the treatment or prevention of a disease, ailment, defect or injury affecting persons; or
 - (ii) for use in making a medical diagnosis of the condition of persons; or
 - (iii) for use in influencing, inhibiting or modifying a physiological process in persons; or
 - (iv) for use in testing the susceptibility of persons to a disease or ailment; or
 - (v) for use in the replacement or modification of parts of the anatomy in persons.
- (2) The Secretary may, by legislative instrument, specify things for the purposes of subparagraph (1)(a)(ii).
- (3) The Secretary may, by legislative instrument, determine that a specified thing is not a biological for the purposes of the Act;

cell(s) means individual cells or a collection of cells when not bound by any form of connective tissue.

collection means the process of removing a biological or a source of a biological from a donor.

container has the same meaning as in “container” in subsection 3(1) of the *Therapeutic Goods Act 1989* (the Act), as amended from time to time.

critical material means all components, materials or supplies which could have a direct impact on the quality, safety and function of the end product.

donor means every source, whether living or deceased, of blood, blood components, cells or tissues.

manufacture has the same meaning as in ‘manufacture’ in subsection 3(1) of the *Therapeutic Goods Act 1989*, as amended from time to time.

microbial means microorganisms including, but not limited to, bacteria, fungi, Mycoplasma and Rickettsia but does not include viruses or prions.

minimal manipulation means a process involving any of the following actions:

- (a) centrifugation;
- (b) trimming, cutting or milling;
- (c) flushing or washing;
- (d) refrigeration;
- (e) freezing;
- (f) any similar thing to a thing mentioned in paragraph (a), (b), (c), (d) or (e).

processing means any operation involved in preparation, manipulation, preservation for storage and packaging of a biological.

recipient means a person who receives blood, blood components, cells or tissues by infusion or implantation.

skin is the outer integument or covering of the body, consisting of the dermis and the epidermis and resting upon the subcutaneous tissues.

specified microorganism means a microorganism which, if isolated from the tissue, necessitates discard of the tissue.

storage means maintaining a substance, material or product under appropriate controlled conditions.

tissue means all constituent parts of the body formed by cells.

transport means transfer within or between premises of a substance, material or product under appropriate controlled conditions.

5. Application of this Order

- (1) The requirements of this Order apply to biologicals that are human skin collected from
 - (a) living human donors and intended for autologous or allogeneic use; or
 - (b) deceased human donors and intended for allogeneic use;
- (2) This Order specifies requirements for biological and other therapeutic goods that are critical materials used in the manufacture of biologicals in subsection 5(1).

6. Exemptions

- (1) Biologicals exempt from the requirements set out under this Order are the following:
 - (a) human skin that is a biological and to which an exemption from compliance with this Order in relation to the supply of the skin has been granted by the Secretary in accordance with section 14 and 14A of the Act; and
 - (b) human skin cells and tissue biopsied for the purpose of an *in vitro* diagnosis and not for manufacture and/or reintroduction or transplant to a recipient; and
 - (c) human skin that is processed beyond minimal manipulation.

7. General Requirements

- (1) Critical materials employed in the collection and manufacture of skin must be of a design, composition, quality and safety to protect the quality and safety of the biological.
- (2) Collected skin must be maintained at 2°C to 8°C during storage or transport for a period of no more than 72 hours prior to processing or banking.
- (3) Collected skin must be sampled for bioburden determination, using a validated sampling technique, prior to being packaged within at least one moisture impermeable barrier using aseptic technique, maintained and transported at 2°C to 8°C.
- (4) Each manufacturing facility must have a defined and documented microbial contamination reduction procedure in place.

- (5) Each manufacturing facility must have a list of microorganisms of clinical significance which must be developed using a risk assessment process to specify those microorganisms that, if detected on the sampled tissue specimens when tested for bioburden, will result in discard of the skin.
- (6) Microbial growth detected when the sample/specimens are cultured must be reported by the manufacturer to the medical practitioner who is treating the recipient of the human skin.
- (7) Where antimicrobial agents have been used, validation of bioburden test must include neutralisation of the antimicrobial agents present in the sample.
- (8) If terminal sterilisation is performed on the skin, the manufacturing process must comply with the requirements of Annex 1 of the Code of GMP for Medicinal Products, available on the TGA website <http://www.tga.gov.au/industry/manuf-pics-gmp-medicines.htm#technical>.
- (9) Human skin must be sealed within a sterile container and at least double packaged so as to
 - (a) prevent ingress/egress of material other than gas sterilant (if applicable); and
 - (b) ensure any breach of integrity will be evident.
- (10) Storage conditions for each type of skin must be established. Conditions for storage of skin must be
 - (a) less than minus 40°C for a maximum period of 5 years; or
 - (b) 2°C to 8°C for no more than 14 days; or
 - (c) 2°C to 8°C for no more than 2 years if stored in greater than 75% glycerol; and
 - (d) these temperatures must be maintained during transport.