

Isofield Beta Kit

Sterile Cleanroom coverall with mandarin collar, hood with integrated facemask & overboots

PRODUCT INFO



MANDARIN COLLAR COVERALL

Two-layer mandarin collar provides secure fit at neck area
Zip flap with double-sided tape prevents ingress and egress of particles

Low-linting, anti-static fabric suitable for chemo handling

Elasticated thumb loops

Back elastic to prevent bellows effect



HOOD WITH INTEGRATED FACEMASK

Integrated mask with two ties for quick and easy donning

Latex-free enclosed elastic face opening for comfort fit

Extra-long yoke for added protection



OVERBOOTS

Extra long — 50cm knee height
Two ties for added security
Anti-slip sole



QUALITY ASSURANCE

Type 5/6 certified

Manufactured in a facility operating under ISO 9001:2015 quality management system

Processed in a NEBB certified ISO Class 5 cleanroom

STORAGE & SHELF LIFE

Store in a dry, cool place (<40°C) away from direct sunlight

Do not expose open cartons to prolonged direct fluorescent light

Five (5) years from date of manufacture

CLEANROOM COMPATIBILITY

GMP Grade A cleanroom
GMP Grade B cleanroom

ISO Class 4 cleanroom
ISO Class 5 cleanroom

Class 10 cleanroom
Class 100 cleanroom

APPLICATIONS

Pharmaceutical product preparation

Cleanroom cleaning and preparation

Aseptic filling & labelling

Medical device manufacturing

Handling of active materials

Blending operations for biotechnologies

Handling chemotherapy in hospital pharmacy


PACKAGING

1 set (hood/coverall/boots) per sealed inner bag,

1 inner bag per sealed outer bag,

40 outer bags per carton liner with twist tie (XS-2XL),

35 outer bags per carton liner with twist tie (3XL-4XL)

 Three items are aseptically folded

PRODUCT CODE

REF

80451

XSMALL	80451XS	XLARGE	80451XL
SMALL	80451S	XXLARGE	80451XXL
MEDIUM	80451M	3XLARGE	80451XXXL
LARGE	80451L	4XLARGE	80451XXXXL



MATERIAL PERFORMANCE PARAMETERS

DESCRIPTION	UNITS	METHOD	SPECIFICATION	TYPICAL
Basic weight PP/PE film laminate	g/m ²	ISO 9073-1-1989	±2	60
Hydrostatic head	mmH ₂ O	ISO 811-1981	≥100	213
Air permeability	l/m ² /S	GB/T5453	≥	2000
Surface resistivity	Ω / sq	ASTM D257	Static dissipative	10 ¹⁰
Overboot slip resistance	Coefficient of Friction (COF)	ASTM D1894	≥0.5	0.6 (Static) 0.5 (Dynamic)

HELMKE DRUM TEST RESULT CLASS 1

PARTICLE SIZE	CUMULATIVE RELEASE RATE (COUNTS/MIN)	SPECIFICATION	CLASS	TEST METHOD
≥ 0.3µm	743*	Less than 2,000	1	IEST-RP-CC003.4
≥ 0.5µm	318*	2,000 - 20,000	1	IEST-RP-CC003.4
≥ 5.0µm	43*	20,000 - 200,000	1	IEST-RP-CC003.4

*Test carried out on coverall and hood. Typical results.

PERMEATION TEST AGAINST CHEMO DRUGS

CHEMOTHERAPY DRUGS	BREAKTHROUGH TIME	TEST METHOD
Carmustine	30 min	ASTM F739-20
Cisplatin	> 480 min	ASTM F739-20
Cyclophosphamide	> 480 min	ASTM F739-20
Doxorubicin HCl	> 480 min	ASTM F739-20
Etoposide	> 480 min	ASTM F739-20
Fluorouracil	> 480 min	ASTM F739-20
Methotrexate	> 480 min	ASTM F739-20
Paclitaxel	> 480 min	ASTM F739-20
Thiotepa	60 min	ASTM F739-20

*Results achieved under controlled laboratory conditions, by accredited ISO 17025 third party testing laboratory

**Mask not tested

TECHNICAL PROPERTIES

TEST REFERENCE	EXPLANATION	TEST RESULTS
EN 14325:2004 EN ISO 6530:2005	Repellency to chemicals	10% Sodium hydroxide Level 3
		30% Sulphuric acid Level 3
		O-Xylene Level 2
		Butan-1-ol Level 2
		70% Isopropyl alcohol Level 2
		70% Ethanol Level 2
EN 14325:2004 EN ISO 6530:2005	Resistance to penetration by chemicals	10% Sodium hydroxide Level 3
		30% Sulphuric acid Level 3
		O-Xylene Level 3
		Butan-1-ol Level 3
		70% Isopropyl alcohol Level 3
		70% Ethanol Level 3
EN 14325:2004 EN ISO 9073-4:1997	Trapezoidal tear resistance	Machine direction Class 2
		Cross direction Class 2
EN 14325:2004 EN ISO 13934-1:2013	Tensile strength	Machine direction Class 1
		Cross direction Class 2
EN ISO 13982- 2:2004 EN ISO 13982- 1:2004 (Type 5)	Inward leakage of aerosols and fine particles into suits	Pass
	IL _{82/90}	0.544%
	IL _{8/10}	0.233%
EN 14325:2004 EN ISO 12947-2:2016	Abrasion resistance	Class 2
EN 14325:2004 EN ISO 7854:1997, Method B	Flex cracking resistance	Class 6
EN 14325:2004 EN 863:1995	Puncture resistance	Class 1
EN 14325:2004 [5.5]	Seam strength	Class 2
EN 13034:2015 + A1:2009 ISO 17491-4:2008 (Type 6)	Resistance to penetration by a spray of liquid (Spray Test)	Pass
In-house AQL 1.5	Test plan for major defect	Pass
EN ISO11137 Part 2:2015	Sterility validation	SAL 10 ⁻⁶



Hood with Integrated Tie-on Facemask

FACEMASK MATERIALS

Outer layer	Non-woven spunbond polyester
Filtration Layer	Non-woven meltblown polyester
Inner facing layer	Non-woven polypropylene / polyethylene
Tie-tapes	Non-woven polyester

FACEMASK FILTRATION PROPERTIES

Particle Filtration Efficiency (PFE) @ 0.1 Micron	94%
Bacterial Filtration Efficiency (BFE) @ 0.3 Micron	97%
Differential Pressure (ΔP), mm H ₂ O/cm ²	6.8

LOADING

	EURO-PALLET	STANDARD PALLET
Pallet size	W80 L120cm	W100 L120cm
Gross weight	13.31 - 16.76kg	13.31 - 16.76kg
Carton size	W38 L58 H47cm	W38 L58 H47cm
Nett weight	10.51 - 13.96kg	10.51 - 13.96kg
Air freight pallet	Max height: 109cm Layers: 2 Cartons: 8	Max height: 109cm Layers: 2 Cartons: 10
Sea freight pallet	Max height: 156cm Layers: 3 Cartons: 12	Max height: 156cm Layers: 3 Cartons: 15

DOCUMENTATION



CERTIFICATE OF CONFORMANCE (COC)
CERTIFICATE OF ANALYSIS (COA)
CERTIFICATE OF PROCESSING (COP)

Please [email us](#)



FACTORY RELATED CERTIFICATIONS
To request ISO9001 Certificate,
please [email us](#)

Country of origin: **China**
HS Code: 6210109000

This data sheet and any other claims made by or on behalf of Isofield shall not be taken as a warranty of merchantability or as a statement that any Isofield products are suitable for a specific purpose. Isofield shall not be held responsible for the end user's choice of product for a particular application.



EUROPE

ISOFIELD (IRELAND) LTD
70 Northumberland Road, Ballsbridge Dublin 4,
Ireland T +44 (0) 1638 6762 39

ASIA

ISOFIELD SDN BHD
6 Jalan Gudang 16/9, Seksyen 16, 40200, Shah Alam,
Selangor, Malaysia, T +603 5512 1709

CONTACT

www.isofield.com
info@isofield.com