Product Data Sheet

Product:	IsoCoat Zytex®	
Trademark:	SAFE®	
REF:	435	
Manufacturer:	DACH Schutzbekleidung GmbH & Co. KG	

Classification:	CAT III according to the Personal Protective Equipment (PPE) Regulation (EU) 2016/425. Class I of Regulation (EU) 2017/745 on medical devices; UMDNS code: 11-897.		
Protection class:	**Type PB [6]-B**	EN 13034:2005+A1:2009	Protective clothing against liquid chemicals
		EN 14126:2003+AC:2004	Protective clothing against infective agents
		EN ISO 13688:2013	Protective clothing - General requirements
			
Materials:	SMS-PP-nonwoven coated with PE-film.		
Product description:	The SAFE® IsoCoat Zytex® is a protective gown that offers maximum all-round protection - back and front! It protects the wearer against blood, viruses, bacteria, contaminated particles and liquid aerosols according to EN 14126. Also suitable for handling cytostatic drugs. The gown is maintenance-free due to its single use and thus offers increased safety and protection. Thanks to the signal colour coding, it saves time and effort in everyday life. The gown fastens at the neck with a tie. The knitted cuffs are free from natural latex and the tie belt around the waist ensure a perfect fit and excellent coverage, even in combination with protective gloves. The labelling of the packaging fulfills the requirements of EN ISO 15223-1:2021: “Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements”. Ideal for applications in wet and extremely demanding environments. Possible fields of application: ▪ Hospitals, care facilities, rescue services ▪ Animal welfare ▪ Microbiological laboratories ▪ Biotechnological industry ▪ Sewage work, waste disposal		

Product performance:

Physical Properties

Property	*Standard*	*Unit*	*Result*	*EN-Class/Pass*
Abrasion resistance	EN ISO 12947-2:2016	Cycles	> 40	Pass
Flex cracking resistance / at -30°C	EN ISO 7854:1997	Cycles	>50000 / >4000	6
Tear resistance (trapezoidal)	EN ISO 9073-4:1997	N	>20	Pass
Tensile strength	EN ISO 13934-1:2013	N	>30	Pass
Puncture resistance	EN 863:1995	N	>5	Pass
Seam strength	EN ISO 13935-2:2014	N	>50	Pass

Resistance against penetration by liquid chemicals accordingly EN ISO 6529:2003:

Chemical	*Repellency-index [%]*	*EN-Class*	*Penetration-index [%]*	*EN-Class*
Sulphuric Acid (30%)	>90	3	<1	3
Sodium Hydroxide (10%)	>90	3	<1	3

Resistance against permeation by liquid cytostatic drug accordingly EN ISO 6529:2013:

Chemical	*Breakthrough time (min)*	*EN-Class*
Cytostatic drug (5mg/ml)	>480	6

Protective gown is unsuitable for use with Butan-1-ol o-xylene, and organic chemicals.

Protection against infective agents accordingly EN 14126:2003/AC:2004

Test method	*Standard*	*Unit*	*Result*	*EN-Class*
Resistance to Penetration by Blood-Borne Pathogens - Test method using Phi-X174 Bacteriophage	ISO 16604:2004 Methode D	kPa	3,5	3
Resistance to Wet Microbial Penetration	EN ISO 22610:2006	min	> 75	6

	Resistance to Liquid Aerosol Penetration	ISO 22611:2003	CFU*	$Log_{10} > 5$	3
	Resistance to Dry Microbial Penetration	EN ISO 22612:2005	CFU*	$Log_{10} \leq 1$	3
	*CFU = Colony forming units				
	The testing has been performed on the garment material. Seams and knitted cuffs have not been tested . Resistance to ignition has not been tested				

Sizes and Dimensions:	Size	Length (cm)	Width (cm)
	M	120	130
	L	130	140
	XL	140	150

Colour:	Yellow	
Packaging and variants:	**Packaging**	**Quantity**
	Bag	5 pcs.
	Shipping Carton	50 pcs.
GTIN:	435/M	4049825007135
	435/L	4049825007142
	435/XL	4049825007159
Use:	For single use only. Read instructions before use. Check for any damages before use and ensure that all seams and closures are intact. Do not use if you see any damage.	
Storage:	Store dry in original packaging without direct sunlight. (see packaging) If the storage conditions are observed, the product has a storage life of 5 years. (see labeling on the product)	
Environmental sustainability and disposal:	In the case of contaminated products, the type and extent of contamination determines the disposal, and the applicable laws and regulations of the relevant country must be followed. A non-contaminated product can be thermally recycled or disposed of in landfills without releasing toxic substances.	