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Read the user information carefully and keep it near the workstation. Employees should be taught how to use the emergency cleaning kit at least once a year. Ignoring the user information can impair the performance of the spill kit components and be harmful to the health of the user and the environment.

2 General information

2.1 Manufacturer

BERNER INTERNATIONAL GMBH

2.2 CE mark

CE 0299 In accordance with PPE¹ Directive 89/686/EEC [1] for complex PPE (category III), based on DIN EN 467 [2]; DIN EN 374, Parts 1-3 [3]; DIN EN 166 [4]; DIN EN 149 [5]. EC type test (type test certificate in annex), certification and control measures by Notified Body "0299".

2.3 Notified Body "0299"



Technical Committee for Personal Protective Equipment, Testing and Certification Body of BG-PRÜFZERT, Centre for Safety Technology, Klinkerweg 4, 40699 Erkrath, Germany.

2.4 DGOP and ESOP



The **BERNER SpillKit XP** contains all of the components listed in section 4.2 of QuapoS [6] and therefore complies with German Society of Oncology Pharmacy (**DGOP**) and European Society of Oncology Pharmacy (**ESOP**) recommendations for a spill kit.

2.5 Quality assurance



Tested and certified in accordance with DIN EN ISO 9001:2000 [7] by TÜV Product Service GmbH (certificate in annex).

2.6 Copyright and industrial property rights



The **Z*** product group symbol is a registered and protected trademark. Infringement of industrial property rights will be prosecuted. BERNER INTERNATIONAL GMBH assumes no warranty or liability for **BERNER SpillKit XP** components that are employed beyond the scope of their intended use. For translations into foreign languages, the German version of the user information is binding. The content can be changed at any time and without notice. This user information is the property of BERNER INTERNATIONAL GMBH and may not be forwarded to third parties, copied, photocopied or used for promotional purposes, either wholly or in part, without written consent. Subject to technical and production-related changes.
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3 Description

The emergency cleaning kit is type tested and certified for safe disposal of small quantities of spilt CMR² drugs (e.g. cytostatic drugs). The **BERNER SpillKit XP** contains a complete set of personal protective equipment, a warning sign and a pen for marking out the accident site, cleaning utensils for dry and liquid contamination as well as broken glass, waste disposal utensils and an accident report form.

3.1 Contents of BERNER SpillKit XP

Item No.	Name of Item	Quantity/Pairs	Item No.	Name of Item	Quantity/Pairs
BI-4104	BERNER SpillKit XP , size S->M *	1	Tools		
BI-4114	BERNER SpillKit XP , size L->XL**	1	120014	ChemoSorb pad	1
Personal Protective Equipment (PPE)			121500	ISYSOFT cloths	4
125520	Protective overall, size M *	1	121516	Scoop	1
BI-4020	Protective gloves, size M *	1	121513	Sweeper	1
121550	Yellow protective gloves, size M *	1	121514	Tongs	1
125540	Protective overall, size XL **	1	121518	Bottle, Distilled water	500 ml
BI-4040	Protective gloves, size XL **	1	121512	Waste bag, blue	1
121560	Yellow protective gloves, size XL **	1	121510	Special waste bag, white	1
125501	Protective overshoes, universal	1	13147	Cable ties	2
121270	FFP3 respirator mask, universal	1	121135	LDPE Minigrip bag	1
121400	Safety goggles, universal	1	120099	User guide	1
Tools			120353	Accident report	1
121515	Marker pen	1	121012	Box	1
121013	Warning sign	1			

* in BI-4104; ** in BI-4114

¹ Personal Protective Equipment.
² Carcinogenic, Mutagenic, toxic to Reproduction.

3.2 Usage



The emergency cleaning kit must **only be used once** to dispose of spilled cytostatic drugs. Do not reuse individual utensils either.

3.3 Disposal



After use, all BERNER SpillKit™ XP components should be treated as waste requiring special supervision (waste code: 18 01 08* in accordance with 2000/532/EC [8]). Use the waste disposal utensils provided. Only approved specialist waste disposal companies may collect, transport and dispose of used kits.

3.4 Storage and transport



Dark (away from direct UV light and sunlight); cool (+15 to +40°C); dry; no contact with pointed and/or sharp objects. Away from equipment or installations that can produce ozone (e.g. through mercury vapour lamps, high-voltage equipment, etc.); avoid direct contact with metals, e.g. copper, manganese, magnesium and iron; avoid contact with oil-based antiseptic phenols and their derivatives, fats, petrolatum, petroleum, paraffin or other similar compounds. Do not use oxidising cleaning agents.

Fragile.

3.5 Date of manufacture



1st + 2nd digit = month, 3rd-6th digit = year.

3.6 Shelf life



Entire BERNER SpillKit™ XP: 3 years from the date of manufacture.

3.7 LOT number



LOT number: 4 digits, allocated consecutively.

4 Instructions for use

EC Directive 2000/54/EC [9] and the relevant national regulations (e.g. Germany: ChemG [10], GefStoffV [11], TRGS 525 [12]) specify the behaviour that is required in situations in which employees are exposed to unusually high concentrations of hazardous carcinogenic substances. Appropriate precautions need to be taken in this regard. Employers have an obligation and responsibility to carry out a preliminary risk analysis, produce a user guide and train all relevant employees at least once a year. This should be recorded in writing. Keep a BERNER SpillKit™ XP ready and affix brief directions for use. Before using the kit, analyse potentially dangerous situations, e.g. during transportation, delivery, storage, production, application, cleaning and disposal, etc.

In the event of an accident resulting in cytostatic contamination, please follow the instructions below:



Step 1: Keep calm.

Always deal with personal contamination before material contamination. In the event of contact with skin, rinse immediately in plenty of cold running water. Do not use soap. In the event of contact with the eyes, rinse immediately with plenty of water or isotonic saline solution for at least 10 minutes. Remove contaminated pieces of clothing immediately. If possible, ask someone else for help. Please note that decontamination should only be performed by trained staff.



Step 2: Follow the brief directions for use/user guide.

The brief directions for use should be kept near the workstation and visible. Follow the individual steps practised at your annual training session.



Step 3: Put on PPE.

First protect those involved. Put on the appropriate PPE and ensure that the person assisting you also has sufficient protection. Protective clothing must be put on in the correct order:

→ Put on the **respirator mask**. Hold the mask in your hand with the straps hanging down (1). Place the mask under your chin. Guide the short strap over your head as far as the nape of your neck and the long strap over the back of your head (2). Adjust the nosepiece to fit your nose (3). Cover the half-mask with both hands and breathe out strongly (4). The mask will lift up. If air escapes at the edge of the mask, move the mask into the correct position and adjust the nosepiece to fit your nose. Please note that facial hair and scars can impair the fit of the mask.



→ Put on the **safety goggles**. Use the head strap to adjust them and ensure a secure fit. Safety goggles can be worn over corrective glasses.



→ Put on the **Z* protective overall for use with cytostatic drugs**: undo the zip and put your arms and legs inside the overall. Fasten the zip and press studs and pull the hood over your head.



→ Put on the blue **Z*** protective gloves for use with cytostatic drugs and pull the cuffs over the ends of the overall sleeves.



→ Now pull the yellow protective gloves over the blue **Z*** gloves.



→ Put on the **Z*** protective overshoes for use with cytostatic drugs.



Step 4: Mark out and close off the accident site.

Secure the site of the accident to prevent the spread of contamination (this applies particularly to freely accessible areas, e.g. stations, corridors, etc.). Liberally mark out the accident site using the pen provided and close off the affected area with the warning sign. Take steps to prevent turbulence: switch off the ventilation system, close windows and doors and stop people using the area. In the event of a spillage inside a safety cabinet, switch on the ventilation and leave it running.



Step 5: Dispose of the spillage and clean as directed.

Please note that the gloves do not usually provide adequate protection against cuts. The tongs or sweeper should therefore be used for glass and sharp fragments. Liquid contamination is absorbed using ChemoSorb pads and cloths: spread the pad out over the spill liquid and it will soon turn into a jelly-like mass. For contamination in powder form, use the distilled water and ISYSOFT cloths: place the dampened cloths over the spillage. Always clean from the outside in. Do not use a hand brush or other similar tool as this produces turbulence.



Step 6: Place the contamination in the blue waste bag.

Pick up glass and sharp fragments with the tongs and place in the box. Use the spatula and scoop for pads and cloths. Always carry out several stages of cleaning (basic cleaning -> follow-up cleaning, see section 6). First place the contamination in the box. Then put the box, tools and cleaning utensils in the blue waste bag and seal with a cable tie.



Step 7: Place PPE and blue waste bag in the white special waste bag.

Place the blue waste bag in the white special waste bag. Take off the protective clothing and place it in the white special waste bag. This must be done in the correct order: 1. Yellow gloves 2. Safety goggles 3. Respirator mask 4. Overshoes 5. Overall 6. Gloves for use with cytostatic drugs. Now close the white special waste bag with the second cable tie. Follow the disposal instructions in section 3.3.



Step 8

Shower well.



Step 9

If necessary, consult a doctor, particularly if you were contaminated personally.



Step 10

Write a precise accident report. You can use the accident report form provided for this. Information can vary from country to country but the following applies to Germany: minor injuries and an inability to work lasting no more than 3 days must be recorded in the first-aid book. An inability to work lasting more than 3 days must be reported as an accident and your employer or an authorised representative must be informed. The accident must be reported within 3 days to: the accident insurance fund (x 2), the health and safety supervisor (x 1), those responsible for in-house documentation (x 1) and the works council if appropriate (x 1). The insured also receives a copy of the accident report on request. Inform the employee responsible for health and safety at work and the company doctor about the accident.

After an accident, hold a meeting and/or further training if necessary. In all cases, ensure you obtain a new BERNER SpillKit™ XP.

5 Product features

5.1 Z* protective overall and overshoes for use with cytostatic agents



Features

Maximum protection and comfort: type tested and certified as complex PPE (category III); optimal personal protection; impervious to liquids in coated areas; pleasant and comfortable to wear; material is low in lint with low particle generation; elasticated at the ends of the arms/legs and feet. **Protective overall for use with cytostatic agents:** raised neckline; zip with overlapping strap and hood. **Area of application:** protective overall and overshoes for handling CMR drugs (e.g. cytostatic and virustatic agents). **Protection capacity:** not guaranteed for all CMR drugs and chemicals. The coated side should always face outwards. **Before use:** check for damage. Do not use protective overalls or overshoes that are damaged.

5. Product features



Types

Z⁺ protective overall for use with cytostatic agents

Size	M	XL
Item no.	12 55 20	12 55 40
Colour	Blue	
Chest measurement (cm)	76-100	100-124
Height (cm)	152-170	170-194

Z⁺ protective overshoes for use with cytostatic agents

Size	Universal
Item no.	12 55 01
Colour	Blue/white

Material properties

Material	Spun polypropylene
Material weight	42 g/m ²
Liquid-tight coating	Polyethylene (approx. 25 µm thick)
Total weight of overall	212 g (M) or 249 g (XL) [± 10 g]
Total weight of a pair of overshoes	30 g [± 5 g]

Protection from mechanical hazards:

Requirement	Performance Level	
Abrasion resistance (1-6) in accordance with EN 530 [13]	2	
Perforation resistance (1-5) in accordance with prEN 863 [14]	1	
Seam resistance (1-5) in accordance with ISO 5082 [15]	2	
Tear propagation resistance (1-5) in accordance with ISO 4674 [16]	Longitudinal	Transverse
	2	3

Slip resistance of overshoes:

The slip resistance of the overshoes was tested in accordance with DIN 4843, Part 100 (08.93) [17]. The overshoes are fit for their intended purpose.

Protection from chemical hazards; permeation³ in accordance with EN 374, Part 3

Chemical	Breakthrough Time ⁴ [min]	Performance Class (1-6) ⁵
Carmustine	> 140	4
Amsacrine	> 480	6
Cisplatin	> 480	6
Cyclophosphamide	> 480	6
Doxorubicin	> 480	6
5-fluorouracil	> 480	6
Methotrexate	> 480	6
Paclitaxel	> 480	6
Thiotepa	> 480	6
Vincristine	> 480	6
30% NaOH	> 480	6

Protection from liquids

Type 4 protective clothing for use with chemicals: spray test performed in accordance with DIN EN 468 (09.94) [18].

Spray-tight joins between the different parts of the clothing.

Penetration	Size of Area	Number of Areas
No	0	0



Maintenance information

Do not wash, iron, tumble dry or dry clean.

CE marking

In accordance with PPE Directive 89/686/EEC for complex PPE (category III), based on DIN EN 467; DIN EN 374, Part 3; DIN EN 340 [19]. EC type test, certification and control measures by Notified Body "0299".

³ Movement of a chemical through a material on a molecular level.

⁴ At a permeation rate of 1 µg/min-cm².

⁵ The performance class does not reflect the actual duration of protection at the workstation.

5. Product features

5.2 Protective gloves

5.2.1 Z* protective gloves for use with cytostatic agents



Features

Maximum protection and comfort: type tested and certified as complex PPE (category III); anatomically shaped; extra long, rolled cuff; good grip; good tactile sensitivity; AQL⁶ = 1.5. **Area of application:** protective gloves for handling CMR drugs (e.g. cytostatic and virustatic agents) and micro-organisms. **Protection capacity:** not guaranteed for all CMR drugs and chemicals. **Before use:** check for damage. Do not use damaged gloves.

Types

Size	M or 7½	XL or 9
Item no.	BI-4020	BI-4040
Colour	Blue	

Material properties

Natural latex (latex allergen < 0.5 µg/g); low protein (protein = 17 µg/g); powder free in accordance with TRGS 540 [20]; latex and carbamates can trigger allergies.

Material thickness

Measurement Points	Material Thickness d (Measured Twice)
Finger, 15 mm from the end of the tip	≥ 0.91 mm
Middle of the palm	≥ 0.78 mm
Shaft, 25 mm from the end of the shaft	≥ 0.52 mm



Protection from mechanical hazards tested in accordance with EN 388 [21]. Performance level⁷ coding as follows:

Requirement	Performance Level
Abrasion resistance (1-4)	1
Cut resistance (1-5)	0
Tear propagation resistance (1-4)	X
Stab resistance (1-4)	X



Protection from chemical hazards; permeation in accordance with EN 374, Part 3:

Chemical	Breakthrough Time ⁸ [min]	Performance Class ⁹ (1-6)
Bleomycins	> 180	4
Carboplatin	> 180	4
Carmustine	> 60	3
Isopropanol/carmustine	> 30 / > 120	2 / 4
Cisplatin	> 180	4
Cyclophosphamide monohydrate	> 120	4
Doxorubicin hydrochloride	> 180	4
Daunorubicin hydrochloride	> 60	3
5-fluorouracil	> 180	4
Methotrexate	> 180	4
Mitomycin	> 180	4
Vinblastines	> 180	4
Vincristines	> 180	4
40% sulphuric acid	> 480	6
10% sodium hydroxide	> 480	6
5% glutaraldehyde	> 480	6
30% NaOH	> 480	6



Protection from bacteriological hazards; penetration⁸ in accordance with EN 374, Part 2:

Feature	Evident?
Tears (visual)	No
Cracks (visual)	No
Holes (visual)	No
Air bubbles (air leakage test)	No

In accordance with current knowledge, it should be assumed that meeting the penetration requirements provides effective protection from microbiological hazards (Paragraph 1 of EN 374, Part 2 and Paragraph 3.2 of EN 374, Part 1).

CE 0299

CE marking

In accordance with PPE Directive 89/686/EEC for complex PPE (category III), based on DIN EN 374, Parts 1-3; ASTM D3577 [22]; DIN EN 388; DIN EN 420 [23]; DIN EN 455, Parts 1-3 [24]. EC type test, certification and control measures by Notified Body "0299".

⁶ Acceptable Quality Level

⁷ If the value is less than 1, the result should be given as "0". "X" means that the test could not be performed.

⁸ Movement of a chemical and/or micro-organism through a porous material on a non-molecular level.

5. Product features

5.2.2 Yellow protective gloves



Features

Lightweight protective gloves that are particularly kind to the skin; anatomically shaped; extremely comfortable to wear; excellent tactile sensitivity; good mechanical strength with extreme sensitivity; aromatic. **Protection capacity:** not guaranteed for all chemicals. These gloves do not usually provide sufficient protection against cuts. **Area of application:** to be worn over the protective gloves for use with cytostatic drugs. **Before use:** check for damage. Do not use damaged gloves.

Types

Size	M	XL
Item no.	121550	121560
Weight	60 ± 3 g	68 ± 3 g
Colour	Yellow	

Material properties

Natural latex, pure cotton velour inside lining; latex and carbamates can trigger allergies.

Thickness	Material thickness d (measured twice) 0.9 ± 0.04 mm
Glove length	300 ± 10 mm

Protection from mechanical hazards tested in accordance with EN 388. Performance level coding⁷ as follows:

Abrasion resistance (1-4)	2
Cut resistance (1-5)	0
Tear propagation resistance (1-4)	1
Stab resistance (1-4)	0



Protection from chemical hazards; permeation in accordance with EN 374, Part 3

Chemical	Breakthrough Time ⁴ [min]	Performance Class (1-6) ⁵
10% hydrochloric acid	> 480	6
Glacial acetic acid	> 10	1
50% sodium hydroxide	> 480	6
37% formaldehyde	> 60	3



Protection from bacteriological hazards; penetration in accordance with EN 374, Part 2:

Feature	Evident?
Tears (visual)	No
Cracks (visual)	No
Holes (visual)	No
Air bubbles (air leakage test)	No



In accordance with current knowledge, it should be assumed that meeting the penetration requirements provides effective protection from microbiological hazards (Paragraph 1 of EN 374, Part 2 and Paragraph 3.2 of EN 374, Part 1).



CE marking

In accordance with PPE Directive 89/686/EEC for complex PPE (category II), based on DIN EN 420. Type test and certification by Notified Body "0194".

0194

Notified Body "0194"

Inspec Certification Limited, The Buckland Wharf GB - Aylesbury, Buckinghamshire HP22 5LQQ.

5.3 FFP3V respirator mask



Features

Half-mask with high filtering capacity, tight-fitting and leakproof. Its soft material, special shape and nose clip ensure it can be easily adjusted to fit the face. Minimal respiratory resistance and the exhalation valve make it extremely comfortable to wear. The threaded elastic strap makes it easy to put on and take off. **Area of application:** protection from solid and liquid particles, e.g. for handling CMR drugs. **Before use:** check for damage. Do not use damaged masks. **Limitation:** laboratory test results can differ from values obtained in practice considerably and, as a result, the useful life of the mask may increase or decrease. Facial hair and scars can impair the fit of the mask and therefore the level of protection.

Type

Size	Universal
Item no.	121270
Colour	White mask, blue valve

Material properties

Particle filter	Synsafe®
Strap	Elasticated material
Nose clip	White metal
Exhalation valve	Nylon casing, rubber disc
Design	Several layers of material patented under the name Synsafe®
Filtration principle	Particles are filtered through the Synsafe® particle filter
Dimensions	155 mm x 115 mm
Weight	Excluding packaging: 18.6 g

5. Product features

The safety system

Degree of particle filtration	
Test Aerosol	Minimum Degree of Filtration
Sodium chloride:	> 99%
Paraffin oil:	> 99%
Gases	Not applicable

Inhalation resistance	
Flow Rate (Constant Flow)	Resistance (mbar)
30 litres/min	≤ 1.0
95 litres/min	≤ 3.0

Exhalation resistance	
Flow Rate (Constant Flow)	Resistance (mbar)
160 litres/min	≤ 3.0

CE 0200

CE marking

In accordance with PPE Directive 89/686/EEC for complex PPE (category III), based on DIN EN 149. Type test, certification and control measures by Notified Body "0200".

0200

Notified Body "0200"

Force-Dantest Cert, DK-2605 Brøndby, Park Alle 345.

5.4 Safety goggles



Features

Full vision; non-fogging; can be worn over corrective glasses. **Area of application:** protection from mechanical risks, liquids and coarse dust. **Protection capacity:** does not provide protection from high-speed particles, laser beams, temperatures of over 55°C, arcing faults, molten metals, contagious substances or organisms. **Before use:** check for damage. Do not use goggles if the mark is missing or illegible.

Type

Size	Universal
Item no.	121400
Colour	Transparent

Frame and lens marking

Marking	Protects against	With lenses
GSF 166 3 4 DIN CE 0196 2-1.2 GW 1 S N DIN 0196 CE	Mechanical risks, liquids, coarse dust	Colourless safety lenses

CE

CE marking

In accordance with PPE Directive 89/686/EEC for complex PPE (category II), based on DIN EN 166. Type test and certification by Notified Body "0196".

0196

Notified Body "0196"

DIN CERTCO, Gartenstraße 133, D-73430 Aalen, Germany.

5.5 ChemoSorb pads

Features

For absorbing and setting liquids.

Type

Size	380 x 540 mm ± 10 mm
Item no.	120014
Colour	Natural white

Material properties

Material	Pulp fibre, dual component polyolefin fibre super absorber
Material weight	105 g/m ² ± 7%

Mechanical material properties (average values):

Material thickness	1.3 mm ± 7%
Elastic strength	10 N / 50 mm
Liquid absorption capacity ⁹	≤ 3 litres

⁹ Internal test methods.

5.6 ISYSOFT cloths

Features

Extremely absorbent cloths, particularly suitable for absorbing spilt liquids.

Type

Size	400 x 300 mm
Item no.	121500
Colour	Natural white

Material properties

Material	"Airlaid" paper (paper, manufactured dry, made of cellulose and a latex binding agent, embossed), finely structured
Weight	80 g/m ²
Liquid absorption capacity ^d	≤ 65 ml

5.7 Further BERNER SpillKit™ XP components

Marker pen

Item no.: 121515; Colour: black, waterproof on almost all materials, 1.5-3 mm stroke thickness.

Warning sign

Item no.: 121013; Cardboard display, size: 210 x 150 mm (set up), warning text in German and English.

Scoop

Item no.: 121516; Dustpan, material: plastic, 210 x 200 mm (pan size), colour: assorted, without rubber lip.

Sweeper

Item no.: 121513; Material: plastic, size: 135 x 100 mm, colour: dark blue, nitro-resistant, beaded back, untoothed.

Tongs

Item no.: 121514; Dried beech wood, size: 300 mm, no chemicals in the manufacturing process.

Bottle of distilled water

Item no.: 121518; Plastic bottle, 500 ml of distilled water.

Waste bag

Item no.: 121512; Material: polyethylene, size: 576 x 1000 mm, thickness: 50 µm, colour: blue, weight: 48 g ± 5 g

Special waste bag

Item no.: 121510; Material: polyethylene, size: 700 x 1000 x 0.1 mm, printed with „Zytotoxische und zytostatische Arzneimittel / Cytotoxic and cytostatic drugs / Farmaci Citotossici e Citostatici / Medicamentos Citotóxicos y citostáticos / Médicaments dytotoxiques et cytostatiques"
 Colour: white, weight: 127 g ± 5 g

Cable ties

Item no.: 13147; Material: plastic, size: 200 x 3.6 mm, colour: white.

LDPE Minigrip bag

Item no.: 121135; Material: polyethylene, size: 300 x 400 x 0.05 mm, colour: transparent, resealable.

6 Cleaning

Cytostatic contamination must be cleaned thoroughly several times. In the main, testing focused on cleaning contaminated primary packaging although the results also provide a starting point for the problems caused by accident-related cytostatic contamination. The following table contains the results¹⁰ of individual swab tests [25]. Different cloths and solvents were tested on a glass plate:

Results of two-stage swab tests

Solvent used for swab test		Proportion of Substance Removed ¹¹ (Mean Recovery Rate in Eluate)		
Stage 1	Stage 2	Fluorouracil	Methotrexate	Etoposide
Ethanol	Isopropanol	85%	59%	94%
0.05M caustic soda	Isopropanol	99%	95%	92%

Preference should therefore be given to two-stage cleaning (using a combination of caustic soda and isopropanol) over one-stage cleaning. The more frequent the cleaning (at least 3-4 times), the more effective it is (95-99%).

Removal of pen markings: the markings usually disappear completely during the multi-stage cleaning process. Use isopropyl alcohol, for example, for removal.

7 Literature

Literature in "GB" & "D". Contact: BERNER INTERNATIONAL GMBH

¹⁰ The best cleaning agent/combination of cleaning agents for the relevant cytostatic drug is highlighted grey.

¹¹ Sum of the substance amounts recovered on both cloths.