



SpillKit XP Duo

Benutzerinformation

Notfall- und Reinigungsset für verschüttete Zytostatika

User Information

Emergency cleaning kit for spilled cytotoxic drugs

Empfohlen durch:



berner

1. User information

Read the user information carefully and keep it in the SpillKit. In accordance with the applicable legal guidelines, for example the German Employers' Liability Insurance Association for Health Service and Welfare Work (BGW) and the „Quality standard for pharmaceutical oncological service (Quapos) all personnel who are involved in handling cytostatics 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 SpillKit components and be harmful to the health of the user and the environment.

2. General information

2.1 Manufacturer Berner International GmbH

2.2 DGOP and ESOP

The BERNER SpillKit contains all of the components listed in section 4.2 of Quapos and therefore complies with German Society of Oncology Pharmacy (DGOP) and the European Society of Oncology Pharmacy (ESOP) recommendations for a SpillKit.

2.3 Quality Assurance

Tested and certified in accordance with EN ISO 9001:2008 by the TUV Product Service GmbH (certificate see www.berner-safety.de).

2.4 Copyright and Industrial Property Rights

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3. Description

The procedure of cleaning up cytotoxic spills should, if at all possible, be carried out by two people. The emergency cleaning set Berner **SpillKit XP Duo** contains two complete sets of personal protective equipment, a warning sign, a special marker pen for marking off the accident site, cleaning utensils for dry and liquid contamination as well as broken glass, waste disposal utensils and an accident report form (only relevant for Germany) to ensure the safe disposal of small quantities of spilt CMR drugs (e.g. cytostatic drugs).

3.1 Contents BERNER SpillKit

Order No.	Item Description	Quantity
100101	BERNER SpillKit XP Duo Gr. M + M	1
100102	BERNER SpillKit XP Duo Gr. M + L	1
100103	BERNER SpillKit XP Duo Gr. M + XXL	1
100104	BERNER SpillKit XP Duo Gr. L + L	1
100105	BERNER SpillKit XP Duo Gr. L + XXL	1
100106	BERNER SpillKit XP Duo, Gr. XXL + XXL	1

Item Description	Quantity / Pair		Quantity / Paar
Personal Protective Equipment (PPE) per Set		Tools	
Cytostatic protective overall	2	Scoop	1
Cytostatic protective gloves	2	Sweeper	1
Chemical protective gloves	2	Tongs	1
Cytostatic protective overboots	2	Bottle, distilled water (500 ml)	1
FFP3 respirator mask	2	Waste bag, transparent	1
Safety goggles	2	Special cytotoxic waste bag, white	1

Additional Tools		Cable ties	2
Marker pen	1	LDPE Minigrip bags	2
Warning sign	1	User guide	1
ChemoSorb Pad	1	Accident report (only for Germany)	1
ISYSOFT Wipes	6	Cardboard box	1

3.2 Usage

The emergency and cleaning kit must only be used once to dispose of spilt cytostatic drugs.

Do not reuse any parts of the SpillKit contents!

3.3 Disposal

After use, all BERNER SpillKit components should be treated as waste requiring special supervision (waste code: 18 01 08* in accordance with 2000/532/EC. 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 (+5 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. Breakable.

3.5 Durability

The components of the SpillKit are subject to aging. This process known as degradation can lead to the loss of protective functions or general effectiveness. SpillKits which have exceeded their use-by date should therefore not be used for the clean up of „real“ accidents/spills. We recommend using these SpillKits for training and instruction purposes of personnel.

Shelf life complete BERNER SpillKit: 3 years from date of manufacture.

3.6 LOT-Number

LOT-No.: 4 Digits, allocated consecutively.

4. Instructions for use

The EC Directive 89/686/EEC, and the successor, the new EC directive 2016/425 plus any the relevant national regulations (e.g. in Germany: ChemG, GefStoffV, TRGS 525) 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 ready and affix brief directions for use. Before using the kit, carry out a risk assessment to 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 user instructions should be kept, clearly visible, near the workplace. Follow the individual steps exactly as you have been taught in the annual training session. Berner Internation offers a pictorial quick guide as a poster suitable for cleanrooms.

Step 3: Put on PPE!

First protect all affected personnel. Put on the appropriate PPE and also ensure that the person assisting you also has sufficient protection.

Protective clothing must be put on in the correct order:

1. Put on the respirator mask. Hold the mask in your hand with the straps hanging down. Guide the first strap over your head as far as the nape of your neck. Place the mask under your chin. Guide the the second strap over the back of your head. Adjust the nosepiece to fit your nose. Cover the half-mask with both hands and breathe out strongly. The mask material will move up and down. 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. **2. 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. **3. Put on the protective overall** for use with cytostatic drugs: Undo the zip and put your arms and legs inside the overall. **4. Put on the blue or buff-coloured** protective gloves for use with cytostatic drugs and pull the cuffs over the ends of the overall sleeves. **5. Then don the green protective gloves** over the blue or buff coloured gloves. **6. Lastly, put on the protective overboots.**

Step 4: Mark clearly 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 spilt 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 transparent 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 at least three cleaning stages first with an alkaline cleaner (> ph 11) and followed by an alcohol (preliminary cleaning > subsequent cleaning). 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: PPE and transparent waste bag in white special waste disposal bag!

Place the transparent 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. Overgloves 2. Safety goggles 3. Overall and Overboots 4. Respirator mask 5. Cytostatic gloves. Now close the white special waste bag with the second cable tie. Follow the disposal instructions in section 3.3.

Step 8: Shower! Shower thoroughly.

Step 9: See a GP. If necessary see a doctor, especially in case of personal contamination.

Step 10: Accident Report

Write a precise accident report. 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. Make sure you comply with your national and local laws. In all cases, ensure you obtain a new BERNER SpillKit.

5. Product properties

5.1. Protection overall and protective overboots

Properties

Maximum protection and wearing comfort protective coverall: Type-tested and certificated as complex PPE category III; Chemical protective equipment type PB [4]; partial body protection. Optimum personal and product protection; impermeable to liquids in coated region, comfortable to wear; material is low in lint and particles. Protective overboots: Elasticated leg with ribbon at ankle. Protective coverall: High neckline, zip with overlapping flap, elasticated sleeves and ankles, hood. Application range: Protective overall for the handling of CMR pharmaceuticals (e.g cytostatics, virostatics) and biological agents (e.g. bacteria and viruses). Protective barrier: Liquid-impermeable coating in the front area. Protective properties: Protection against all CMR drugs or chemicals cannot be guaranteed! In case of exposure to biohazards, which do not correspond to the degree of imperviousness of the protective clothing, bio-contamination of the wearer is possible. Keep away from naked flames and heat sources. Before use: Check for any damage! Do not use damaged coverall or overboots!

Types protective coverall

SpillKit XP Duo	Size	Chest (cm)	Height (cm)	Colour
depending on version	M	92 – 100	170 – 176	white
	L	100 – 108	176 – 182	white
	XXL	116 – 124	188 – 194	white

Types protective overboots

Size	Uni	Colour	white
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Material properties

Material	Tyvek®
Material weight	65 g/m ²
Seams of coverall	blue overtaped

Protection against mechanical hazards

Requirement	Performance level
Abrasion resistance (1-6) to EN 530	2
Puncture resistance (1-5) to EN 863	2
Seam resistance (1-5) to ISO 13935-2	> 75 N
Trapezoidal tear strength (1-5) to ISO 9073-4	6

Protection against chemical hazards

Permeation ¹⁾ tested to EN 14325. Determined for the following substances:	
Sulphuric acid, 30%	Class 6
NAOH, 40%	Class 6
5-Fluorouracil, 10 mg/ml	Class 6
Cyclophosphamide, 20 g/ml	Class 6
Doxorubicin, 5 mg/ml	Class 6
Methotrexate, 25 mg/ml	Class 6
Paclitaxel, 6 mg/ml	Class 6
¹⁾ : Movement of a chemical through material on a molecular level. The performance class does not reflect the actual duration of protection at the workplace!	

Care instructions

Do not wash, do not iron, do not tumble dry, do not dry clean, single use only.

CE-Marking

In accordance with the PPE directive 89/686/EEC for complex PPE category III, based on DIN EN 14605; Manufacturer DuPont.

5.2. Protective gloves BERNER Manu L and Ultranitril

Properties

Maximum protection and comfort: type tested and certified as complex highest level PPE of the category III; good grip, good tactile sensitivity. Area of application: Protective gloves for handling CMR drugs (e.g. cytostatics, virostatics) and biological agents (e.g. bacteria and viruses). Protective capacity: No guarantee for all CMR drugs or chemicals! In case of exposure to biological hazards, which do not correspond to the degree of imperviousness of the protective clothing, bio-contamination of the wearer is possible. Before use: Check for any damage! Do not use damaged gloves!

Types

SpillKit Duo	M	L	XXL	M	L	XXL
Size	7.5	8.5	9	9	9	10
Glove	Manu L			Ultranitril		

Material properties

5.2.1 Protective glove BERNER Manu L

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

Material thickness

Measurement points	Material thickness d (measured twice)
Finger, 15 mm from the end of the tip	≥ 0,96 mm
Middle of the palm	≥ 0,86 mm
Shaft, 25 mm from the end of the shaft	≥ 0,48 mm

Protection from mechanical hazards tested in accordance with EN 388 . Performance level 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 [min]	Performance class (1-6)
Bleomycin 3 mg/ml	> 180	4
Carboplatin 10 mg/ml	> 180	4
Carmustine 4 mg/ ml	> 60	3
Isopropanol 70%	> 30	2
Isopropanol 70% + Carmustine 4 mg/ml	> 120	4
Cisplatin 50 mg/ml	> 120	4
Cyclophosphamide Monohydrate 20 mg/ml	> 480	6
Doxorubicin Hydrochloride 1 mg/ml	> 120	4
Daunorubicin Hydrochloride 1,5 mg/ml	> 60	3
5-Fluorouracil 1,5 mg/ml	> 60	3
Methotrexate 2 mg/ml	> 120	4
Mitomycin 1 mg/ml	> 180	4
Vinblastine 1 mg/ml	> 180	4
Vincristine 1 mg/ml	> 120	4
Sulphuric acid 40%	> 480	6
Sulphuric acid 96%	> 30	2
Sodium hydroxide 10%	> 480	6
Sodium hydroxide 30%	> 480	6
Sodium hydroxide 40%	> 60	3
Glutaraldehyde 5%	> 480	6
Diethylamin (undiluted)	> 30	2

Protection against biological hazards; penetration in accordance to EN 374-2:

Requirement	Present?
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 the PPE directive 89/686/EEC for complex PPE category III, based on EN 14605; EN 374 parts 1-3; EN 166; EN 166; EN 149, EC type test (type test certificate at the end), certification and control measures by the notified body „0299“.

5.2.2 Protective glove Ultranitrite

Properties

Chemical protective glove, anatomically shaped; AQL= 0.65; very good mechanical capacity for extreme sensitivity. Do not use if sensitized to dithiocarbamate and thiazoles. Protective capacity: No guarantee against all chemicals! Area of application: To be worn over the protective gloves for use with cytostatic drugs. Before use: Check for any damage! Do not use damaged gloves!

Glove	Nitrile, latex-free
Colour	mint green

Glove length	320 mm
Material thickness	0,38 mm
Material	inner flock lining

Protection from mechanical hazards, in accordance to EN 388. Coding as follows:

Requirement	Performance class (1-4)
Abrasion (1-4)	4
Cut (1-5)	1
Tear (1-4)	0
Puncture (1-4)	2

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

Chemicals	Breakthrough time [min]	Performance class(1-6)
Methanol	>480	2
n-heptane	>10	6
Sodium hydroxide 40%	>480	6
Sulphuric acid 96%	>60	3

CE-Marking

In accordance with PPE Directive 89/686/EEC for complex PPE (category III), based on EN 420, EN 374, EN 388. EC type test, certification and control measures by Notified Body "0075" Notified body 0075 and 0334. No. 0075: CTC, 4, rue Herman Frenkel, F-69367 Lyon, Cedex 07. No. 0034: ASQUAL, 14 rue des reuillettes, F-75013 Paris, France.

5.3 FFP3 respiratory mask

Properties

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. 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.

Types

Size	Universal
Colour	silver grey

Material properties

Latex-free	complete mask
Dimension	125 mm x 135 mm
Weight excl. packaging	18 g

Degree of particle filtration

Degree of particle filtration	Minimum degree of filtration
Sodium chloride	> 99%
Paraffin oil	> 99%
Dolomite dust test for FFP3- respiratory masks (Dolomite DRB4/15b testaerosol)	passed
Gases	not suitable

CE-Marking

In accordance with PPE-directive 89/686/EEC for complex PPE category III, based on EN 149. Type-tested, certified.

Notified body 0194

INSPEC International Ltd, 56 Leslie Hough Way, Salford, Gt. Manchester, M6 6AJ, England.

5.4 Safety goggles

Properties

Full vision goggles; non-fogging and can be worn over corrective glasses. The elastic strap ensures a firm and fit. 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. Before use: Check for any damage! Do not use goggles if label is absent or illegible.

Version

Size	Universal
Colour	Transparent

Marking of the frame and lens

W 166 DIN CE 0196	Protection against mechanical risks, liquids, large particles
W 1N DIN CE 0196	Non-fogging, colourless plastic lens

CE-Marking

In accordance with the PPE directive 89/686/EEC for complex PPE category II based on EN 166. Type-tested and certified. notified body „0196“. Manufactured by UVEX Arbeitsschutz GmbH, Fürth, Germany. Notified body 0196. DIN CERTCO, Gartenstraße 133, D-73430 Aalen, Germany.

5.5 Further components of the BERNER SpillKit XP

ChemoSorb-Pads	For absorption and binding of liquids
ISYSOFT Wipes	Extremely absorbent cloths, especially suitable for absorbing spilt liquids.
Marker pen	Colour black
Warning sign	Cardboard sign, Size: 210 x 150 mm (upright), Warning instructions in German & English.
Scoop	Material: Plastic, size: 135 x 100 mm, colour: dark blue, nitro-resistant, beaded back, untoothed.
Sweeper	Material: Plastic, size 135 x 100 mm
Tongs	Wood, no chemicals in manufacturing process.
Bottle, distilled water	Plastic bottle, 500ml distilled water.
Waste bag	Material: Polyethylene, size 576 x 1000 mm, thickness: 50 µm, colour: blue, weight: 48 g ± 5g.
Special waste bag	Polyethylene with print: „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 ± 5g
Cable tie	Plastic, size 200 x 3,6 mm, colour: white
LDPE-Minigrip-bag	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. Different cloths and solvents were tested on a glass plate:

Solvent used for swab test		Proportion of substance removed (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.