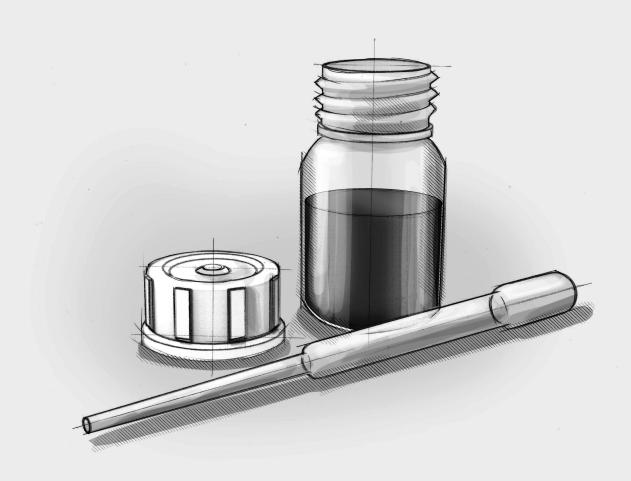
# **SEAL DYE TESTING**

# DP 150 SPECIFICATIONS







# **OVERVIEW**

The DP-150 has taken a sometimes arduous and messy test protocol and reduced it down to its simplest elements. You no longer need to use color metric reference sheets, surfactants and dye pigments to develop a dye solution for the ASTM F-1929 protocol. With the DP-150 the test solution is ready to go right out of the bottle and the kit includes a reference guide so you can quickly identify and evaluate a seal failure. Te DP-150 kit is small and portable so additional kits can be purchased for wide access to encourage pouch and machine performance testing throughout your facility. Stay compliant and test and inspect your medical pouch seal quality ofen for a more confident sterile packaging program.



DP 150 1 of 2



# **OVERVIEW**

### **SPECIFCATIONS**

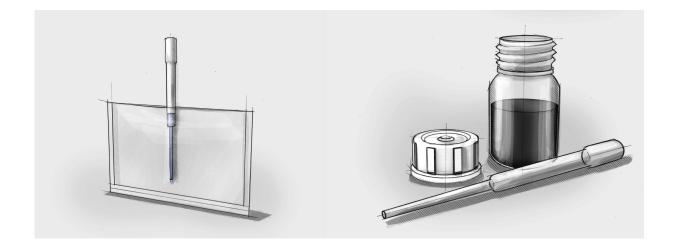
The pathway to sterile device packaging compliance is regular testing of pouch seals through destructive and nondestructive methodologies. Our premixed dye solution is designed to encourage regular seal inspection on your medical device pouches.

# **DP 150 KIT CONTAINS THE FOLLOWING:**

- 1 75ml bottle of premixed testing dye
- 20 disposable droppers
- Instructions for proper use and interpretation of results

### **DP PRO KIT CONTAIN THE FOLLOWING:**

- 30 premixed individual testing pouches for 4 side studies
- 1 Instructions for proper use and interpretation of results
- 1- MSDS sheets included with each kit style



DP 150 1 of 2

# 1. Identification of the preparation and of the company

**Product Identification-**

Trade Name: hawo InkTest Seal Seam Test; 6.061.035

hawo InkTest Pro Seal Seam Test, 6.061.044v

Use of the preparation:

The product is a water-based, surfactant containing and blue coloured ink intended for integrity testing of seals.

Manufacturer:

hawo GmbH Obere Au 2-4 74847 Obrigheim

Phone: +49 (0) 6261-9770-0 E-Mail: info@hawo.com

**Emergency Call:** 

National Poison Information Centre, Medical Toxicology

Unit, London +44 (171) 635 91 91

# 2. Hazards indentification

No classified as dangerous in compliance with Regulation (EG) Nr. 1272/2008 (CLP).

# 3. Composition/information on ingredients

Chemical characterization: Preparation

Name	CAS Number	Concentration	Classification according to Regulation (EG) Nr. 1272/2008 (CLP)
TRITON-X 100	9002-93-1	< 1%	Eye Dam. 1, H318 causes serious eye damages Acute Tox. 4, H302 Harmful if swallowed
Toluidene Blue	92-31-9	< 1%	n/a
Water	7732-18-5	> 98%	n/a

The information is based on our present knowledge. It describes our product from the point of view of safety requirements and therefore does not have not the purpose of assuring particular properties.

DP PRO TEST KIT 1 of 7

### **SVHC:**

This solder product contains a Substance of Very High Concern (SVHC) in quantities higher than the applying limit (> 0,1% (w/w), REACH Regulation (EG) Nr. 1907/2006, Article 57)

#### Contains:

Polyethylene glycol mono (octylphenyl) ether (CAS Number 9002-93-1)

### 4. First-aid Measures

Inhalation: Remove person to ventilated fresh air. With respiratory problems consult a

doctor/medical service.

Skin Contact: Rinse with water. Consult a physician if irritation occurs.

Eye Contact: Immediately flush eye with room temperature, low pressure and clean water.

Seek medical attention if eye irritation occurs.

Ingestion: Rinse mouth with water and drink a glass of water. Never induce vomiting.

Seek medical attention if you feel unwell.

# 5. Fire-fighting measures

Extinguishing media:

There are no restrictions for extinguishing media from this product. Extinguishing media should be chosen matching the surroundings.

Special exposure hazards:

The preparation is not presenting a fire hazard.

Upon combustion (small amounts of) CO, CO2, HCl, SO2 and nitrose fumes are formed.

## 6. Accidental relase mesures

Personal precautions:

Do not inhale vapors.

Avoid eye contact and skin contact.

Caution, wet floor may be slippery.

Environmental protection measures:

Do not allow to enter soil, drains or watercourses.

The information is based on our present knowledge. It describes our product from the point of view of safety requirements and therefore does not have not the purpose of assuring particular properties.

DP PRO TEST KIT 2 of 7

# Methods for cleaning up or taking up:

Take up with absorbent material.

The material should be disposed according to the regulations.

Dispose contaminated materials according to chapter 13 of this material safety data sheet.

# 7. Handling and Storage

### Handling:

Handling according to the Guidelines for Laboratories (e.g. TRGS 526).

# Fire-hazard and explosion-hazard protection:

No specific instructions available.

#### Storage:

No specific requirements for containers or warehouse.

Do not store together with foodstuff.

Storage at room temperature (recommendation: 15°C to 25°C) -

# 8. Exposure controls/personal protection

### Exposure limit values:

No data available.

Occupational exposure controls

# Engineering controls:

No special measures required

Personal Protection

## Common measures:

Keep away from foodstuff.

Wash hands carefully at end of work.

Avoid contact with Eyes and Skin.

### Hand protection:

Protective gloves

#### Eye protection:

Protective goggles

### Skin Protection:

**Protective Clothing** 

The information is based on our present knowledge. It describes our product from the point of view of safety requirements and therefore does not have not the purpose of assuring particular properties.

DP PRO TEST KIT 3 of 7

# 9. Physical und chemical properties

Appearance (20°C): liquid
Colour: blue
Odour: odourless

Boiling point: approx. 100°C / 212°F

Flash point: not applicable

**Explosive properties**: product is not explosive

# 10. Stability and reactivity

# Chemical stability:

Stabile under regular storage and conditions.

Hazardous decomposition products:

In case of fire: see chapter 5 of this material safety data sheet

# Thermal decomposition:

No thermal decomposition under regular storage and conditions.

#### Hazardous reactions:

No hazardous reactions under regular storage and conditions.

Materials to avoid:

No data available

# 11. Toxicological information

# Ingredients:

TRITON-X 100 (CAS Nr. 9002-93-1) Oral LD50 rat: 1900 – 5000 mg/kg Dermal LD50 rabbit: >3000 mg/kg

(The ingredient Triton-X 100 can cause serious eye damages)

#### Acute effects

After Skin Contact:

No data available.

After Eye Contact:

No data available.

After Inhalation:

No data available.

Sensitization:

No sensitizing effects are known.

The information is based on our present knowledge. It describes our product from the point of view of safety requirements and therefore does not have not the purpose of assuring particular properties.

DP PRO TEST KIT 4 of 7

# CMR toxicity:

No special effects or dangers are known.

#### Further Remarks:

Chemical products should always be handled carefully

# 12. Ecological information

### Ingredients:

TRITON-X 100 (CAS Nr. 9002-93-1)

Fish toxicity to LC50: 4 – 8,9 mg/l/96h (Pimephales promelas) Daphnia toxicity EC50: 18 – 26 mg/l/48h (Daphnia magna)

(Biological degradability of TRITON-X 100 is > 60%/28h (modified screening test)

#### Persistence and degradability:

No relevant data available.

# Bioaccumulative potential:

No relevant data available.

#### Mobility:

No relevant data available.

#### **Ecological toxicity:**

#### Remark:

Do not allow to enter soil, drains or watercourses

# Results of PBT assessment:

PBT: not applicable vPvB: not applicable

#### Other adverse effects:

No relevant data available.

# 13. Disposal considerations

Do not allow to enter soil, drains or watercourses. Should not be disposed together with household garbage. Disposal should be in accordance with federal, state and local requirements.

# 14. Transport information

Not restricted for any mode of international transport. No special safety precautions required (ADR / RID, IMDG or IATA).

The information is based on our present knowledge. It describes our product from the point of view of safety requirements and therefore does not have not the purpose of assuring particular properties.

DP PRO TEST KIT 5 of 7

# 15. Regulatory information

#### European legislation:

The product is not subject to identification regulations under EU Directives / Ordinance on Hazardous Materials.

# German Regulation:

### Water pollution class:

Water polluting substance (WGK 1, own classification)

#### 16. Other information

This information is based on the present state of knowledge and experience. The safety data sheet to describe the products in regard to safety requirements. The data do not have the importance of property assurances. The user is obliged, before using this product, to make his own tests with the original materials under the actual application conditions. For damages for the purposes for which the product is not provided, we assume no liability. Existing laws and regulations, the beneficiary of our product on its own responsibility to consider.

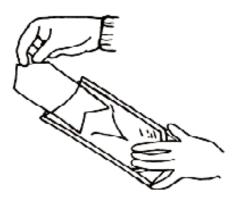


www.vanderstahl.com

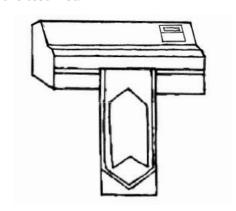
The information is based on our present knowledge. It describes our product from the point of view of safety requirements and therefore does not have not the purpose of assuring particular properties.

DP PRO TEST KIT 6 of 7

1. Insert InkTest PRO into a pouch and make sure that the indicator is pointed towards the seal that shall be checked.



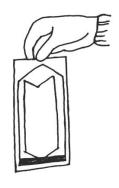
2. Seal the pouch. If the sealer is equipped with "hawo InteligentScan" scan the QR code on the test first.



3. Place the pouch onto horizontal surface, push the liquid into the front chamber and press onto it to release the liquid.



4. Inspect the seals. If there is no visible penetration of liquid throughout the sealing area within 5s, seals are considered as





QR code compatible with IntelligentScan

DP PRO TEST KIT 7 of 7