



## **SAFETY DATA SHEET**

(conforming to Regulation (EC) No 1907/2006, as amended)

### **Hyg a Contenance Care**

#### **SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING**

##### **1.1 Product Identifier**

Product Name	Hyg�a Contenance Care Washcloths
Product Code	DXP00384C01
Product type	Medical Device
Ref No.	40226 (MS4227A1)

##### **1.2 Relevant Identified uses of the substance or mixture and uses advised against**

Identified uses:	Cleaning wipes for skin
Uses Advised against:	None

##### **1.3 Details of the supplier of the safety data sheet**

<b>Company:</b>	PDI Ltd. Aber Park Flint CH6 5EX UK
	Tel: +44 (0) 1352 736700
	Fax: +44 (0) 1352 736701

<b>Compiled by:</b>	<a href="mailto:sales@pdi-hc.co.uk">sales@pdi-hc.co.uk</a>
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##### **1.4 Emergency Telephone Number**

+44 (0) 1352 736700 (09.00 – 17.00 UK time only)

## **SECTION 2: HAZARDS IDENTIFICATION**

### **2.1 Classification of the substance or mixture**

None.

This product is classified to Regulation (EC) No. 1272/2008 (CLP)

### **2.2 Label elements**

None.

### **2.3 Other hazards**

This mixture does not contain any substances that are assessed to be PBT or vPvB.

## **SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

### **3.1 Substances**

All ingredients are legally permitted under Regulation (EC) No. 1272/2008 (CLP).

INCI LISTING:

Aqua, Cetearyl Isononanoate, Glycerin, Inulin, Alpha-glucan oligosaccharide, Ceteareth-20, Cetearyl Alcohol, Glyceryl Stearate, Ceteareth-12, Lactic Acid, Sodium Caproyl/Lauroyl Lactylate Triethyl Citrate, Allantoin, Aloe Barbadensis Leaf Juice, Calendula Officinalis (Calendula) Flower Extract, Panthenol, Polysorbate 20, PEG-40 Hydrogenated Castor Oil, Parfum, Sodium Citrate, Citric Acid, Sodium Gluconate, Phenoxyethanol, Benzoic Acid, Dehydroacetic Acid, Potassium Sorbate, Sodium Benzoate,

## **SECTION 4: FIRST AID MEASURES**

Product is formulated to be use in contact with skin.

Contact with eyes should be avoided.

### **4.1 Description of first aid measures**

#### **General :**

As product consists of applicator material impregnated with small amounts of liquid and contained in a pack, any harmful exposure should be limited.

#### **Inhalation :**

It is unlikely that inhalation will be a route of exposure.

#### **Ingestion :**

Wash out mouth with water. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway.

#### **Skin contact :**

The product is supplied for skin use. It may cause only minimal skin irritation even when its exposure is prolonged and/or repeated. Repeated exposure of the formulation as supplied on wipes is unlikely to produce any allergy when in skin contact. Exposure to this product is unlikely to result in phototoxic effects. This product is highly unlikely to damage any internal organs following adsorption through skin.

**If reaction does occur, discontinue use. Seek medical advice if symptoms persist.**

**Eye contact :**

Avoid contact with eyes, accidental exposure of the eyes to the product as supplied may result in slight eye irritation.

Wash out eye cautiously with copious amounts of water, holding the eye lid open, continue for 15 minutes. Remove contact lenses if present and easy to do so – continue rinsing.

If any irritation persists, seek medical advice.

**4.2 Most important symptoms and effects, both acute and delayed**

**Over–exposure signs/symptoms**

**Inhalation :**

Unlikely to occur.

Unlikely to be a route of exposure but should it occur rinse out mouth with water. Do not induce vomiting. Obtain medical advice if any discomfort continues.

**Skin :**

This product is supplied for skin use. No symptoms are expected to occur; however if any acute or delayed reaction occurs rinse immediately with plenty of water. Remove contaminated clothing. Obtain medical advice if any discomfort continues.

**Eyes :**

Wash out eye cautiously with copious amounts of water, holding the eye lid open, continue for 15 minutes. Remove contact lenses if present and easy to do so – continue rinsing.

If any irritation persists, seek medical advice.

**Notes to physician :**

No specific treatment. Treat symptomatically. Show this Safety Data Sheet to the doctor in attendance.

**Protection of first aid personnel**

No action shall be taken involving any personnel risk or without suitable training.

No product specific requirements.

**4.3 Indication of any immediate medical attention and special treatment need**

No recommendation given. If any effects persist obtain medical advice.

**SECTION 5: FIRE FIGHTING MEASURES (for bulk quantities)**

**5.1 Extinguishing media**

**Suitable** : This product is not flammable. Use water spray, fog or foam. Use an extinguishing agent suitable for surrounding fire.

**Not Suitable** : N/A

**5.2 Special hazards arising from the substance or mixture**

N/A; This product does not present any particular risk for personnel or environment.

**Hazardous thermal decomposition products**

In combustion emits toxic fumes; may liberate carbon oxides and other toxic gases or vapours.

**5.3 Advice for fire fighters**

**Special precautions for fire fighters** : No special precautions.

**Special Protective equipment for fire-fighters:** No special equipment required. Draining with plenty of water will suffice with its dilution.

## **SECTION 6: ACCIDENTAL RELEASE MEASURES**

### **6.1 Personal precautions, protective equipment and emergency procedures**

Put on appropriate personal protective equipment (See section 8).

### **6.2 Environmental precautions:**

N/A

### **6.3 Methods and materials for containment and cleaning up**

#### **Small spill :**

Move packed product from spill area. If satisfactory, return to stock. For any disposal should be via a licensed waste disposal contractor or in accordance with national regulations.

#### **Large spill :**

Move containers from spill area. Dispose of via a licensed waste disposal contractor.

### **6.4 Reference to other sections**

For Emergency contact information, see section 1, personal protection, see section 8. See section 11 for additional information on health hazards. For waste disposal, see section 13.

No further advice available.

## **SECTION 7: HANDLING AND STORAGE**

### **7.1 Precautions for safe handling**

No special handling procedures are required for packed wipes other than those applied as best practice or specified by local working authorities.

### **7.2 Conditions for safe storage, including any incompatibilities**

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool area, away from incompatible materials (see section 10) and food and drink. Keep container closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers.

### **7.3 Specific end use(s)**

Identified use is detailed in Section 1.2

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

If product packaging is undamaged then no special personal protective equipment should be required other than those applied as best practice or specified by local working regulations.  
If packaging is broken and continuous bulk handling necessary, then approved eye protection and gloves are recommended.

### 8.2 Exposure controls

#### Hygiene Measures

When using do not eat, drink or smoke. Good personal hygiene is necessary.

#### Derived No-Effect Levels' (DNEL's) and Predicted No-Effect Concentrations' (PNEC's)

**DNEL's** : No information available

**PNEC's**: No information available

Eye and face protection (EN166) : No special protective equipment is required.  
Skin and body protection (EN14605) : No special protective equipment is required.  
Hand protection (EN374) : No special protective equipment is required.  
Respiratory protection : No special protective equipment is required.

#### Environmental exposure controls

General advice : Consider the provision of containment around storage vessels.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

<b>Appearance</b>	White non-woven substrate dosed with liquid.
<b>Physical state</b>	Liquid
<b>Colour</b>	Colourless
<b>Odour</b>	Characteristic
<b>pH</b>	Extracted liquid 4.5 - 5.0

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

No specific reactivity hazards associated with this product.

### 10.2 Chemical stability

The product is stable under normal conditions of storage and use.

### 10.3 Possibility of hazardous reactions

Under normal conditions of storage and use, hazardous reactions will not occur.

### 10.4 Conditions to avoid

Avoid exposure to extremes of temperature.

### 10.5 Incompatible materials

No specific; or groups of materials are likely to react to produce a hazardous situation.

### 10.6 Hazardous decomposition products

N/A

## **SECTION 11: TOXICOLOGICAL INFORMATION**

### **11.1 Information on toxicological effects**

#### **General Information:**

If used as directed this product is unlikely to present any hazard.

#### **a) Acute Toxicity:**

##### **Oral**

Not classified as harmful by ingestion.

##### **Dermal**

Not classified as harmful by skin contact.

##### **Inhalation**

Not classified as harmful by inhalation.

##### **Other routes**

No data.

#### **b) Skin corrosion/irritation**

Based on available data component substances, the classification criteria skin corrosion/irritation, is not met.

#### **c) Serious eye damage/irritation**

Based on available data component substances, the classification criteria serious eye damage/irritation, is not met.

#### **d) Respiratory or skin sensitisation**

Based on available data component substances, the classification criteria for respiratory or skin sensitisation, is not met.

#### **e) Germ cell mutagenicity**

Based on available data component substances, the classification criteria for germ cell mutagenicity, is not met.

#### **f) Carcinogenicity**

Based on available data component substances, the classification criteria for carcinogenicity, is not met.

#### **g) Reproductive toxicity**

Based on available data component substances, the classification criteria for reproductive toxicity, is not met.

#### **h) STOT – Single exposure**

Based on available data component substances, the classification criteria for specific target organ toxicity, is not met.

## **SECTION 12: ECOLOGICAL INFORMATION**

### **12.1 Toxicity**

Bio-concentration in aqueous organisms is low.

**Reasoning** : Not hazardous to environment.

**Ecologically** : Based on ingredients, this product is not expected to be harmful to aquatic organisms or environment.

The amount of mixture obtained from the wipes would be negligible to cause any hazards unless it is disposed in large quantities into rivers, waters and environment.

### **12.2 Persistence and degradability**

The product does not contain any PBT or vPvB substances.

### **12.3 Bioaccumulative potential**

No information available.

### **12.4 Mobility in soil**

No information available.

### **12.5 Other adverse effects**

None known.

## **SECTION 13: DISPOSAL CONSIDERATIONS**

### **13.1 Waste treatment methods**

#### **General Information:**

Do not discharge into drains, water courses or onto the ground.

#### **Method of disposal:**

The generation of waste should be avoided or minimized wherever possible. Empty packs or used wipes may retain some product residues. This material and its pack must be disposed of in a safe way. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor.

<b>Product</b>	: Dispose of according to local/national waste regulations.
<b>Single pack/wipe</b>	: Dispose of in general waste.
<b>Contaminated packaging</b>	: Dispose of in accordance with local, state, and federal regulations.
<b>Hazardous waste</b>	: The classification of the product may meet the criteria for non-hazardous waste.

## **SECTION 14: TRANSPORT INFORMATION**

### **Section 14 – Transport Information**

Not classified under ADR, IMDG or IATA regulations.

## **SECTION 15: REGULATORY INFORMATION**

### **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture EU regulations**

#### **Environmental**

Environmental Protection Act 1990 (and amendments)  
Hazardous Waste Regulations 2005 (and amendments)

#### **EU Regulations / Directives**

Biocidal Product Regulation (BPR, Regulation (EU) 528/2012)  
EC Directive 93/42/EEC (and amendments) concerning medical devices.  
Regulation (EC) No 1907/2006 (and amendments) Registration, Evaluation, Authorisation and Restriction of Chemicals – REACH.  
Regulation (EC) No 1272/2008 (and amendments) Classification, Labelling and Packaging Regulations (applies to ingredients only) – CLP.  
Road Transport Regulations ADR.  
COSHH – Control of Substances Hazardous to Health Regulations 2002 (as amended).

### **15.2 Chemical safety assessment**

Not available.

## **SECTION 16: OTHER INFORMATION**

#### **Other abbreviations**

PBT : Persistent, bioaccumulative and toxic.  
vPvB : Very persistent and very bioaccumulative.

***Safety Data Sheet compiled according to Regulation (EC) No. 1907/2006, as amended***

#### **Notice to readers**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.