

# Readiwipes® Wet

## Cosmetic Product Data Sheet

### Product Range

Readiwipes® Wet - Skin Cleansing Wipes

### Product Type

Body Wipes - Non Maceratable

### Product Part Codes

5165

### Manufacturer

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### Country of Manufacture

United Kingdom of Great Britain and Northern Ireland



Product No	5165
Unit of Sale	Case
Case Quantity	12
Pack Quantity	60
Case Dimensions (mm)	395 x 278 x 226
Case Weight (kg)	6
Case Barcode	05010058151659
Pack Dimensions (mm)	325 x 130 x 55
Pack Weight (g)	502
Pack Barcode	5010058051652

## Section 1 - Product Information

### 1.1 Product Description

Skin cleansing wet wipes consisting of non-woven substrate dosed with aqueous-based liquor, presented in a sealed, laminated, flow wrapped pack with re-sealable opening. Large size intended for body cleansing - non maceratable

### 1.2 Product Features

- A gentle and highly effective skin cleanser which loosens, lifts and locks contamination into the wipe
- Sting free, rinse free and non greasy in use
- Soap, lanolin and alcohol free
- pH balanced to help maintain the skin's natural protective barrier
- Mild, high quality IFRA compliant fragrance provides a slight scent on cleansed skin
- Dermatologically tested and hypoallergenic
- Suitable for sensitive skins
- Contains premium ingredients in meaningful quantities for exceptional performance

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- Naturally derived ingredients:
  - Aloe Vera - for the reduction of skin sensitivity
  - Lavender - for skin soothing
  - Witch Hazel - a natural astringent for skin cleansing and toning and reduction of excess oil on the skin
  - Chamomile - calms the skin reducing skin irritation and soreness
  - Natural Betaine for skin conditioning and moisture retention - derived from sugar beet molasses
  - Glycerin (Pharma Grade Rapeseed Glycerine BP) - derived from rapeseed oil
- Also contains:
  - Panthenol (D-Panthenol Pro-Vitamin B5) for enhanced skin epithelialisation and moisturisation making it suitable for soothing sore skin
  - Propylene Glycol to provide optimal skin moisturisation properties which enhance the appearance of the skin by reducing flaking and improving suppleness
- Use of this product will cleanse, calm, soothe, condition and moisturise the skin
- Premium lotion optimises cleansing and maximises skin condition for optimum patient/user care and experience
- Preservative system uses Phenoxyethanol - known for its excellent skin compatibility and broad spectrum anti microbial performance to maintain optimal product preservation during shelf life and period after opening

## 1.3 Intended Uses

- Intended for skin cleansing and is suitable for all areas of the body including intimate areas. Suitable for use on all skin types and ages - from newborns to the elderly
- Suitable for body cleansing
- Suitable for gentle cleansing of greasy, dry, cracked, chafed and chapped skin
- Suitable for professional use in hospitals, nursing homes, care home and domiciliary care and also for personal care in the home or at work
- Suitable for use on or by patients and also for occupational use by care workers to cleanse and care for their skin
- There is no need to dry the skin after use as this is a leave-on product
- Suitable for the reduction of skin bioburden by highly effective non biocidal cleansing action

## 1.4 Contraindications

- Not for use on wounds or diseases of the skin
- Not intended for biocidal skin decontamination
- Can be used to harmlessly cleanse surfaces, but residual moisturisers and conditioners may be left on the surface

## 1.5 Liquor Ingredients

Aqua, Phenoxyethanol, Glycerin, Cocamidopropyl Betaine, Betaine, Polysorbate 20, Propylene Glycol, Panthenol, Disodium EDTA, Sodium Chloride, Parfum, Aloe Barbadosensis Leaf Juice, Chamomilla Recutita Flower Extract, Hamamelis Virginiana Leaf Extract, Lavandula Angustifolia Flower Extract, Sodium Hydroxide, Potassium Sorbate, Sodium Benzoate, Hexyl Cinnamal, Limonene, Linalool

## 1.6 Nonwoven Material

- 45 gsm polyester/viscose blend
  - Disposal - not flushable, not dispersible, not maceratable
  - Extremely strong and suitable for vigorous use. Non linting



## 1.7 Wipes Presentation, Dispensing & Use

- Peel back the anti rip adhesive opening to access the wipes. This can be temporarily attached in the open position to aid dispensing
- Wipes are 'Z' folded and non interleaved for single dispensing
- Wipe seam is presented in the middle of the aperture for ease of dispensing
- Wipe seam is always the same direction to aid dispensing. With the pack the correct way around to read the information on it, stroke towards the user with finger tip to elevate edge of wipe. Then pinch lightly between fingertips and gently remove from pack
- Cleanse the body as required. Allow skin to dry naturally to allow the skin conditioners and moisturizers to work. Do not rinse off. Do not dry unless the patient is cold
- Dispose of responsibly

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- Reseal the adhesive opening avoiding creases in the seal which could lead to leakage and the product drying out
- Use each wipe once only

## 1.8 Packaging Materials

- Individual packaging is a PET/PE printed laminate
- Cases made of cardboard using a high percentage of recycled fibre

## 1.9 Information on Basic Physical & Chemical Properties

**State:** Clear, colourless liquid on non-woven substrate

**Colour:** White

**Odour:** Characteristic - mild and pleasant perfume

**Boiling Point:** No data available

**Flash Point:** No data available

**Oxidising:** Non-oxidising (by EC criteria)

**pH:** 5.5 - 6.5

## 1.10 Stability & Reactivity

- **Stability** - stable under recommended transport or storage conditions
- **Chemical Stability** - Stable under recommended transport or storage conditions
- **Possibility of Hazardous Reactions** - Will not occur under normal transport or storage conditions
- **Conditions to Avoid** - Excessive heat or temperatures below 4°C
- **Incompatible Materials** - None in particular. Product should not be mixed with other substances

## Section 2 - Hazards Identification

- 2.1 The formulation of this product does not require the inclusion of any of the mandatory warnings required under Regulation (EC) No 1223/2009 of The European Parliament and of The Council on Cosmetic Products

## Section 3 - Handling Advice

### 3.1 Precautions During Use

- Avoid getting fluid into the eyes. Suitable for cleansing closed eyelids
- Do not ingest fluid. Suitable for lip cleansing - mild taste will be experienced
- Do not use to cleanse wounds
- Do not boil or freeze the product

### 3.2 Exposure Controls/Personal Protection

- None required under the normal conditions of use

## Section 4 - Storage Considerations

### 4.1 Conditions for Safe Storage, Including Any Incompatibilities

- Storage conditions:
  - Keep out of reach of children
  - Observe packing case orientation instructions
  - Store in a cool, dry environment between 5°C and 35°C and away from direct heat and sunlight
  - Retain individual packs in closed packing case during bulk storage
  - Individual packs may be secured in vertical holder for dispensing though some liquid stratification may occur
  - Shelf life - 2 years from date of manufacture
  - Use within 3 months of opening (Period After Opening)

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- Incompatibilities:
  - Exposure of individual pack to sunlight or artificial light for prolonged periods will fade pack printing
  - Exposure to elevated temperatures will accelerate the drying out of the wipes
  - Failure to reseal the pack after use will accelerate the drying out of the wipes
  - Must be kept in original packaging

## Section 5 - First Aid Measures

### 5.1 Most Important Potential Symptoms and Effects - Both Acute and Delayed

- Skin contact:
  - Cosmetic product designed for skin contact. This product uses premium ingredients selected for their efficacy and skin compatibility profile. In addition the product has been extensively tested in the laboratory and on human subjects. It has been assessed by a Consultant Dermatologist. These factors mean that a skin reaction is extremely unlikely. If a reaction occurs the user may experience itchy skin, slight swelling, reddening of the skin and the development of small bumps in the area of contact. No permanent effects are likely
- Eye contact:
  - The user may experience discomfort and redness. The eyes may water. No permanent effects are likely
- Ingestion of liquor:
  - There may be an unpleasant taste and gastrointestinal tract discomfort. No permanent effects are likely
- Ingestion of wipe:
  - Seek urgent medical attention
- Inhalation of wipe vapour:
  - Adverse effects from inhalation considered to be extremely unlikely. If experienced, the user may experience mild discomfort. No permanent effects are likely

### 5.2 Indication of Any Immediate Medical Attention and Special Treatment Needed

- Seek urgent medical attention if the wipe is ingested

### 5.3 Description of First Aid Measures

- Skin contact:
  - If skin irritation occurs, discontinue use and rinse skin with water. Seek medical attention if irritation or symptoms persist for more than 72 hours
- Eye contact:
  - Flush immediately with water. Seek medical attention if adverse symptoms persist
- Ingestion of fluid:
  - If this occurs wash mouth out with water and then drink plenty of water. Seek medical attention if adverse symptoms persist
- Inhalation of fluid:
  - Inhalation is extremely unlikely due to the nature of the product. If adverse symptoms occur, stop inhalation. Seek medical attention if adverse symptoms persist

## Section 6 - Accidental Release Measures

### 6.1 Personal Precautions, Protective Equipment and Emergency Procedures

- No special PPE or procedures are required
- Contaminated surfaces may become slippery

### 6.2 Environmental Precautions

- Dispose of in accordance with local and national policies and as directed on the product and data sheet
- Ingredients are all EU approved and spillage does not pose a risk to the environment

### 6.3 Methods for Containment & Cleaning Up

- Collect solids and dispose of in normal waste
- Spilled liquor can be absorbed using an inert material or can be washed down with water

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## Section 7 - Fire Fighting Measures

### 7.1 Extinguishing Media

- Suitable extinguishing media should be used such as foam, water spray or CO<sub>2</sub>

### 7.2 Special Hazards Arising From the Substance or Mixture

- None

### 7.3 Advice for Firefighters

- Do not breathe fumes. Wear suitable respiratory equipment when necessary

## Section 8 - Disposal Considerations

### 8.1 Precautions for Disposal

Dispose of in accordance with instructions in data sheet, on product packaging or in normal waste with regard to local and national waste disposal polices. Not maceratable. Not to be flushed

## Section 9 - Transport Information

### 9.1 Precautions for Transport

This product does not require a classification for transport

## Section 10 - Regulatory

### 10.1 Regulatory Details

- The above product is in compliance with the Regulation (EC) No 1223/2009 of The European Parliament and of The Council of Cosmetic Products
- All products are registered on the Cosmetic Products Notification Portal

### 10.2 Regulatory - Production Details

- Products are produced in the UK, in a clean room located in a medical device manufacturing facility to EU Cosmetic GMP requirements
- Biological contamination risk is strictly managed for raw materials, production equipment and production environment
- Water used in the process is super purified water
- Production plant is additionally certified to:
  - ISO 9001 Production quality assurance
  - ISO 13485 Medical device production quality assurance
  - Animal Medicinal GMP licensed production (VMD UK)
  - Marketing Authorisations for animal medicinal products
  - BRC consumer product production quality assurance
  - ISO 14001 Environmental management system
  - EC Annex V for the production of sterile medical devices
  - EC Annex VI for the production of Class IIa medical devices
  - Wholesale Dealers License for human medicinal products
  - SEDEX registered and SMETA audited for ethical trading practices
  - NHS LSAS level 4 (the top level) for ethical trading practices

### 10.3 Regulatory - Product Testing & Review Details

- Product stability tested to confirm formulation and finished goods stability for the period of its indicated shelf life
- Preservation efficacy tested to ensure product remains contamination free and safe throughout its indicated shelf life and period after opening
- Compatibility tested to confirm substrate/lotion/packaging compatibility
- Dermatologically tested on humans (no animal testing)
- Toxicologically assessed for safe use on skin (including infants and the elderly and for contact with mucous membranes)
- Formal independent user trials to substantiate subjective product performance claims

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- All ingredients are EU approved and within legally prescribed concentration limits
- Labelling compliance reviewed to confirm regulatory compliance of pack information and claim substantiation

## 10.4 Regulatory - Pack Marking

- Packs indicate the following:
  - Brand
  - Product description (by application)
  - Wipe size
  - Pack quantity
  - Disposal information
    - Non maceratable
  - Disposal warning symbol and text to current EDANA standards
    - Do not flush
    - Do not macerate
  - Description
  - Product claims
  - Product code
  - Instructions for use
  - Ingredients list
  - Warnings
  - Storage instructions
  - Manufacturers address
  - Date of manufacture
  - Manufacturing lot number
  - Expiry date
  - Period after opening symbol
  - Conventional bar code
  - UDI 2D matrix bar code containing lot and expiry data as required by the UK Department of Health and the EU for medical devices

## Section 11 - General Information

### 11.1 Other Products

Other products are available in this range. Please contact Robinson Healthcare for details

### 11.2 Legal Disclaimer

Legal disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The company reserves the right to change this information at any time