

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

|                 |  |
|-----------------|--|
| Product form    | : Article  |
| PRODUCT NAME    | : Allevyn Ag Adhesive and Non-adhesive Dressings   |
| Product code    | : 66800072, 66800073, 66800074, 66800075, 66800076, 66800080, 66800081, 66800082, 66800083, 66800084, 66800086, 66800087, 66800089, 66800090, 66800091, 66800092, 66800094, 66800095, 66800097, 66800098, 66801126, 66801127, 66801128, 66801129, 66801130, 66801131, 66801132, 66801133, 66801134, 66801135, 66801136, 66801137, 66801138 |
| Type of product | : Medical devices  |
| Product group   | : Consumer use   |

**1.2. Relevant identified uses of the substance or mixture and uses advised against****Relevant identified uses**

|                              |   |
|------------------------------|---|
| Intended for general public  |   |
| Main use category            | : Professional use, Consumer use                                    |
| Use of the substance/mixture | : Wound Dressing  |
| Function or use category     | : Consumer uses: Private households (= general public = consumers). |

**1.3. Details of the supplier of the safety data sheet****Supplier**

Smith & Nephew Medical Ltd  
101 Hessle Road  
HU3 2BN Hull, East Ridings of Yorkshire  
T +44 (0) 1482 225181  
<https://www.smith-nephew.com/en/contact-us#general>

**REACH Legal Entity**

Smith & Nephew Operation B.V.  
Bloemlaan 2  
2132 NP Hoofddorp  
Netherlands

**1.4. Emergency telephone number**

|                  |  |
|------------------|--|
| Emergency number | : (UK) or 112 (EU) - 24 Hours, +1-703-527-3887 (Chemtrec 24 Hours) |
|------------------|--|

**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Not classified

**Adverse physicochemical, human health and environmental effects**

No additional information available

**2.2. Label elements****Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

No labelling applicable

**2.3. Other hazards**

Contains no PBT and/or vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

# Allevyn Ag Adhesive and Non-adhesive Dressings

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### SECTION 3: Composition/information on ingredients

#### 3.2. Mixtures

| Name                | Product identifier  | %          | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|---------------------|---------------------|------------|---|
| Silver Sulfadiazine | CAS-No.: 22199-08-2 | ≥ 5 – < 10 | Skin Irrit. 2, H315<br>Eye Irrit. 2, H319<br>STOT SE 3, H335    |

Full text of H- and EUH-statements: see section 16

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

|                                       |  |
|---------------------------------------|--|
| First-aid measures general            | : If you feel unwell, seek medical advice (show the label where possible).   |
| First-aid measures after inhalation   | : Adverse effects not expected from this product. Remove person to fresh air and keep comfortable for breathing.   |
| First-aid measures after skin contact | : Not expected to present a significant skin hazard under anticipated conditions of normal use.  |
| First-aid measures after eye contact  | : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. |
| First-aid measures after ingestion    | : Ingestion is not considered a potential route of exposure.   |

#### 4.2. Most important symptoms and effects, both acute and delayed

|                                     |   |
|-------------------------------------|---|
| Symptoms/effects after inhalation   | : Not expected to present a significant inhalation hazard under anticipated conditions of normal use. |
| Symptoms/effects after skin contact | : Not expected to present a significant skin hazard under anticipated conditions of normal use.       |
| Symptoms/effects after eye contact  | : Not expected to present a significant hazard under anticipated conditions of normal use.            |
| Symptoms/effects after ingestion    | : Ingestion is not considered a potential route of exposure.  |

#### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

|                                |                                    |
|--------------------------------|------------------------------------|
| Suitable extinguishing media   | : Dry powder. Water spray or fog.  |
| Unsuitable extinguishing media | : Do not use a heavy water stream. |

#### 5.2. Special hazards arising from the substance or mixture

|  |   |
|--|---|
| Fire hazard                                      | : Will ignite if exposed to intensive heat. |
| Hazardous decomposition products in case of fire | : Toxic fumes may be released.              |

#### 5.3. Advice for firefighters

|                                |   |
|--------------------------------|---|
| Firefighting instructions      | : Do not enter fire area without proper protective equipment, including respiratory protection. |
| Protection during firefighting | : Do not enter fire area without proper protective equipment, including respiratory protection. |

# Allevyn Ag Adhesive and Non-adhesive Dressings

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### SECTION 6: Accidental release measures

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

General measures : Evacuate area. For further information refer to section 8: "Exposure controls/personal protection". Eliminate ignition sources. Ensure adequate ventilation, especially in confined areas.

##### For non-emergency personnel

Protective equipment : Wear respiratory protection.  
Emergency procedures : Do not breathe dust.

##### For emergency responders

Protective equipment : Equip cleanup crew with proper protection.  
Emergency procedures : Ventilate area.

#### 6.2. Environmental precautions

Avoid formation of dust. Avoid release to the environment.

#### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.

#### 6.4. Reference to other sections

See Section 8. Exposure controls and personal protection.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Precautions for safe handling : Avoid formation of dust.  
Hygiene measures : Do not eat, drink or smoke when using this product.

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

Technical measures : Store in a dry, well ventilated place away from sources of heat, ignition and direct sunlight.  
Storage temperature : Ambient temperatures  
Heat and ignition sources : No flames, no sparks. Eliminate all sources of ignition.  
Packaging materials : Keep only in original container.

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

No additional information available

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

No additional information available

#### 8.2. Exposure controls

##### Personal protection equipment

**Personal protective equipment:**  
Avoid all unnecessary exposure.

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## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### Eye and face protection

#### Eye protection:

Not required for normal conditions of use

### Skin protection

#### Hand protection:

Not required for normal conditions of use

### Respiratory protection

#### Respiratory protection:

Not required for normal conditions of use

### Environmental exposure controls

#### Other information:

Do not eat, drink or smoke during use.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

|   |                  |
|---|------------------|
| Physical state                                  | : Solid          |
| Colour  | : Not available  |
| Odour   | : Not available  |
| Odour threshold                                 | : Not available  |
| Melting point                                   | : Not available  |
| Freezing point                                  | : Not available  |
| Boiling point                                   | : Not available  |
| Flammability                                    | : Not available  |
| Lower explosion limit                           | : Not applicable |
| Upper explosion limit                           | : Not applicable |
| Flash point                                     | : Not applicable |
| Auto-ignition temperature                       | : Not applicable |
| Decomposition temperature                       | : Not available  |
| pH  | : Not available  |
| pH solution                                     | : Not available  |
| Viscosity, kinematic                            | : Not applicable |
| Solubility                                      | : Not available  |
| Partition coefficient n-octanol/water (Log Kow) | : Not available  |
| Vapour pressure                                 | : Not available  |
| Vapour pressure at 50°C                         | : Not available  |
| Density   | : Not available  |
| Relative density                                | : Not available  |
| Relative vapour density at 20°C                 | : Not applicable |
| Particle size                                   | : Not available  |

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Non-reactive under normal conditions of use.

### 10.2. Chemical stability

Stable under normal conditions of use.

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### 10.3. Possibility of hazardous reactions

Not established.

### 10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

### 10.5. Incompatible materials

Strong acids. Strong bases. Strong oxidizing agents.

### 10.6. Hazardous decomposition products

Carbon monoxide. Carbon dioxide.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

|                                   |  |
|-----------------------------------|--|
| Acute toxicity (oral)             | : Not classified   |
| Acute toxicity (dermal)           | : Not classified   |
| Acute toxicity (inhalation)       | : Not classified   |
| Skin corrosion/irritation         | : Not classified   |
| Additional information            | : Based on available data, the classification criteria are not met |
| Serious eye damage/irritation     | : Not classified   |
| Respiratory or skin sensitisation | : Not classified   |
| Additional information            | : Based on available data, the classification criteria are not met |
| Germ cell mutagenicity            | : Not classified   |
| Additional information            | : Based on available data, the classification criteria are not met |
| Carcinogenicity                   | : Not classified   |
| Additional information            | : Based on available data, the classification criteria are not met |
| Reproductive toxicity             | : Not classified   |
| Additional information            | : Based on available data, the classification criteria are not met |
| STOT-single exposure              | : Not classified   |

#### Silver Sulfadiazine (22199-08-2)

|                        |  |
|------------------------|--|
| STOT-single exposure   | May cause respiratory irritation.                                  |
| STOT-repeated exposure | : Not classified   |
| Additional information | : Based on available data, the classification criteria are not met |
| Aspiration hazard      | : Not classified   |
| Additional information | : Based on available data, the classification criteria are not met |

### 11.2. Information on other hazards

#### Other information

|   |  |
|---|--|
| Potential adverse human health effects and symptoms | : Based on available data, the classification criteria are not met |
|---|--|

## SECTION 12: Ecological information

### 12.1. Toxicity

|   |                  |
|---|------------------|
| Hazardous to the aquatic environment, short-term (acute)  | : Not classified |
| Hazardous to the aquatic environment, long-term (chronic) | : Not classified |

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### 12.2. Persistence and degradability

#### Allevyn Ag Adhesive and Non-adhesive Dressings

|                               |                  |
|-------------------------------|------------------|
| Persistence and degradability | Not established. |
|-------------------------------|------------------|

#### Silver Sulfadiazine (22199-08-2)

|                               |                    |
|-------------------------------|--------------------|
| Persistence and degradability | Rapidly degradable |
|-------------------------------|--------------------|

### 12.3. Bioaccumulative potential

#### Allevyn Ag Adhesive and Non-adhesive Dressings

|                           |                  |
|---------------------------|------------------|
| Bioaccumulative potential | Not established. |
|---------------------------|------------------|

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

#### Allevyn Ag Adhesive and Non-adhesive Dressings

|                   |                                   |
|-------------------|-----------------------------------|
| Other information | Avoid release to the environment. |
|-------------------|-----------------------------------|

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

|  |   |
|--|---|
| Product/Packaging disposal recommendations | : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. |
| Ecological waste information               | : Avoid release to the environment.   |

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

| ADR                                     | IMDG          | IATA          | ADN           | RID           |
|---|---------------|---------------|---------------|---------------|
| <b>14.1. UN number or ID number</b>     |               |               |               |               |
| Not regulated for transport             |               |               |               |               |
| <b>14.2. UN proper shipping name</b>    |               |               |               |               |
| Not regulated                           | Not regulated | Not regulated | Not regulated | Not regulated |
| <b>14.3. Transport hazard class(es)</b> |               |               |               |               |
| Not regulated                           | Not regulated | Not regulated | Not regulated | Not regulated |

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## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

| ADR                                    | IMDG          | IATA          | ADN           | RID           |
|--|---------------|---------------|---------------|---------------|
| 14.4. Packing group                    |               |               |               |               |
| Not regulated                          | Not regulated | Not regulated | Not regulated | Not regulated |
| 14.5. Environmental hazards            |               |               |               |               |
| Not regulated                          | Not regulated | Not regulated | Not regulated | Not regulated |
| No supplementary information available |               |               |               |               |

### 14.6. Special precautions for user

#### Overland transport

Not regulated

#### Transport by sea

Not regulated

#### Air transport

Not regulated

#### Inland waterway transport

Not regulated

#### Rail transport

Not regulated

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

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

#### EU-Regulations

##### REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

##### REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

##### PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

##### POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

##### Ozone Regulation (2024/590)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 2024/590 on substances that deplete the ozone layer)

##### Council Regulation (EC) for the control of dual-use items

Contains no substance subject to the COUNCIL REGULATION (EC) for the control of dual-use items

##### Explosives Precursors Regulation (EU 2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

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### Drug Precursors Regulation (EC 273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

### National regulations

#### France

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

### Full text of H- and EUH-statements:

|               |  |
|---------------|--|
| Eye Irrit. 2  | Serious eye damage/eye irritation, Category 2  |
| Skin Irrit. 2 | Skin corrosion/irritation, Category 2  |
| STOT SE 3     | Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation |
| H315          | Causes skin irritation.  |
| H319          | Causes serious eye irritation.   |
| H335          | May cause respiratory irritation.  |

The classification complies with : ATP 12

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.