

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Chemical type : Substance  
 Name : Aluminum Hydroxide Wet Gel VAC 20  
 EC no : 244-492-7  
 CAS No. : 21645-51-2

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

##### 1.2.1. Relevant identified uses

Use of the substance/preparation : Vaccine Support

##### 1.2.2. Uses advised against

No reliable data available.

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

SPI Pharma  
 Chemin du Vallon du Maire  
 Septemes - France  
 T 33 4 91 96 36 00 - F 33 4 91 65 39 03  
[CBlasquez@spipharma.com](mailto:CBlasquez@spipharma.com)

### SECTION 2: Hazards identification

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

##### 2.1.1. Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

##### 2.1.2. Classification according to Directive 67/548/EEC or 1999/45/EC

Not classified

##### 2.1.3. Adverse physicochemical, human health and environmental effects

No reliable data available.

#### 2.2. Label elements

##### 2.2.1. Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

##### 2.2.2. Labelling according to Directive 67/548/EEC or 1999/45/EC

No labelling applicable

#### 2.3. Other hazards

No reliable data available.

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Name	Product identifier	%	Classification according to Directive 67/548/EEC
Aluminium Hydroxide	(CAS No.) 21645-51-2 (EC no) 244-492-7	> 50	Not classified
Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Aluminium Hydroxide	(CAS No.) 21645-51-2 (EC no) 244-492-7	> 50	Not classified

#### 3.2. Mixtures

Not applicable

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures after inhalation : If respiratory irritation occurs upon inhalation, remove to fresh air. Seek medical attention if symptoms develop or persist.

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according to Regulation (EC) No. 453/2010

- First-aid measures after skin contact : After contact with skin, wash immediately with water and soap. If skin irritation occurs: Get medical advice/attention.
- First-aid measures after eye contact : Immediately rinse with plenty of water. If eye irritation persists: Get medical advice/attention.
- First-aid measures after ingestion : If the quantity swallowed is significant : Immediately get medical attention. Do not induce vomiting. Never give anything by mouth to an unconscious person.

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

- Symptoms/injuries : May cause irritation to the skin and eyes. Not expected to be acutely toxic.
- Symptoms/injuries after skin contact : Repeated or prolonged contact may cause slight irritation to the skin. No skin irritation can be expected from single short-term exposure to this product.
- Symptoms/injuries after eye contact : Significant irritation would not be expected. Prolonged contact may cause slight irritation.
- Symptoms/injuries after ingestion : Ingestion of small amounts would not be expected to produce toxicity.
- Symptoms/injuries upon intravenous administration : Overexposure may be irritating to the respiratory system.

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

No reliable data available.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

- Suitable extinguishing media: : carbon dioxide (CO<sub>2</sub>), dry chemical powder, foam. Water fog.
- Unsuitable extinguishing media : Use of heavy stream of water may spread fire.

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

- Fire hazard : Not combustible. minimal fire hazard.
- Reactivity : Combustion generates : Oxides of Aluminium.

### 5.3. Advice for firefighters

- Protective equipment for firefighters : Extra personal protection: complete protective clothing including self-contained breathing apparatus.

## SECTION 6: Accidental release measures

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

#### 6.1.1. For non-emergency personnel

- Protective equipment : Refer to section 8.

#### 6.1.2. For emergency responders

- Protective equipment : Wear suitable protective clothing, gloves and eye/face protection. Refer to section 8.

### 6.2. Environmental precautions

Do not discharge into drains or the environment.

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

- For containment : If sweeping of a contaminated area is necessary, use a dust suppressant agent.
- Methods for cleaning up : Avoid raising powdered materials into airborne dust. Use of a moist absorbent is recommended. Ventilate affected area.

### 6.4. Reference to other sections

No reliable data available.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

- Precautions for safe handling : Avoid contact with skin and eyes. Wash hands thoroughly after handling. Avoid raising powdered materials into airborne dust. avoid breathing dust.

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

- Storage condition(s) : Keep container tightly closed. Store at room temperature.

### 7.3. Specific end use(s)

No reliable data available.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Aluminum hydroxide (21645-51-2)		
Austria	MAK (mg/m <sup>3</sup> )	5 mg/m <sup>3</sup> (respirable fraction)
Austria	MAK Short time value (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup> (respirable, 2x60 min)
Germany	TRGS 900 Occupational exposure limit value (mg/m <sup>3</sup> )	4 mg/m <sup>3</sup> (dust, inhalable fraction)
Germany	TRGS 900 Occupational exposure limit value (mg/m <sup>3</sup> )	1.5 mg/m <sup>3</sup> (dust, respirable fraction)

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### 8.2. Exposure controls

- Appropriate engineering controls : Ensure adequate ventilation. Avoid raising powdered materials into airborne dust. Exposures should be minimized in accordance with good industrial hygiene practices.
- Personal protective equipment : Safety glasses. Gloves.



- Hand protection : Wear impervious gloves for prolonged contact.
- Eye protection : safety glasses with side-shields. chemical goggles if dust is generated.
- Respiratory protection : In case of insufficient ventilation, wear suitable respiratory equipment.

## SECTION 9: Physical and chemical properties

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

- Physical state : Solid
- Appearance : Paste.
- Colour : white.
- Odour : No data available
- Odour threshold : No data available
- pH : No data available
- pH solution : 5.5-8 % Aqueous solution 40 g/L
- Melting point : No data available
- Solidification point : No data available
- Boiling point : No data available
- Flash point : No data available
- Relat. evapor. rate comp. to butylacetate : No data available
- Flammability (solid, gas) : No data available
- Explosive limits : No data available
- Vapour pressure : No data available
- Relative vapour density at 20 °C : 1.1
- Relative density : No data available
- Solubility : Slightly soluble.
- Log Pow : No data available
- Self ignition temperature : No data available
- Decomposition temperature : No data available
- Viscosity : No data available

### 9.2. Other information

No reliable data available.

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Combustion generates : Oxides of Aluminium.

### 10.2. Chemical stability

Stable.

### 10.3. Possibility of hazardous reactions

No reliable data available.

### 10.4. Conditions to avoid

Avoid generation of dust. Incompatible materials.

### 10.5. Incompatible materials

Oxidizing agents.

### 10.6. Hazardous decomposition products

Aluminium oxides. irritating gases. Toxic fumes may be released.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

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### Aluminium Hydroxide (21645-51-2)

LD50 oral rat	> 5000 mg/kg
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## SECTION 12: Ecological information

### 12.1. Toxicity

No reliable data available.

### 12.2. Persistence and degradability

No reliable data available.

### 12.3. Bioaccumulative potential

No reliable data available.

### 12.4. Mobility in soil

No reliable data available.

### 12.5. Results of PBT and vPvB assessment

No reliable data available.

### 12.6. Other adverse effects

No reliable data available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Regional legislation (waste) : Disposal must be done according to official regulations.

Waste disposal recommendations : Empty containers can be dumped according to local legislation.

## SECTION 14: Transport information

Not a dangerous good in sense of transport regulations.

## SECTION 15: Regulatory information

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

#### 15.1.1. EU-Regulations

No reliable data available.

#### 15.1.2. National regulations

No reliable data available.

### 15.2. Chemical safety assessment

No reliable data available.

## SECTION 16: Other information

Sources of Key data : SDS.

Abbreviations and acronyms : ASTM - American Society for Testing and Materials . CLP - Classification, Labelling and Packaging. CSR - Chemical Safety Report. EC - European Community. EEC - European Economic Community. GHS - Globally Harmonised System. REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals. SDS - Safety Data Sheet.

*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.*