

Material Safety Data Sheet

ALHYDROGEL "85" 2 % EP quality

Edition number 2
August 2009

Status Active

1. Identification of the substance and the supplier

Trade name Alhydrogel "85" 2%

Formula $\text{Al}(\text{OH})_3$

Supplier Brenntag Biosector,
Elsenbakken 23
DK-3600 Frederikssund
Phone: (+45) 47 38 47 00

2. Information on the contents

Contents	Acceptable range
Aluminium hydroxide gel EINECS-nr. 244-492-7 (White gelatinous precipitate) CAS no. 21645-51-2	
Aluminium content	9.0 – 11.0 mg/ml
pH (at the time of production)	pH 5.5 - 8.5
Adsorption power	No detectable BSA in sol.
Sedimentation	< 5 ml clear supernatant
Chlorides	Max. 0.33 % w/w
Nitrates	Max. 100 ppm
Sulphates	Max. 0.5 % w/w
Ammonium	Max. 50 ppm
Arsenic	Max. 1 ppm
Fe	Max. 15 ppm
Heavy metals (as Pb)	Max. 20 ppm
Pyrogenicity in 3 rabbits ⁽¹⁾	Max. 1.15°C
(Pyrogenicity in 6 rabbits)	Max. 2.80°C
Sterility	No growth in test samples



Note : The bacterial endotoxin test 2.6.14 prescribed in EP monography 1664 is problematic with Alhydrogel, since the phosphate residues of LPS (used as positive control and standard curve) bind unspecifically to Alhydrogel. This opinion is shared by the Danish Medicines Agency. We carry out the pyrogenicity test on the liquid phase of the product according to the EP 2.6.8 instead of the bacterial endotoxin test.

3. Danger identification

People Harmless

4. First aid precautions

Inhalation Inhalation unlikely.
First aid: Remove person from exposure area to fresh air

Skin contact May cause irritation, dryness and dermatitis.
First aid: Wash affected areas with soap and large amounts of water for a minimum of 15-20 minutes. Seek medical attention if skin symptoms persist.

Eye contact May cause redness, irritation and conjunctivitis.
First aid: Wash eyes immediately with large amounts of water for a minimum of 15-20 minutes. Remove contact lenses if relevant before rinsing. Seek medical attention.

Ingestion Ingestion of large amounts of aluminium hydroxide may cause gastrointestinal irritation with nausea, vomiting and constipation.
First aid: Seek medical attention.

5. Fire and explosion data

Fire fighting media Non-combustible
Remove material from area if possible. Extinguish using media appropriate for fire source.

6. Precautions in case of accidental leakage

Spill procedures	Spills should be collected, stored and disposed of in accordance with the environmental regulations of the local authorities.
People	Reference to section 13: Disposal Reference to section 8: Exposure control/personal protection equipment.

7. Handling and storage

Handling	According to good industrial hygiene.
Storage	Store in sealed packing. Do not expose to freezing.

8. Exposure control/personal protection equipment

Technical precautions.

Contents	GV (ppm)	GV (mg/m ³)	Anm.
Aluminium hydroxide as white gelatinous precipitate	-	10	-
	-	5	-

Reference	At-instruction C.0.1 October 2002 threshold limiting value for substances and materials.
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Protective equipment	Clothing: Appropriate protective clothing is recommended. Cloves: Appropriate protective gloves are recommended. Eye protection: Appropriate eye protection is recommended.
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9. Physical-chemical properties

Description/smell	White gelatinous precipitate in aqueous suspension /smell: neutral
Mass density	
pH	5.5 – 8.5

**Brenntag Biosector**

Solubility	Insoluble in water. Soluble in strong alkalines and acids.
Molecular weight	78.0 g/mol

10. Stability and reactivity

Generally: Stable by normal use. Decomposes at high temperatures (>200°C)

**Circumstances/
Materials that should
be avoided:** None established

11. Toxical information on (health damaging characteristics)

Inhalation:	Not likely
Skin contact:	frequent or long-term skin contact may cause dryness and irritation.
Eye contact:	May cause irritation of the eye and conjunctivitis.
Ingestion:	Ingestion of larger quantities may cause uneasiness.
Long-term effects:	None established
Reference:	EU directive 67/548/EEC: R66

12. Environmental information

Generally:	insoluble in water
Degradability	Not biodegradable (inorganic)

13. Disposal

Waste/ leftovers/spill Must be disposed of in accordance with the environmental regulations of the local authorities.

14. Transport information

Status Not classified as dangerous goods at transport
Must be protected from freezing during transport
A specific set of guidelines for transporters available upon request.

15. Information on adjustment

Status: Brenntag Biosector has concluded that the material is not affected by the rules for labelling issued by the Miljø- og Energiministeriet in Denmark.

16. Further information

Scope of application: The product is used as an Immunological adjuvant and for purification of certain serum components.