

Safety Data Sheet

Conforms to Regulation (EC) No. 1907/2006 (REACH) and the amendment Regulation (EC) No. 2015/830 EU

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

1.1 Product identifier

Product name	BabyBio™ affimAb 1 ml
Article number(s)	45 800 101, 45 800 102, 45 800 103, 45 800 104
Product name	BabyBio affimAb 5 ml
Article number(s)	45 800 105, 45 800 106, 45 800 107, 45 800 108
Product description	Agarose-based resin prepacked in chromatography column delivered in 20% ethanol.

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

For research and process chromatography

1.3 Manufacturer/Supplier of Safety Data Sheet

Bio-Works Sweden AB
Virdings allé 18
SE-754 50 Uppsala, Sweden
Phone: +46 8 5626 7430
E-mail: info@bio-works.com

1.4 Emergency telephone number

+46 8 5626 7430 (Bio-Works Sweden AB)

National advisory body/Poison centre

Please contact the regional company representation in your country.

SECTION 2: HAZARDS IDENTIFICATION

Hazardous components	Ethanol
Prevention	Wear protective gloves, eye or face protection. Keep away from heat, sparks and flames, and hot surfaces. Use explosion-proof electrical, ventilating, lighting and all material-handling equipment.

2.1 Classification of the substance or mixture

Product definition	Mixture
Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]	Hazardous, Flammable. Liquid Category 3, H226
Ingredients of unknown toxicity	None, based on available information.
Ingredients of unknown ecotoxicity	None, based on available information.

2.2 Label elements

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

Hazard pictogram



Signal word

Warning

Hazard statements

H226 Flammable liquid and vapour

Precautionary statements

General

Prevention

P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P233 Keep container tightly closed.
P240 Ground/bond container and receiving equipment.
P241 Use explosion-proof electrical/ventilating/lighting/.../equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response

P303 + P361 + P353 IF ON SKIN (or hair): Remove/take off immediately all contaminated clothing. Rinse skin with water/shower.
P370 + P378 In case of fire: Use dry chemicals, CO₂, water spray, or alcohol-resistant foam for extinction.

Storage

Disposal

P403 + P235 Store in a well-ventilated place. Keep cool.
P501 Dispose of contents/container in accordance with local, regional, national/international regulations.

Hazardous ingredients

Contains 20% ethanol as preservative.

Supplemental label elements None

2.3 Other hazards

None known

SECTION 3: COMPOSITION/INFO ON INGREDIENTS

3.1 Substances

Not applicable

3.2 Mixtures

Contains cross-linked agarose beads with 20% ethanol as preservative.

Product/Ingredient name	Identifiers	Content (%)	Classification according to Regulation (EC) No 1272/2008 (CLP)*	
			Hazard class and category codes	Hazard statements
Ethanol	CAS: 64-17-5 REACH #: 01-2119457610-43 EC: 200-578-6 INDEX: 603-002-00-5	17-19	Flam. Liq. 2	H225

* See list of abbreviations in section 16.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs or vPvBs or have been assigned a workplace exposure limit and hence require reporting in this section.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes	None
Inhalation	Not expected to be a significant hazard under anticipated conditions of normal use. If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Skin contact	Remove/take off immediately all contaminated clothing and shoes. Rinse skin with water/shower. Consult doctor in case of complaints.
Eye contact	Remove contact lenses, if present and easily done. Rinse eyes with plenty of water for at least 10 minutes. Consult doctor if irritation occurs.
Ingestion	Not expected to be a significant hazard under anticipated conditions of normal use. Remove victim to fresh air. Rinse mouth with water. If the victim is conscious, give small quantities to drink. Do not give anything to drink or eat if the person is unconscious. Do not induce vomiting. Consult doctor for advice.
Self-protection of first aider	Wear personal protection equipment (PPE).
Notes to physician	Treat symptomatically. Contact poison treatment specialist if large quantities have been ingested or inhaled.

4.2 Most important symptoms and effects, both acute and delayed

Inhalation	No known significant effects or critical hazards
Skin contact	No known significant effects or critical hazards
Eye contact	No known significant effects or critical hazards
Ingestion	Upon ingestion of large quantities: Dizziness, vomiting, narcosis, respiratory paralysis.

4.3 Indication of any immediate medical attention and special treatment needed

No information available

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media Use water, alcohol-resistant foam, dry powder/dry chemical or carbon dioxide (CO₂)

Unsuitable extinguishing media Do not use water jet

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture Flammable liquid and vapour. In a fire or if heated, a pressure increase will occur and the container may burst, with the risk of a subsequent explosion. Runoff to sewer may create fire or explosion hazard.

Hazardous combustion products In the event of fire may produce hazardous combustion gases or vapours, including carbon dioxide and carbon monoxide

5.3 Advice for firefighters

Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Wear self-contained breathing apparatus. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing vapour or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment according to Section 8.

For emergency responders If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

6.2 Environmental precautions

Avoid discharge into soil, waterways, drains and sewers.

6.3 Methods and material for containment and cleaning up

Small spill

Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Large spill

Stop leak if without risk. Move containers from spill area. Cover drains. Use spark-proof tools and explosion-proof equipment. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite and place in container for disposal according to local regulations. Dispose of product and contaminated absorbent material according to local, regional, national or international regulations.

6.4 Reference to other sections

See SECTION 1 for emergency contact information
See SECTION 8 for personal protection information
See SECTION 13 for waste treatment information

SECTION 7: HANDLING AND STORAGE

Store and handling at 2 to 25°C. Small amounts can be flushed down a sink with a large quantity of water unless local rules prohibit this. The product is stable. Under normal conditions of storage and use hazardous polymerization will not occur. Avoid strong oxidizing agents.

7.1 Precautions for safe handling

Protective measures

Always wear recommended protective equipment, see SECTION 8. Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing vapour or mist. Use adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Do not enter storage areas and confined spaces unless adequately ventilated. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers may retain product residue and can be hazardous. Do not reuse container. Store and use away from heat, sparks, open flame or any other ignition source. Use explosion-proof electrical (ventilating, lighting and material handling) equipment. Take precautionary measures against electrostatic discharges.

Advice on general occupational hygiene

Eating, drinking and smoking must be prohibited in areas where this material is handled, stored and processed. Users should wash hands before eating, drinking and smoking. Remove protective equipment and clothing, and contaminated clothing, before entering eating areas. See Section 8 for additional information.

7.2 Conditions for safe storage, including any incompatibilities

Store at 4 to 30°C (39 to 86°F). Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct in a well-ventilated area. Do not store with incompatible materials (see Section 10) or food and drinks. Do not store close to ignition sources or hot surfaces. Separate from oxidizing materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage.

7.3 Specific end use(s)

Research sector Recommended for laboratory use

Industrial sector Guidance not available

SECTION 8: LIMIT EXPOSURE

Use gloves and eye protection. Use in ventilated environment.

8.1 Control parameters

Occupational exposure limits (OEL)

Geographical area	Ethanol CAS: 64-17-5
EU OEL (TWA)	None
EU OEL (STEL)	None
Austria	1000 ppm 1900 mg/m ³
Belgium (TWA)	1000 ppm 1907 mg/m ³
Denmark (TWA)	1000 ppm 1900 mg/m ³
Finland (TWA)	1000 ppm 1900 mg/m ³
France (VME)	1000 ppm 1900 mg/m ³
Germany (TWA)	500 ppm exposure factor 2 960 mg/m ³ exposure factor 2
Ireland (TWA)	None
Italy (TWA)	None
Lithuania (TWA)	500 ppm 1000 mg/m ³
Norway	None
Netherlands (MAC)	260 mg/m ³
Poland	None
Spain (TWA)	None
Sweden (TLV/LLV)	500 ppm LLV 1000 mg/m ³ LLV
Switzerland (STEL/TWA)	1000 ppm STEL 1900 mg/m ³ STEL 500 ppm TWA 960 mg/m ³ TWA
United kingdom	None
US NIOSH (TWA)	1000 ppm 1900 mg/m ³

Recommended monitoring procedure	<p>Workplace atmosphere monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following:</p> <p>European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy)</p> <p>European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents)</p> <p>European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents)</p> <p>Reference to national guidance documents may also be required.</p>
DNELs/DMELs PNECs	<p>Not applicable No information available</p>
8.2 Exposure controls Appropriate engineering controls	<p>Use adequate ventilation using explosion-proof equipment. Use process enclosures, local exhaust ventilation or other engineering controls to airborne contaminants below any recommended or statutory limits, and gas, vapour or dust concentrations below any lower explosive limits.</p>
Individual protection measures	<p>The personal protective equipment selected must comply with the EC Council Directive 89/686/EEC.</p>
Hygiene measures	<p>Wash hands, forearms and face after handling the product, before eating, smoking and using the lavatory and at the end of the working period. Remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location and regularly tested.</p>
Eye/face protection	<p>Use safety glasses, and/or face shield.</p>
Hand protection	<p>Use chemically resistant protective gloves that comply with the standard EN374; e.q., gloves based on butyl rubber or neoprene, 0.7 mm thickness or more, with breakthrough time of 2 hours or more.</p>
Body protection	<p>Flame retardant antistatic clothing, e.g., lab coat or when required antistatic overalls, boots and gloves. Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Refer to European Standard EN 1149 for further information on electrostatic properties of protective clothing.</p>

Respiratory protection

Select a respirator based on the hazard and potential for exposure, which meets the appropriate standard or certification. Ensure proper fitting, training, and other important aspects of use. Recommended filter type: Filter A according to DIN 3181. Maintenance, cleaning and testing must be done according to the manufacturer, and properly documented.

Environmental exposure controls

Do not let product enter drain. Emissions from equipment or ventilation should be checked to ensure they comply with the requirements of the environmental protection legislation. Consider the use of fume scrubbers, filters or engineering modifications to the process equipment to reduce emissions.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Agarose-based resin prepacked in chromatography column delivered in 20% ethanol. White to off-white color.

9.1 Information on basic physical and chemical properties

Appearance

Physical state	Suspension
Color	White to off-white
Odour	Alcohol
Odour threshold	No information available.
pH	No information available.
Melting point/freezing point	No information available.
Initial boiling point and boiling range	No information available.
Flash point	38°C, closed cup
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Upper/lower flammability or explosive limits	No information available.
Vapour pressure	No information available.
Vapour density	No information available.
Relative density	No information available.
Solubility(ies)	Ethanol soluble in water, particles insoluble.
Partition coefficient: n-octanol/water	No information available.
Auto-ignition temperature	No information available.
Decomposition temperature	No information available.
Viscosity	No information available.
Explosive properties	No information available.
Oxidising properties	No information available.

9.2 Other information

No additional information available.

SECTION 10: STABILITY AND REACTIVITY

Product is stable. Reactivity data not available.

10.1 Reactivity

Vapour/air-mixtures are explosive at intense heating.

10.2 Chemical stability

Stable

10.3 Possibility of hazardous reactions

No hazardous reactions known under normal use or storage.

10.4 Conditions to avoid

Heating and sources of ignition.

10.5 Incompatible materials

Strongly oxidizing materials.

10.6 Hazardous decomposition products

No hazardous decompositions products produced under normal use or storage.

SECTION 11: TOXICOLOGICAL INFORMATION

Not available. We are not aware of any other hazards for the product.

1.1 Information on toxicological effects

Acute toxicity	Ethanol LC50 Inhalation vapour in rat is 124700 mg/m ³ for 4 hours exposure. Ingestion causes nausea and vomiting
Irritation	No information available
Corrosivity	No information available
Sensitisation	No information available
Repeated dose toxicity	No information available
Carcinogenicity	No information available
Mutagenicity	No information available
Toxicity for reproduction	No information available

SECTION 12: ECOLOGICAL INFORMATION

Not available. We are not aware of any other hazards for the product.

12.1 Toxicity

Ingredient name	Results	Species	Exposure
Ethanol	Acute EC50 17.921 mg/l Marine water	Algae - Ulva pertusa	96 hours
	Acute EC50 2000 µg/l	Fresh water Daphnia - Daphnia magna	48 hours
	Acute LC50 25500 µg/l	Marine water Crustaceans - Artemia franciscana - Larvae	48 hours

12.2 Persistence and degradability

Ethanol is degraded readily in fresh water in 20 days.

12.3 Bioaccumulative potential

None

12.4 Mobility in soil

No information available

12.5 Results of PBT and vPvB assessment

PBT	Not applicable
vPvB	Not applicable

12.6 Other adverse effects

No known significant effects or critical hazards.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal of product should be handled in accordance with regional requirements. Dispose via approved waste disposal contractor.

13.1 Waste treatment methods

Product

Hazardous waste This product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC.

Waste treatment methods The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of local, regional, national or international environmental protection and waste disposal legislation. Disposal of mentioned materials must be done via approved waste disposal contractor. Waste must not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. The emptied container may contain residues of the product and must be disposed of accordingly.

European waste catalogue (EWC) According to Decision 2014/955/EU list of waste pursuant to Directive 2008/98/EC.

Waste code 07 07 99

Waste designation Wastes not otherwise specified

Packaging

Waste treatment methods The generation of waste should be avoided or minimised wherever possible. Packaging waste should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

SECTION 14: TRANSPORTATION INFORMATION

Not classified; IATA special provisions A 58- Aqueous solutions containing 24% or less alcohol by volume is not subject to these regulations.

14.1 UN number

Not regulated

14.2 UN proper shipping name

Not available

14.3 Transport hazard class(es)

Not available

14.4 Packing group

Not available

14.5 Environmental hazards

None

14.6 Special precautions for user

Transport in closed container, upright and secure. The person transporting the product must know what to do in the event of an accident or spillage.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not available

SECTION 15: REGULATORY INFORMATION

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer.

None of the components listed.

Regulation (EC) No 850/2004 of the European Parliament on persistent organic pollutants and amending Directive 79/117/EEC.

None of the components listed.

Regulation (EC) No 649/2012 concerning the export and import of dangerous chemicals.

None of the components are listed.

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

Regulation (EC) No 1907/2006 (REACH)

Annex XIV – List of substances subject to authorisation

None of the components are listed.

Substances of higher concern: None

Annex XVII – Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

None of the substances listed.

Other regulations

Directive 2008/105/EC – Environmental quality standards in the field of water policy

Annex I – Environmental quality standards (EQS)

No information

German water hazard classes (Wassergefährdungsklassen) (VwVwS)

Annex 2 – Substances hazardous to water

Ethanol Hazard class 1 – low hazard

DIRECTIVE 2012/18/EU (Seveso III)

Ethanol P5c Flammable liquid Category 2 Limit 5000 tonnes

15.2 Chemical safety assessment

SECTION 16: OTHER INFORMATION

H-Statements

- H225 Highly flammable liquid and vapour.
- H226 Flammable liquid and vapour.
- H302 Harmful if swallowed.
- H317 May cause an allergic skin reaction.
- H400 Very toxic to aquatic life.
- H410 Harmful to aquatic life with long lasting effects.

P-statements

- P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
- P233 Keep container tightly closed.
- P240 Ground/bond container and receiving equipment.
- P241 Use explosion-proof electrical/ventilating/lighting/.../equipment.
- P242 Use only non-sparking tools.
- P243 Take precautionary measures against static discharge.
- P303 + P361 + P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
- P370 + P378 In case of fire: Use ... for extinction.
- P403 + P235 Store in a well-ventilated place. Keep cool.
- P501 Dispose of contents/container in accordance with local, regional, national or international regulations.

Abbreviations

BCF	Bioconcentration factor
CAS	Chemical Abstracts Service
CLP	Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
DMEL	Derived Minimal Effect Level
DNEL	Derived No Effect Level
EQS	Environmental Quality Standard
IC50	Lethal concentration in water required to kill 50% of the population
LC50	Lethal concentration required to kill 50% of the population
LD50	Lethal dose required to kill 50% of the population
LLV	Lower Limit Value
MAC	Maximum Allowable Concentration
NIOSH	National Institute for Occupational Safety and Health
NOEC	No Observed Effect Concentration
OELs	Occupational Exposure Limits
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No Effect Concentration
STEL	Short-Term Exposure Limits
TLV	Threshold Limit Value
TWA	Time-Weighted Average
vPvB	very Persistent, very Bioaccumulative and/or Toxic

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The approve panel to be removed in published version, and signed and archived together with the published version (For pagination purposes).

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Revision

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1.0	First version	2017-10-24