

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

1.1. Product identifier

Trade name or designation of the mixture L2 ADIAPURE™

Registration number -

Synonyms None.

Publication date cf PDF footer.

Issue date cf PDF footer.

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

Identified uses For veterinary in vitro use only – For animal use only.

Uses advised against None known.

1.3. Details of the supplier of the safety data sheet

Supplier

Company name Bio-X Diagnostics
Address 38 rue de la Calestienne - 5580 Rochefort - Belgium
Telephone + 32 (0) 84 32 23 77
Fax + 32 (0) 84 31 52 63
e-mail export@biox.com

Manufacturer

Company name ADIAGENE SARL
Address 9 rue Gabriel Calloët-Kerbrat - 22440 Ploufragan - France
Telephone + 33 (0) 2 96 68 40 20
e-mail export@biox.com

1.4 Emergency telephone Number 999 or Call a POISON CENTRE or doctor/physician

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Regulation (EC) No 1272/2008 as amended

Health hazards

Respiratory sensitization	Category 1	H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
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Hazard summary May cause allergy or asthma symptoms or breathing difficulties if inhaled.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Contains: PROTEINASE, MICROBIAL NEUTRAL

Hazard pictograms



Signal word Danger

Hazard statements

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements

Prevention

P261 Avoid breathing mist or vapour.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response

P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.lenses,

Storage

Not available.

Disposal

Not available.

Supplemental label information

None.

2.3. Other hazards

None known.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
PROTEINASE, MICROBIAL NEUTRAL	1 - < 3	9068-59-1 232-966-6	-	647-013-00-3	
Classification :	Skin Irrit. 2;H315, Eye Irrit. 2;H319, Resp. Sens. 1;H334, STOT SE 3;H335				

Other components below reportable levels 90 - 100

List of abbreviations and symbols that may be used above

CLP : Regulation No. 1272/2008.

DSD : Directive 67/548/EEC.

M : M-factor

vPvB : very persistent and very bioaccumulative substance.

PBT: persistent, bioaccumulative and toxic substance

#: This substance has been assigned Community workplace exposure limit(s).

Composition comments

The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

General information

Not available.

4.1. Description of first aid measures

Inhalation

If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician.

Skin contact

Wash off with soap and water. Get medical attention if irritation develops and persists

Eye contact

Rinse with water. Get medical attention if irritation develops and persists.

Ingestion

Rinse mouth. Get medical attention if symptoms occur.

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

Difficulty in breathing

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

Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed

SECTION 5: Firefighting measures

General fire hazards

No unusual fire or explosion hazards noted.

5.1. Extinguishing media

Suitable extinguishing media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media

Do not use water jet as an extinguisher, as this will spread the fire.

5.2. Special hazards arising from the substance or mixture

During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special fire fighting procedures	Move containers from fire area if you can do so without risk
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Avoid breathing mist or vapour. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

6.2. Environmental precautions Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use.

6.4. Reference to other sections For personal protection, see section 8. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	Avoid breathing mist or vapour. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
7.2. Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).
7.3. Specific end use(s)	Not available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Recommended monitoring procedures	Follow standard monitoring procedures.
Derived no-effect level (DNEL))	Not available.
Predicted no effect effect concentrations (PNECs)	Not available.

8.2. Exposure controls

Appropriate engineering controls General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

General information	Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.
Eye/face protection	Wear safety glasses with side shields (or goggles).
Skin protection	
- Hand protection	Wear protective gloves. Use protective gloves made of: Nitrile.
- Other	Wear suitable protective clothing.
Respiratory protection	No personal respiratory protective equipment normally required.
Thermal hazards	Not applicable.

Hygiene measures Handle in accordance with good industrial hygiene and safety practices.

Environmental exposure controls Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Liquid.
Form	Liquid.
Colour	Not available.

Odour Not available.

Odour threshold Not available.

pH Not available

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available

Flash point Not available

Evaporation rate Not available

Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Vapour pressure Not available.

Vapour density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Solubility (other) Not available.

Partition coefficient (n-octanol/eau) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available

Viscosity Not available.

Explosive properties Not available.

Oxidizing properties Not available.

9.2. Other information No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability Material is stable under normal conditions.

10.3. Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

10.4. Conditions to avoid Contact with incompatible materials.

10.5. Incompatible materials Strong oxidizing agents.

10.6. Hazardous decomposition products No hazardous decomposition products are known.

SECTION 11: Toxicological information

General information Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

Inhalation May cause allergy or asthma symptoms or breathing difficulties if inhaled. Prolonged inhalation may be harmful.

Skin contact No adverse effects due to skin contact are expected.

Eye contact Direct contact with eyes may cause temporary irritation.

Ingestion May cause discomfort if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Symptoms Difficulty in breathing.

11.1. Information on toxicological effects

Acute toxicity No data available.
Skin corrosion/irritation Due to partial or complete lack of data the classification is not possible.
Serious eye damage/eye irritation Due to partial or complete lack of data the classification is not possible.
Respiratory sensitization May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin sensitization Due to partial or complete lack of data the classification is not possible.
Germ cell mutagenicity Due to partial or complete lack of data the classification is not possible.
Carcinogenicity Due to partial or complete lack of data the classification is not possible.
Reproductive toxicity Due to partial or complete lack of data the classification is not possible.
Specific target organ toxicity - single exposure Due to partial or complete lack of data the classification is not possible.
Specific target organ toxicity - repeated exposure Due to partial or complete lack of data the classification is not possible.
Aspiration hazard Due to partial or complete lack of data the classification is not possible.
Mixture versus substance information No information available.
Other information Not available.

SECTION 12: Ecological information

12.1. Toxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
12.2. Persistence and degradability No data is available on the degradability of this product.
12.3. Bioaccumulative potential No data available.
Partition coefficient n-octanol/water (log Kow) Not available.
Bioconcentration factor (BCF) Not available.
12.4. Mobility in soil No data available.
12.5. Results of PBT and vPvB assessment Not available.
12.6. Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.
EU waste code The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/informations Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations
Special precautions Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR Not regulated as dangerous goods.
RID Not regulated as dangerous goods.
ADN

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk Not established.

**according to Annex II of
MARPOL 73/78 and the IBC
Code**

SECTION 15: Regulatory information

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

EU- regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I, as amended
Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II, as amended
Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended
Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended
Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended
Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended
Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended
Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended
Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA
Not listed.

Authorizations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended
Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended
Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended
Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding, as amended
Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances
Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, as amended

PROTEINASE, MICROBIAL NEUTRAL (CAS 9068-59-1)

Directive 94/33/EC on the protection of young people at work, as amended

PROTEINASE, MICROBIAL NEUTRAL (CAS 9068-59-1)

Other regulations

The product is classified and labeled in accordance with EC directives or respective national laws.
This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

National regulations

Young people under 18 years old are not allowed to work with this product according to EU Directive 94/33/EC on the protection of young people at work. Follow national regulation for work with chemical agents.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations	Not available.
References	Not available.
Information on evaluation method leading to the classification of mixture	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
Full text of any H-statements not written out in full under Sections 2 to 15	H315 Causes skin irritation. H319 Causes serious eye irritation. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. H335 May cause respiratory irritation.
Revision information	None.
Training information	Follow training instructions when handling this material.
Disclaimer	ADIAGENE cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.