

Material Safety Data Sheet



According to Regulation (CE) n°1907/2006

Reference: ADL26Y1-100	ADL26Y1- ORTR – SD - (EN) -V01 Version: 01	Creation date: 13-09-2024
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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE and COMPANY

1.1 Product identifier

ADIALYO™ ORT Kit – A6

CAS No.: N/A

EC No.: N/A

REACH No.: A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

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

For in vitro diagnostic use only. For animal use only

1.3 Details of the supplier of the safety data sheet

Company	ADIAGENE SAS 9 rue Gabriel Calloët-Kerbrat 22440 Ploufragan – France
Phone	+33 (0) 2 96 68 40 20
e-mail	support.pcr@biox.com

1.4 Emergency telephone number

Emergency telephone number	France : (I.N.R.S) +33 (0)1 45 42 59 59 (Or contact your local Poison Control Center)
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2. HAZARDS IDENTIFICATION

2.1 Classification of substance or mixture

Classification according to Regulation (EC) No 1272/2008

Not a hazardous substance or mixture

2.2 Label elements

According to Regulation (EC) No. 1272/2008.

Hazard symbol(s) : N/A

H phrase(s) : None

P phrase(s) : None

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2.3 Other hazards

Possible hazards from physicochemical properties:

Some hazards associated with individual components of this mixture are not relevant because the substances are present in concentrations below the GHS cut-off levels, change of physical state or because the mixture solution is buffered to pH 4-9 (see GHS Directive 1272/2008/EC Annex I, chapter 3.2.3.1.2.).

PBT : None

vPvB : None

3. COMPOSITION/INFORMATION ON INGREDIENTS

The product is a mixture of the hazardous substances listed below along with unlisted non-hazardous substances.

Ingredients	CAS #	EINECS #	Classification	Weight ratio %
N/A	N/A	N/A	N/A	N/A

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II

4. FIRST AID MEASURES

4.1 Description of the first aid measure

Eye contact	After contact with the eyes rinse thoroughly with plenty of water for at least 15 minutes with the eyelid wide open.
Skin contact	Remove contaminated clothing. Rinse the affected skin or mucous membrane thoroughly under running water. (If possible) use soap.
Inhalation	Remove to fresh air, keep the patient warm and provide resuscitation if necessary. If symptoms develop, obtain medical attention.
Ingestion	Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth and drink plenty of water.
General advice	If necessary, consult a physician. Show this safety data sheet to the medical professional in attendance.

4.2 Most important symptoms and effects both acute and delayed

The most important known symptoms and effects are described in the labelling section 2.2 and/or in section 11
Not expected to present a significant hazard under anticipated conditions of normal use.

4.3 Indication of immediate medical attention and special treatment needed

No additional recommendations.

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5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Extinguishing agents Water spray, fire extinguishing powder, carbon dioxide or foam.

Non-suitable extinguishing agents None known

5.2 Special hazards arising from substance of mixture

Hazardous decomposition products formed under fire conditions. - CO_x ; NO_x ; HCl, Phosphorous oxides
Potassium oxides, Magnesium oxides, Sulphur oxides, Sodium oxides, Lithium oxides.

5.3 Advice for firefighters

Protective equipment Protective breathing apparatus, independent of the ambient air (isolated equipment), and sealed protective clothing is necessary in the event of large-scale formation of toxic substances.

Other information Product package burns like paper or plastic.
Spray any vapours released with water.
Retain fire water where possible.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid contact with skin, eyes and clothing. Do not breathe vapours; aerosols.
Ensure adequate ventilation. Evacuate the danger area, observe emergency procedure.

6.2 Environmental precautions

Isolate spill area. Do not allow entering drains or watercourses. Notify authorities if large amounts of the product enters sewers or public waters

6.3 Methods and materials for containment and cleaning up

Methods for cleaning up Contain spill material. Absorb the material with e.g. tissues or other liquid-absorbent material (eg Chemizorb®) place in a container in conformity with local regulations and subsequently, dispose properly and clean up affected area.

6.4 Reference to other sections

Section 5.4: Additional fire precautions.

Section 8: Exposure controls/personal protection

Indications about waste treatment, see section 13.

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7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Safe handling advice

Handling in accordance with the instructions supplied with the product. Provide adequate ventilation. Avoid breathing dust. Avoid contact with skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Take off contaminated clothing and wash before reuse.

Hygiene measures

Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Store at temperatures below 25°C

7.2 Conditions for safe storage including any incompatibilities

Conditions for safe storage

Follow information on labelling and/or user manual. Keep only in the original container. Store in a cool well-ventilated place out of direct sunlight. Keep container closed when not in use..

Requirements for storage

Keep closed. Shelter from light.
Store separately from: Strong acids, Bases, Oxidizing agents, Reducing agents, Alkali metals.

7.3 Other information Specific end use(s)

Handle in accordance with good industrial hygiene and safety practice.

Take off contaminated clothing and wash before reuse.

Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

Contains no substances with occupational exposure limit values

8.2 Exposure control

8.2.1 Appropriate engineering controls:

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

8.2.2 Individual protection measures

Technical measures

No specific recommendations.

Personal protection:

Respiratory

Respiratory protection not normally required.

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For dust exposures use type P95 (US) or type P1 (EU EN 143) particle respirator. For higher level protection use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 14385) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Eye Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN166 (EU) with integrated side shields or wrap-around protection.

Hand Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product.
Wear protective gloves that satisfy the specifications of EU Directive 89/686/EEC and the standard EN374 derived from it. Exact breakthrough times to be found through the manufacturer of the protective gloves and must be observed. Gloves should be removed and replaced if there are any signs of degradation or breakthrough. If used in solution, or mixed with other substances, and under conditions which differ from EN374, contact the supplier of the CE approved gloves.

Skin and body Wear suitable protective clothing

8.2.3 Environment exposure controls

Prevent product from entering drains. The product must not contaminate groundwater.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state	Powder
Colour	white
Odour	Odourless
Boiling point/boiling range	Not determined
Flash point	Not determined
Flammability	Not determined
Explosive properties	Not determined
Vapour pressure	Not determined
Density	Not determined
Relative density air=1	Not determined
Solubility in water	Not determined

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pH Not determined

Viscosity Not determined

Oxidising properties Not determined

Conductivity Not determined

10. STABILITY AND REACTIVITY

10.1 Reactivity

Stable under normal conditions.

10.2 Chemical stability

Stable under recommended storage and handling conditions

10.3 Possibility of hazard reaction

Data not available

10.4 Conditions to avoid

Extremely high or low temperature

10.5 Incompatible material

Strong oxidizing agents; strong bases and acids; reducing agents, Alkali metals

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions – Carbon oxides, Nitrogen oxides, Phosphorous oxides, Hydrogen chloride gas, Potassium oxides, Magnesium oxides, Lithium oxides, Sulphur oxide.

In case of fire (see Chapter 5)

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

- Acute toxicity oral

Data not available

- Acute skin toxicity

Data not available

- Skin irritation

Data not available

- Eye irritation

Data not available

- Sensitization

Data not available

- In vitro Genotoxicity

Data not available

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- **Specific target organ – single exposure**
Not classified as specific target organ toxicant - single exposure
- **Specific target organ – repeated exposure**
Not classified as specific target organ toxicant, repeated exposure
- **Aspiration hazard**
Not classified

11.2 Other information

HEALTH HAZARDS:

CAUTION: This product contains source materials of animal origin. These materials should be handled as though they might contain potentially infectious agents.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Not classified

12.2 Persistence and degradability

Data not available

12.3 Bioaccumulative potential

Data not available

12.4 Mobility in soil

Data not available

12.5 Results of PBT and vPvB assessment

This substance/mixture does not meet the PBT and vPvB criteria of REACH regulation, annex XIII

12.6 Other information

Data not available

13. DISPOSAL CONSIDERATIONS

Product	Disposal of chemical waste in compliance with corresponding local laws and regulations. We recommend that you contact either the authorities in charge or approved waste disposal companies, which will advise on how to dispose this type of waste. Offer surplus and non-recyclable solutions to a licensed disposal company.
Contaminated packaging	Disposal in compliance with corresponding local laws and regulations. Handle contaminated packaging in the same way as the product itself. Dispose of as unused product.
Other information	If not officially specified differently, non-contaminated packaging may be treated like household waste or recycled.

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14. TRANSPORT INFORMATION

IATA / ADR / DOT-US / IMDG

Not regulated in the meaning of transport regulations

UN number or ID number	Not regulated
UN proper shipping name	Not regulated
Transport hazard class(es)	Not regulated
Packing group	Not regulated

Environmental hazards

No

Special precautions for user

Not regulated

Maritime transport in bulk according to IMO instruments

Not applicable

15. REGULATORY INFORMATION

This Safety Data Sheet conforms to Regulation (EC) n° 1907/2006 (REACH) Annexe II.

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

Regulated explosives precursors

None of the ingredient is listed

Regulated poisons

None of the ingredient is listed

Reportable explosives precursors

None of the ingredient is listed

Reportable poisons

None of the ingredient is listed

Directive 2012/18/EU

Named dangerous substances – ANNEX I

None of the ingredients listed

Classification according to VbF:

Data not available

Substances of very high concern

None

Substances subject to authorisation according to REACH, Annexe XVII

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list $\geq 0,1\%$ / SCL

Contains no REACH Annex XIV substances

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15.2 Chemical safety assessment

No chemical safety assessment has been carried out

16. OTHER INFORMATION

This information only concerns the above-mentioned products and does not need to be valid if used with other product(s) or in any process. The information is correct and complete to our best present knowledge and is given in good faith, but without warranty. It remains the user's own responsibility to make sure that the information is appropriate and complete for his special use of this product.

For diagnostic in vitro use only.

ADN	European agreement concerning the international carriage of dangerous goods by waterways
ADR	European agreement concerning the international carriage of dangerous goods by road
CAS	Chemical Abstracts Service number
CLP	Classification, Labelling and Packaging
DOT-US	Department of Transportation (United states)
EC	European Community
ECx	Effective Concentration x%
EINECS	European inventory of Existing Commercial Chemical Substances
GHS	Globally harmonized system of classification and Labelling of Chemicals
IATA	International Air Transport Association
IBC	Intermediate Bulk Container
IC50	Semi-maximum inhibitory concentration
IUCLID	International Uniform Chemical Information Database
IMDG	International Maritime Dangerous Goods Code
IMO	International Maritime Organization
LC50	Lethal Concentration 50%
LD50	Lethal Dose 50%
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation and Authorisation of CHemicals
RID	Regulations concerning the International Carriage of Goods by Rail
SCL	Lethal concentration threshold
SDS	Security data sheet
STEL	Short term Exposure Limit
TWA	Time Weighted Average
UNxxxx	Number assigned by the United Nations Committee of Experts on the Transport of Dangerous Goods
VbF	Flammable liquids regulations (German regulations)
vPvB	Very Persistent and very Bioaccumulative