

Material Safety Data Sheet



According to Regulation (CE) n°1907/2006

| | | |
|-------------------------------|--|---------------------------|
| Reference: ADL69Y1-100 | ADL69Y1-100 – AIV9 – MSDS - (EN) - V01 Version: 01 | Creation date: 05/07/2024 |
|-------------------------------|--|---------------------------|

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE and COMPANY

1.1 Product identifier

ADIALYO™ H9 100R 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)

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 % |
|---|---------|-----------|----------------|----------------|
| α -D-Glucopyranosyl β -D-fructofuranoside α -D-Glc-(1 \rightarrow 2)- β -D-Fru D(+)-Saccharose Sugar β -D-Fructofuranosyl- α -D-glucopyranoside C12H22O11 | 57-50-1 | 200-334-9 | N/A | \leq 2.5% |
| Glycerol, 1,2,3-Propanetriol Glycerin C3H8O3) | 56-81-5 | 200-289-5 | N/A | \leq 0.5 % |

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

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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.
May cause slight irritation to eyes.

4.3 Indication of immediate medical attention and special treatment needed

No additional recommendations.

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. - COx ; NOx ; 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.

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

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Indications about waste treatment, see section 13.

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.

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.
Hygroscopic.

Requirements for storage

Keep closed. Shelter from light.
Store at a temperature below 25°C. 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

D(+) Saccharose

| Basis | Value | Threshold value | Comment |
|-------|-----------------------------------|------------------------|--|
| FVL | Mean exposition limit value (TWA) | 10.0 mg/m ³ | Occupational exposure values in France |

Glycerol

| Basis | Value | Threshold value | Comment |
|-------|-----------------------------------|------------------------|--|
| FVL | Mean exposition limit value (TWA) | 10.0 mg/m ³ | Occupational exposure values in France |

Additional information: The lists valid during the making were used as basis.

8.2 Exposure control

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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.
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

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| | |
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| 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 | Soluble |
| 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

In case of fire (see Chapter 5)

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11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Information about D(+) Saccharose

- **Acute toxicity oral**

LD50 rat

Dose: 29 700 mg/kg

Symptoms: Vomiting, diarrhea, convulsions

- **Acute inhalation toxicity**

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

- **Specific target organ – single exposure**

Data not available

- **Specific target organ – repeated exposure**

Data not available

- **Aspiration hazard**

Data not available

Information about glycerol

- **Acute toxicity oral**

LD50 rat

Dose : 12 600 mg/kg

Symptoms: Vomiting, diarrhea

- **Acute skin toxicity**

LD50 rabbit

Dose : > 18 700 mg/kg

(IUCLID)

- **Skin irritation**

Rabbit

Result: no irritation

(IUCLID)

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- **Eye irritation**

Rabbit

Result: no irritation
(external SDS)

- **Sensitization**

Patch test: human

Result: negative
(IUCLID)

- **In vitro Genotoxicity**

Ames test

Result: negative
(IUCLID)

- **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

Information about D(+) Saccharose

- *Toxicity to fish*

LC50

Data not available

- *Toxicity to daphnia and other aquatic invertebrates*

EC50

Data not available

Information about glycerol

- *Toxicity to fish*

LC50

Species: Carassius auratus

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Dose: > 5 000 mg/L

Exposure time: 24 h

- *Toxicity to daphnia and other aquatic invertebrates*

EC50

Species: *Daphnia magna*

Dose: > 10 000 mg/L

Exposure time: 24 h

(external SDS)

- *Toxicity to algae*

IC5

Species: *Scenedesmus quadricauda*

Dose: > 10 000 mg/L

Exposure time: 7 days

(external SDS)

- *Toxicity to bacteria*

EC5

Species: *Pseudomonas putida*

Dose: > 10 000 mg/L

Exposure time: 16 h

(external SDS)

12.2 Persistence and degradability

Information about glycerol

- *Biodegradability*

Result: readily biodegradable

63%

Exposure time: 14 days

(OCDE guideline 301c)

Information about D(+) Saccharose

No data available

12.3 Bioaccumulative potential

Information about glycerol

Partition Coefficient: n-octanol/water

Log POW: - 1.76

Bioaccumulation not expected (Log Pow 1-3)

(external SDS)

Information about D(+) saccharose

No data available

12.4 Mobility in soil

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Data not available

12.5 Results of PBT and vPvB assessment

Information about D(+) saccharose

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

Information about glycerol

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. |

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.

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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

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% |

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| 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 |