

ASSY, FILLED DISPENSER, AVIDIN-HRPO

Version 1.1

Revision Date 11-18-2013

Print Date 03-18-2014

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : ASSY, FILLED DISPENSER, AVIDIN-HRPO

Mat.-No./ Genisys-No. : 05261953001

Manufacturer or supplier's detailsCompany : Roche Diagnostics Limited
Charles AvenueAddress : Burgess Hill
RH15 9RY West Sussex

Telephone : +44 1444 256000

Telefax : +44 1444 256239

Emergency telephone : +49(0)621-759-2012 oder +49(0)621-759-4848 oder
number +49(0)8856-60-2629

Emergency telephone number:

In case of emergencies: : Health, Safety & +44 1444 256500 or +44 7802
(Roche Diagnostics Ltd.) Environment 260498

- +44 1444 256561 or +44 7710

Product Safety / Vigilance 391653

-

Toxicology 24Hr help-line: : NPIS: +44 844 892 0111

Health Advice 24Hr help-line: NHS Direct: +44 845 4647

NHS 24: +44 8454 242424

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION**Emergency Overview**

Physical state	liquid
Colour	amber
Odour	none

GHS Classification

Not a hazardous substance or mixture.

GHS Label element

Not a hazardous substance or mixture.

Potential Health Effects**Carcinogenicity:****IARC**

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed

ASSY, FILLED DISPENSER, AVIDIN-HRPO

Version 1.1

Revision Date 11-18-2013

Print Date 03-18-2014

ACGIH

human carcinogen by IARC.

OSHA

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTPNo component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.
No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Preparation

Hazardous components

Chemical Name	CAS-No.	Concentration [%]
Citric acid monohydrate	5949-29-1	>= 1 - < 5

SECTION 4. FIRST AID MEASURES

- General advice : Do not leave the victim unattended.
- If inhaled : Move to fresh air.
Consult a physician after significant exposure.
If unconscious place in recovery position and seek medical advice.
- In case of skin contact : If on skin, rinse well with water.
- In case of eye contact : Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Rinse mouth with water.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : High volume water jet

ASSY, FILLED DISPENSER, AVIDIN-HRPO

Version 1.1

Revision Date 11-18-2013

Print Date 03-18-2014

Specific hazards during firefighting	: No information available.
Further information	: Standard procedure for chemical fires. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Special protective equipment for firefighters	: Wear self contained breathing apparatus for fire fighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Use personal protective equipment. Ensure adequate ventilation. Refer to protective measures listed in sections 7 and 8.
Environmental precautions	: Prevent further leakage or spillage if safe to do so. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	: Wipe up with absorbent material (e.g. cloth, fleece). Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on safe handling	: Avoid formation of aerosol. For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area. Provide sufficient air exchange and/or exhaust in work rooms. Dispose of rinse water in accordance with local and national regulations.
Conditions for safe storage	: Keep container tightly closed in a dry and well-ventilated place. Electrical installations / working materials must comply with the technological safety standards.
Materials to avoid	:

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection	: In the case of vapour formation use a respirator with an approved filter.
------------------------	---

ASSY, FILLED DISPENSER, AVIDIN-HRPO

Version 1.1

Revision Date 11-18-2013

Print Date 03-18-2014

Hand protection	
Material	: Protective gloves
Remarks	: The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.
Eye protection	: Eye wash bottle with pure water Tightly fitting safety goggles
Skin and body protection	: impervious clothing Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Hygiene measures	: When using do not eat or drink. When using do not smoke. Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: liquid
Colour	: amber
Odour	: none
pH	: neutral
Melting point/range	: no data available
Boiling point/boiling range	: no data available
Flash point	: does not flash
Upper explosion limit	: no data available
Lower explosion limit	: no data available
Solubility(ies)	
Water solubility	: completely miscible
Auto-ignition temperature	: no data available
Thermal decomposition	: no data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

SECTION 10. STABILITY AND REACTIVITY

ASSY, FILLED DISPENSER, AVIDIN-HRPO

Version 1.1

Revision Date 11-18-2013

Print Date 03-18-2014

Reactivity	: No dangerous reaction known under conditions of normal use.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: Reacts with the following substances: Oxidizing agents No decomposition if stored and applied as directed.
Conditions to avoid	: no data available
Incompatible materials	: no data available
Hazardous decomposition products	: Carbon oxides Oxides of phosphorus Sodium oxides

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity****Product:**

Acute inhalation toxicity : Acute toxicity estimate : 30.47 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: Calculation method

Components:**Citric acid monohydrate:**

Acute oral toxicity : LD50 mouse: 5,400 mg/kg

LD50 rat: > 6,730 mg/kg

LD50 rabbit: > 7,000 mg/kg

Skin corrosion/irritation**Components:****Citric acid monohydrate:**

Remarks: Extremely corrosive and destructive to tissue.

Serious eye damage/eye irritation**Components:****Citric acid monohydrate:**

Result: Irritating to eyes.
Remarks: May cause irreversible eye damage.

Respiratory or skin sensitisation**Components:**

ASSY, FILLED DISPENSER, AVIDIN-HRPO

Version 1.1

Revision Date 11-18-2013

Print Date 03-18-2014

Citric acid monohydrate:

Classification: Did not cause sensitisation on laboratory animals.

Germ cell mutagenicity

no data available

Carcinogenicity

no data available

Reproductive toxicity

no data available

STOT - single exposure**Components:****Citric acid monohydrate:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT - repeated exposure**Components:****Citric acid monohydrate:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration toxicity**Components:****Citric acid monohydrate:**

no data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Product:**

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : no data available

Components:**Citric acid monohydrate :**

Toxicity to fish : LC0 (Carassius auratus (goldfish)): 625 mg/l

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 120 mg/l
Exposure time: 72 h

Ecotoxicology Assessment

ASSY, FILLED DISPENSER, AVIDIN-HRPO

Version 1.1

Revision Date 11-18-2013

Print Date 03-18-2014

- Acute aquatic toxicity : This product has no known ecotoxicological effects.
- Chronic aquatic toxicity : This product has no known ecotoxicological effects.
- Toxicity Data on Soil : Not expected to adsorb on soil.
- Other organisms relevant to the environment : no data available

Persistence and degradability**Components:****Citric acid monohydrate :**

- Biodegradability : Remarks: Expected to be ultimately biodegradable

Bioaccumulative potential**Components:****Citric acid monohydrate :**

- Partition coefficient: n-octanol/water : log Pow: 1.72

Mobility in soil

no data available

Other adverse effects

no data available

Product:

- Regulation 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
- Remarks This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

- Waste from residues : Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with local regulations.
- Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

ASSY, FILLED DISPENSER, AVIDIN-HRPO

Version 1.1

Revision Date 11-18-2013

Print Date 03-18-2014

International regulation**IATA-DGR**

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

National Regulations**49 CFR**

Not regulated as a dangerous good

Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADNR,
IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION

OSHA Hazards : Moderate eye irritant

WHMIS Classification : D2B: Toxic Material Causing Other Toxic Effects

EPCRA - Emergency Planning and Community Right-to-Know Act

SARA 302 : SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

ASSY, FILLED DISPENSER, AVIDIN-HRPO

Version 1.1

Revision Date 11-18-2013

Print Date 03-18-2014

US State Regulations**Massachusetts Right To Know**

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

non hazardous compounds

Not Assigned 90 - 100 %

New Jersey Right To Know

non hazardous compounds
Citric acid monohydrate

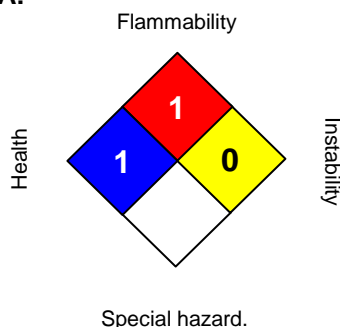
Not Assigned 90 - 100 %
5949-29-1 1 - 5 %

California Prop 65

: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

Inventories

AICS (Australia), DSL (Canada), IECSC (China), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TSCA (USA)

SECTION 16. OTHER INFORMATION**Further information****NFPA:****HMIS III:**

HEALTH	2
FLAMMABILITY	1
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.