

SECTION 1: Identification

1.1. Identification

Product form : Mixture
 Product name : QuickVue® Adenoviral conjunctivitis Test
 Product code : 20324, 20340

1.2. Recommended use and restrictions on use

Recommended use : A rapid, immunoassay test for the visual, qualitative, in vitro detection of Adenoviral antigens (hexon protein) directly from human eye fluid. For in vitro diagnostic use only.
 Restrictions on use : Professional Use of Medical Devices

1.3. Supplier

Quidel Corporation
 10165 McKellar Court
 San Diego, CA 92121 - U.S.A
 T 1.800.874.1517 - F 1.858.453.4338
qehs@quidelortho.com - quidel.com

1.4. Emergency telephone number

Emergency number : 1.866.519.4752

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Not classified

2.2. GHS Label elements, including precautionary statements

GHS US labeling

No labeling applicable

SECTION 3: Composition/Information on ingredients

Name	Chemical name	CAS #	%	GHS US classification
Buffer	tris(hydroxymethyl)aminomethane	77-86-1	4.8	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335

Full text of hazard classes and H-statements : see section 16

SECTION 4: First-aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.
 First-aid measures after skin contact : Wash skin with plenty of water.
 First-aid measures after eye contact : Rinse eyes with water as a precaution.
 First-aid measures after ingestion : Call a poison center/doctor/physician if you feel unwell.

4.2. Most important symptoms and effects (acute and delayed)

Immediate medical attention and special treatment, if necessary : Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Specific hazards arising from the chemical

No additional information available

5.3. Special protective equipment and precautions for fire-fighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Environmental precautions : Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material.

Other information : Dispose of materials or solid residues at an authorized site.

Reference to other sections : For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Appropriate engineering controls

Appropriate engineering controls : Ensure good ventilation of the work station.

Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

Materials for protective clothing:

Lab coat

Hand protection:

Wear protective gloves. Wash your hands

Eye protection:

Safety glasses

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Personal protective equipment symbol(s):



Other information:

Do not eat, drink or smoke when using this product.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid (Buffer)
Color	: Clear (Buffer)
Odor	: Odorless
Odor threshold	: No data available
pH	: No data available
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability	: Not applicable.
Vapor pressure	: No data available
Relative vapor density at 20°C	: No data available
Relative density	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

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

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

tris(hydroxymethyl)aminomethane (77-86-1)

LD50 oral rat	> 5000 mg/kg body weight (OECD 425: Acute Oral Toxicity: Up-and-Down Procedure, Rat, Female, Experimental value, Oral, 14 day(s))
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tris(hydroxymethyl)aminomethane (77-86-1)	
LD50 dermal rat	> 5000 mg/kg body weight Animal: rat, Guideline: OECD Guideline 402 (Acute Dermal Toxicity), Guideline: EPA OPPTS 870.1200 (Acute Dermal Toxicity)
LD50 dermal rabbit	5900 mg/kg Source: Corporate Solution From Thomson Micromedex
ATE US (dermal)	5900 mg/kg body weight

Skin corrosion/irritation : Not classified
 Serious eye damage/irritation : Not classified
 Respiratory or skin sensitization : Not classified
 Germ cell mutagenicity : Not classified
 Carcinogenicity : Not classified
 Reproductive toxicity : Not classified
 STOT-single exposure : Not classified

tris(hydroxymethyl)aminomethane (77-86-1)	
STOT-single exposure	May cause respiratory irritation.

STOT-repeated exposure : Not classified

tris(hydroxymethyl)aminomethane (77-86-1)	
LOAEL (oral,rat,90 days)	1000 mg/kg body weight Animal: rat, Guideline: OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity Study in Rodents)
NOAEL (oral,rat,90 days)	250 mg/kg body weight Animal: rat, Guideline: OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity Study in Rodents)

Aspiration hazard : Not classified
 Viscosity, kinematic : No data available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

tris(hydroxymethyl)aminomethane (77-86-1)	
LC50 - Fish [1]	955.892 mg/l Source: Ecological Structure Activity Relationships
EC50 - Crustacea [1]	19.793 mg/l Source: Ecological Structure Activity Relationships
ErC50 algae	397 mg/l (Equivalent or similar to OECD 201, 72 h, Pseudokirchneriella subcapitata, Static system, Fresh water, Experimental value, Nominal concentration)

12.2. Persistence and degradability

tris(hydroxymethyl)aminomethane (77-86-1)	
Persistence and degradability	Readily biodegradable in water.

12.3. Bioaccumulative potential

tris(hydroxymethyl)aminomethane (77-86-1)	
Partition coefficient n-octanol/water (Log Pow)	-2.31 (Experimental value, OECD 107: Partition Coefficient (n-octanol/water): Shake Flask Method, 20 °C)
Bioaccumulative potential	Not bioaccumulative.

12.4. Mobility in soil

tris(hydroxymethyl)aminomethane (77-86-1)	
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	1.34 - 1.87 (log Koc, QSAR)
Ecology - soil	Highly mobile in soil.

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Disposal methods

- Regional legislation (waste) : Disposal must be done according to official regulations.
- Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.
- Sewage disposal recommendations : Disposal must be done according to official regulations.
- Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

Department of Transportation (DOT)

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

SECTION 15: Regulatory information

15.1. US Federal regulations

QuickVue® Adenoviral conjunctivitis Test

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

tris(hydroxymethyl)aminomethane	CAS No 77-86-1	4.8%
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This product or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

15.2. International regulations

CANADA

tris(hydroxymethyl)aminomethane (77-86-1)

Listed on the Canadian DSL (Domestic Substances List)

EU-Regulations

No additional information available

National regulations

No additional information available

15.3. US State regulations

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

SECTION 16: Other information

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.