

KIT COPAN MSWAB 6X50 TESTS IVDVersion
1.3Revision Date:
04-25-2015Date of last issue: 09-18-2014
Date of first issue: 12-16-2013**SECTION 1. IDENTIFICATION**

Product name : KIT COPAN MSWAB 6X50 TESTS IVD

Mat.-No./ Genisys-No. : 07007248190

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

Address : 9115 Hague Road
46250 Indianapolis IN

Telephone : 1-800-428-5074

Emergency telephone number:

In case of emergencies: : CHEMTREC

1-800-424-9300 (U.S. or Can-
ada)

1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section Label elements contains the resulting labelling for the kit.

GHS Label element

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**MSWAB****GHS Classification**

Not a hazardous substance or mixture.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
dimethyl sulfoxide	67-68-5	≥ 5 - < 10

SECTION 4. FIRST AID MEASURES

General advice : Do not leave the victim unattended.

If inhaled : Move to fresh air.

KIT COPAN MSWAB 6X50 TESTS IVDVersion
1.3Revision Date:
04-25-2015Date of last issue: 09-18-2014
Date of first issue: 12-16-2013

	If unconscious place in recovery position and seek medical advice. If symptoms persist, call a physician.
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.
Most important symptoms and effects, both acute and delayed	: None known.
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
Specific hazards during fire-fighting	: 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 firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: 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	: Wipe up with absorbent material (e.g. cloth, fleece).

KIT COPAN MSWAB 6X50 TESTS IVD
Version
1.3Revision Date:
04-25-2015Date of last issue: 09-18-2014
Date of first issue: 12-16-2013

containment and cleaning up

Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

Advice on safe handling : For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
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.

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
dimethyl sulfoxide	67-68-5	TWA	250 ppm	US WEEL

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

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 con-

KIT COPAN MSWAB 6X50 TESTS IVD
Version
1.3Revision Date:
04-25-2015Date of last issue: 09-18-2014
Date of first issue: 12-16-2013

centration 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
MSWAB

Appearance : liquid

Colour : No data available

Odour : characteristic

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

Flammability (solid, gas) : No data available

Upper explosion limit : No data available

Lower explosion limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : completely miscible

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity : No data available

Explosive properties : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : No decomposition if stored and applied as directed.

Conditions to avoid : Heat, flames and sparks.

Incompatible materials : Oxidizing agents

KIT COPAN MSWAB 6X50 TESTS IVDVersion
1.3Revision Date:
04-25-2015Date of last issue: 09-18-2014
Date of first issue: 12-16-2013**SECTION 11. TOXICOLOGICAL INFORMATION*****MSWAB*****Acute toxicity**

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:**dimethyl sulfoxide:**

Acute oral toxicity : LD50 Oral (Rat): 14,500 mg/kg
LD50 Oral (Mouse): 7,920 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l
Test atmosphere: vapour
Method: Expert judgement

Acute dermal toxicity : LD50 Dermal (Rat): 40,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**dimethyl sulfoxide:**

Remarks: This information is not available.

Serious eye damage/eye irritation

Not classified based on available information.

Components:**dimethyl sulfoxide:**

Remarks: This information is not available.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Product:

Assessment: May be harmful if swallowed.

Components:**dimethyl sulfoxide:**

Species: Guinea pig

Result: Does not cause skin sensitisation.

Assessment: Mild eye irritation, Mild skin irritation

KIT COPAN MSWAB 6X50 TESTS IVDVersion
1.3Revision Date:
04-25-2015Date of last issue: 09-18-2014
Date of first issue: 12-16-2013**Germ cell mutagenicity**

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC

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

NTP

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.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

Components:**dimethyl sulfoxide:**

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

STOT - repeated exposure

Not classified based on available information.

Components:**dimethyl sulfoxide:**

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

Product:Repeated dose toxicity - : May be harmful if swallowed.
Assessment**Components:****dimethyl sulfoxide:**Repeated dose toxicity - : Mild eye irritation, Mild skin irritation
Assessment**Aspiration toxicity**

Not classified based on available information.

Components:**dimethyl sulfoxide:**

No data available

KIT COPAN MSWAB 6X50 TESTS IVDVersion
1.3Revision Date:
04-25-2015Date of last issue: 09-18-2014
Date of first issue: 12-16-2013**SECTION 12. ECOLOGICAL INFORMATION****MSWAB****Ecotoxicity****Components:****dimethyl sulfoxide:**

- Toxicity to fish : LC50 (Fish): 32,500 mg/l
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 24,600 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
- Toxicity to bacteria : EC50 (Photobacterium phosphoreum): ca. 70,000 mg/l
Exposure time: 0.25 h
- Ecotoxicology Assessment
Toxicity Data on Soil : Not expected to adsorb on soil.
- Other organisms relevant to the environment : No data available

Persistence and degradability**Components:****dimethyl sulfoxide:**

- Biodegradability : Biodegradation: 4 %
Exposure time: 1 d
- Biodegradation: 6 %
Exposure time: 8 d
- Biodegradation: 29 %
Exposure time: 15 d
- Biodegradation: 90 %
Exposure time: 28 d
Method: OECD Test Guideline 302

Bioaccumulative potential**Components:****dimethyl sulfoxide:**

- Partition coefficient: n-octanol/water : log Pow: -1.35

Mobility in soil

No data available

Other adverse effects**Product:**

KIT COPAN MSWAB 6X50 TESTS IVDVersion
1.3Revision Date:
04-25-2015Date of last issue: 09-18-2014
Date of first issue: 12-16-2013

Ozone-Depletion Potential : 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**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

SECTION 15. REGULATORY INFORMATION**MSWAB****TSCA list** : Not relevant**EPCRA - Emergency Planning and Community Right-to-Know Act****CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

KIT COPAN MSWAB 6X50 TESTS IVDVersion
1.3Revision Date:
04-25-2015Date of last issue: 09-18-2014
Date of first issue: 12-16-2013

- SARA 311/312 Hazards** : No SARA Hazards
- SARA 302** : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.
- 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 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).

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).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCMII Intermediate or Final VOC's (40 CFR 60.489):

dimethyl sulfoxide	67-68-5	6 %
--------------------	---------	-----

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

Massachusetts Right To Know

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

Pennsylvania Right To Know

non hazardous compounds (liquid)	Not Assigned	90 - 100 %
dimethyl sulfoxide	67-68-5	5 - 10 %

New Jersey Right To Know

non hazardous compounds (liquid)	Not Assigned	90 - 100 %
dimethyl sulfoxide	67-68-5	5 - 10 %

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.

The components of this product are reported in the following inventories:

- REACH : Not in compliance with the inventory
- : non hazardous compounds (liquid)
- : dimethyl sulfoxide
- : trometamol
- : Edetic acid disodium salt dihydrate (EDTA-2Na-2H2O)

KIT COPAN MSWAB 6X50 TESTS IVDVersion
1.3Revision Date:
04-25-2015Date of last issue: 09-18-2014
Date of first issue: 12-16-2013

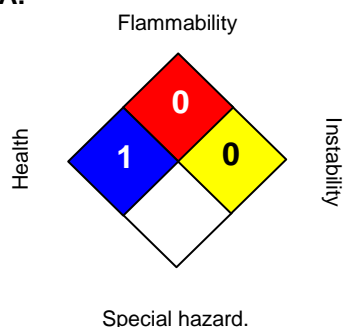
	: 2-amino-2-(hydroxymethyl)propane-1,3-diol hydrochloride
CH INV	: Not in compliance with the inventory
	: non hazardous compounds (liquid)
TSCA	: Not On TSCA Inventory
	: non hazardous compounds (liquid)
DSL	: This product contains the following components that are not on the Canadian DSL nor NDSL.
	: non hazardous compounds (liquid)
AICS	: Not in compliance with the inventory
	: non hazardous compounds (liquid)
NZIoC	: On the inventory, or in compliance with the inventory
ENCS	: Not in compliance with the inventory
	: non hazardous compounds (liquid)
	: 2-amino-2-(hydroxymethyl)propane-1,3-diol hydrochloride
ISHL	: Not in compliance with the inventory
	: non hazardous compounds (liquid)
	: 2-amino-2-(hydroxymethyl)propane-1,3-diol hydrochloride
KECI	: Not in compliance with the inventory
	: non hazardous compounds (liquid)
PICCS	: Not in compliance with the inventory
	: non hazardous compounds (liquid)
IECSC	: Not in compliance with the inventory
	: non hazardous compounds (liquid)

Inventories

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

MSWAB**GHS Label element**

Not a hazardous substance or mixture.

KIT COPAN MSWAB 6X50 TESTS IVDVersion
1.3Revision Date:
04-25-2015Date of last issue: 09-18-2014
Date of first issue: 12-16-2013**SECTION 16. OTHER INFORMATION****Further information****MSWAB
NFPA:****HMIS III:**

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

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

Revision Date : 04-25-2015

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.

US / EN