cobas u pack

Version	Revision Date:	Date of last issue: 02.04.2024
2.2	23.06.2024	Date of first issue: 16.03.2021

SECTION 1: IDENTIFICATION

Product name : cobas u pack

Mat.-No./ Genisys-No. : 06334601001

Manufacturer or supplier's details

Company : Roche Diagnostics Australia Pty Limited

Address : 2 Julius Avenue
North Ryde, NSW 2113, Australia
Australia

Telephone : +61 2 9860 2222

Emergency telephone number:

Emergency contact: : National Support Centre: Tel. 1800 645 619
Follow Voice Prompts

E-mail address : australia.qra@roche.com

Telefax : +61 2 9860 2111

Recommended use of the chemical and restrictions on use

Recommended use : Laboratory chemicals
Refer to product literature for further details.

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	< 10
Boric acid	10043-35-3	< 0.3
Glucose-Oxidase (GOD) from Aspergillus niger	9001-37-0	< 1
Peroxidase (POD)	9003-99-0	< 1

SECTION 4. FIRST AID MEASURES

General advice	:	Move out of dangerous area. Show this safety data sheet to the doctor in attendance. Do not leave the victim unattended.
If inhaled	:	Move to fresh air. 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. Take victim immediately to hospital. 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 firefighting	:	Do not allow run-off from fire fighting to enter drains or water courses.
Hazardous combustion products	:	Carbon oxides Nitrogen oxides (NOx) Sodium oxides Boranes Boron oxides Carbon oxides

Specific extinguishing methods	:	Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
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	:	Use personal protective equipment. Avoid dust formation. Avoid breathing dust.
Environmental precautions	:	Prevent product from entering drains. Prevent further leakage or spillage if safe to do so.
Methods and materials for containment and cleaning up	:	Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	:	Avoid dust formation. Provide appropriate exhaust ventilation at places where dust is formed.
Advice on safe handling	:	Avoid formation of respirable particles. Do not breathe vapours/dust. Avoid exposure - obtain special instructions before use. Avoid contact with skin and eyes. 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.
Hygiene measures	:	When using do not eat or drink. When using do not smoke. Wash hands before breaks and at the end of workday.
Conditions for safe storage	:	Keep container tightly closed in a dry and well-ventilated place. Observe label precautions. Electrical installations / working materials must comply with the technological safety standards.
Further information on storage conditions	:	See label, package insert or internal guidelines
Further information on stor-	:	No decomposition if stored and applied as directed.

age stability

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m3	AU OEL
		TWA	10 mg/m3	ACGIH
Boric acid (H3BO3)	10043-35-3	TWA (Inhalable particulate matter)	2 mg/m3 (Borate)	ACGIH
		STEL (Inhalable particulate matter)	6 mg/m3 (Borate)	ACGIH
Glucose-Oxidase (GOD) from Aspergillus niger	9001-37-0	IOEL	0.00006 mg/m3	Roche Industrial Hygiene Committee (RIHC)
Peroxidase (POD)	9003-99-0	IOEL	0.00006 mg/m3	Roche Industrial Hygiene Committee (RIHC)

Engineering measures : No data available

Personal protective equipment

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.
Effective dust mask

Hand protection

In case of contact through splashing:

Material	:	Nitrile rubber
Break through time	:	> 30 min
Glove thickness	:	> 0.11 mm

In case of full contact:

Material	:	butyl-rubber
Break through time	:	> 480 min
Glove thickness	:	> 0.4 mm

Remarks : The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 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 : Choose body protection according to the amount and concentration of the dangerous substance at the work place.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	solid
Colour	:	No data available
Odour	:	odourless
Odour Threshold	:	Not applicable
pH	:	Not applicable
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Sustains combustion
Flammability (liquids)	:	Sustains combustion
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available

Relative vapour density	:	Not applicable
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	insoluble
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

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	:	No data available
Incompatible materials	:	No data available
Hazardous decomposition products	:	No decomposition if stored and applied as directed. In case of fire hazardous decomposition products may be produced such as: Carbon oxides Nitrogen oxides (NOx) Sodium oxides Boranes Boron oxides

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified due to lack of data.

Components:

Cellulose:

Acute oral toxicity	:	LD50 Oral (Rat): > 5,000 mg/kg
Acute dermal toxicity	:	LD50 Dermal (Rabbit): > 2,000 mg/kg

Boric acid:

Acute oral toxicity	:	LD50 Oral (Rat, male): 3,450 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 2.03 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 Assessment: The substance or mixture has no acute inhalation toxicity Remarks: No mortality observed at this dose.
Acute dermal toxicity	:	LD50 Dermal (Rabbit, male and female): > 2,000 mg/kg

Skin corrosion/irritation

Not classified due to lack of data.

Components:

Boric acid:

Species	:	Rabbit
Result	:	No skin irritation

Serious eye damage/eye irritation

Not classified due to lack of data.

Components:

Boric acid:

Species	:	Rabbit
Result	:	Mild eye irritation
Method	:	OECD Test Guideline 405
GLP	:	yes

Peroxidase (POD):

Remarks	:	Product dust may be irritating to eyes, skin and respiratory system.

Respiratory or skin sensitisation

Skin sensitisation

Not classified due to lack of data.

Respiratory sensitisation

Not classified due to lack of data.

Components:

Boric acid:

Test Type	:	Buehler Test
Species	:	Guinea pig
Assessment	:	Does not cause skin sensitisation.
Method	:	OECD Test Guideline 406

Glucose-Oxidase (GOD) from Aspergillus niger:

Assessment	:	May cause sensitisation by inhalation.
Assessment	:	May cause sensitisation by skin contact.

Peroxidase (POD):

Assessment	:	May cause sensitisation by skin contact.
Assessment	:	May cause sensitisation by inhalation.

Chronic toxicity

Germ cell mutagenicity

Not classified due to lack of data.

Components:

Boric acid:

Genotoxicity in vitro	:	Test Type: Microbial mutagenesis assay (Ames test) Test system: Salmonella typhimurium Method: OECD Test Guideline 471 Result: negative Test Type: In vitro mammalian cell gene mutation test Test system: mouse lymphoma cells Method: OECD Test Guideline 476 Result: negative Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells Method: OECD Test Guideline 482 Result: negative Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells

Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse (male and female)
Application Route: Oral
Method: OECD Test Guideline 474
Result: negative

Carcinogenicity

Not classified due to lack of data.

Components:

Cellulose:

Remarks : 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.

Glucose-Oxidase (GOD) from Aspergillus niger:

Remarks : 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.

Reproductive toxicity

Not classified due to lack of data.

Components:

Boric acid:

Reproductive toxicity - Assessment : May damage fertility. May damage the unborn child., Presumed human reproductive toxicant

STOT - single exposure

Not classified due to lack of data.

Components:

Glucose-Oxidase (GOD) from Aspergillus niger:

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

STOT - repeated exposure

Not classified due to lack of data.

Components:

Glucose-Oxidase (GOD) from Aspergillus niger:

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

Repeated dose toxicity

Components:

Boric acid:

Species	:	Rat, male and female
NOAEL	:	17.5 mg/kg
LOAEL	:	58.5 mg/kg
Application Route	:	Oral

Aspiration toxicity

Not classified due to lack of data.

Components:

Glucose-Oxidase (GOD) from Aspergillus niger:

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cellulose:

Ecotoxicology Assessment

Acute aquatic toxicity	:	This product has no known ecotoxicological effects.
Chronic aquatic toxicity	:	This product has no known ecotoxicological effects.

Boric acid:

Toxicity to fish	:	LC50 (Gambusia affinis (Mosquito fish)): 5,600 mg/l Exposure time: 96 h LC50 (Oncorhynchus mykiss (rainbow trout)): 79 mg/l Exposure time: 96 h Test Type: flow-through test LC50 (Fish): 279 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 133 mg/l Exposure time: 48 h Test Type: static test
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 52.4 mg/l Exposure time: 74.5 h Test Type: static test Analytical monitoring: yes

		Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 17.5 mg/l Exposure time: 74.5 h Test Type: static test Analytical monitoring: yes Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	:	NOEC (Danio rerio (zebra fish)): 6.4 mg/l Exposure time: 34 d Test Type: semi-static test Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 34.2 mg/l Exposure time: 21 d Test Type: semi-static test Method: OECD Test Guideline 211

Glucose-Oxidase (GOD) from Aspergillus niger:

Ecotoxicology Assessment

Toxicity Data on Soil	:	Not expected to adsorb on soil.
Other organisms relevant to the environment	:	No data available

Peroxidase (POD):

Ecotoxicology Assessment

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:

Boric acid:

Biodegradability	:	Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

Bioaccumulative potential

Components:

Cellulose:

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

Boric acid:

Bioaccumulation : Remarks: Due to the distribution coefficient n-octanol/water, accumulation in organisms is not expected.

Partition coefficient: n-octanol/water : log Pow: -1.09 (22 °C)
Method: Regulation (EC) No. 440/2008, Annex, A.8

Glucose-Oxidase (GOD) from Aspergillus niger:

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

Peroxidase (POD):

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

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : The product should not be allowed to enter drains, water courses or the soil.
Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.

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 Regulations

UNRTDG

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable

IATA-DGR

UN/ID No.	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Packing instruction (cargo aircraft)	:	Not applicable
Packing instruction (passenger aircraft)	:	Not applicable

IMDG-Code

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
EmS Code	:	Not applicable
Marine pollutant	:	Not applicable

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

Not applicable

National Regulations

ADG

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Hazchem Code	:	Not applicable

Special precautions for user

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

SECTION 15. REGULATORY INFORMATION

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

Standard for the Uniform Scheduling of Medicines and Poisons	:	Schedule 6 (Please use the original publication of the SUSMP to check for specific uses, specific conditions or threshold limits that might apply for this chemical)
Prohibition/Licensing Requirements	:	There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

AIIC	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. non hazardous compounds Trimorpholinophosphine oxide Polyamide 6 Propiophan Marlon ARL Phenanthridine 4-methoxybenzenediazonium tetrafluoroborate 3-Hydroxy-1,2,3,4-tetrahydro-7,8-benzochinoline 2,6-dichlorobenzenediazonium tetrafluoroborate TSA-Indol 3,3,6,6-Tetramethyl-1,2-dioxane 1-p-tolylsemicarbazide 4,4'-(4,5,6,7-tetrabromo-3H-2,1-benzoxathiol-3-ylidene)bis[2,6-dichlorophenol] S,S-dioxide Tri-lithium citrate-4-hydrate 2,5-Dimethyl-2,5-dihydroperoxy hexane Lithium iodate Phenicarbazide 2-Naphthalenesulfonic acid, 8-hydroxy-5,7-dinitro-, disodium salt 2-methoxy-4-(morpholin-4-yl)benzenediazonium tetrachlorozincate (2:1) Peroxidase (POD)
NZIoC	:	Not in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory

IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not active and not listed on TSCA inventory.
TECI	:	Not in compliance with the inventory

SECTION 16: ANY OTHER RELEVANT INFORMATION

Revision Date	:	23.06.2024
Date format	:	dd.mm.yyyy

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
AU OEL	:	Australia. Workplace Exposure Standards for Airborne Contaminants.
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
AU OEL / TWA	:	Exposure standard - time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOErC - No Observed Effect Concentration based on growth rate; NOEyC - No Observed Effect Concentration based on yield; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-

Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

AU / EN / 2304