

SAFETY DATA SHEET

 Title: COBALEX 2000 B12 INJECTION
 Document: SDS-AU021

 Rev: 2.1
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 Status: Current
 Issue Date: 24-Feb-2023
 Effective Date: 01-Mar-2023
 Review Date: 18-Jan-2028

Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

Product Name: Cobalex 2000 B12 Injection

Product Identifier: 2 mg/mL hydroxocobalamin (as hydroxocobalamin acetate)

solution for injection.

Recommended Use: For the treatment and control of Vitamin B12 deficiency in sheep

and cattle.

Restrictions on Use: For animal treatment only.

Company Identification: Jurox Pty Limited (part of Zoetis)

Address: 85 Gardiner Street

Rutherford NSW 2320

Australia

Customer Service: 1800 022 442 (Mon-Fri, 8:00am – 6:00pm AEST)

Email: customerservice@jurox.com.au

National Poisons Information Centre: 13 11 26 (24 hours)

Emergency Telephone Number: 1800 814 883 (all hours)

Section 2: HAZARDS IDENTIFICATION

GHS Hazard Classifications: This product has been assessed according to GHS and is classified as non-hazardous.

GHS Label Elements:

<u>Hazard Statements:</u> None.

Signal Word: None.

GHS Pictograms: None.

<u>Precautionary Statements:</u> None.

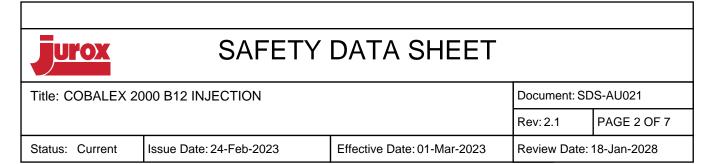
Other hazards: None known.

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

INGREDIENT	CAS No.	CONTENT
Hydroxocobalamin acetate	22465-48-1	0.23%
Ingredients not contributing to the hazards	-	> 99%

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Section 4: FIRST AID MEASURES

General Information: Consult the National Poisons Centre on 13 11 26 or a doctor immediately in every case of suspected chemical poisoning. Never give fluids or induce vomiting if a patient is unconscious or convulsing regardless of cause of injury. If medical advice/attention is needed, have this SDS, product container or label at hand.

Symptoms and Effects of Exposure: None known.

Inhalation: If fumes, aerosols or combustion products are inhaled remove patient from contaminated area. Other measures are usually unnecessary. If respiratory symptoms occur, remove patient to fresh air. Lay patient down and keep warm and rested. If breathing is shallow or has stopped, ensure airway is clear and apply resuscitation. If breathing is difficult, give oxygen and seek medical assistance immediately.

Ingestion: If swallowed, DO NOT induce vomiting. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. Observe the patient carefully.

Skin: If skin contact occurs: Immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.

Eye: If eye contact occurs: Immediately flush the eye continuously with running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Continue flushing for at least 20 minutes. If eye irritation persists, get medical advice/attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

Injection: Treat as for needle stick injury. Wash the wound thoroughly with soap and water or use a waterless cleanser or antiseptic if water is unavailable. Apply a dressing as necessary and apply pressure through the dressing if bleeding is still occurring. Do not squeeze or rub the injury site. Dispose of the needle in a suitable sharps container and seek medical advice/attention if concerned.

Recommended First Aid Facilities: Ready access to running water and soap is required. Accessible eyewash is required.

Advice to Doctor: Treat symptomatically.

Section 5: FIRE FIGHTING MEASURES

Flash Point: Not flammable.

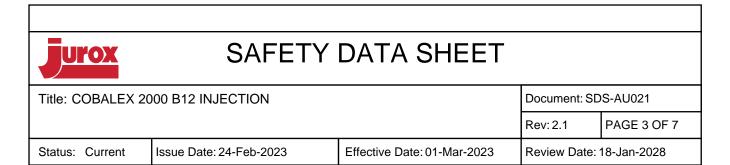
Hazardous Combustion Products: If involved in a fire, may emit toxic and corrosive fumes.

Extinguishing Media: There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.

Protective Equipment: Protective gloves and boots and breathing apparatus.

Hazchem Code: Not specified.

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Section 6: ACCIDENTAL RELEASE MEASURES

Spills and Disposal: Wear gloves and appropriate protective clothing. Avoid breathing vapours and contact with skin and eyes. Clean up all spills immediately. For small spills, clean up spilled product then wipe area and put empty container in garbage. For large spills, exclude non-essential people from the area. Contain and absorb spill with sand, earth, inert material or vermiculite. Prevent spillage from entering drains or water courses and call emergency services.

Protective Clothing: For appropriate personal protective equipment see section 8.

Environmental Precautions: Prevent from entering drains, waterways or sewers. If contamination of drains and waterways occurs, advise local authority.

Section 7: HANDLING AND STORAGE

Handling: This product is classified as non-hazardous under the GHS classification system. However, the product should still be handled with care to avoid exposure, taking all recommended precautions. Avoid contact with skin, eyes and inhalation of vapours. Use in a well-ventilated area. Do not allow clothing wet with material to stay in contact with skin. Take care to avoid accidental self-injection. Use personal protective equipment as required. Do not eat, drink or smoke while handling product.

Storage: Store below 30°C (room temperature). Protect from light. Do not freeze.

Other Information: Always read the label before use. See label for further information on handling and storage.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

This SDS describes personal protective measures relating to long term industrial and manufacturing exposure and emergency situations, such as accidents and spills. See product label for personal protective measures during normal use of the marketed product.

Exposure Limits: No exposure limits have been assigned for this product nor for any ingredients.

Engineering Controls: Use only in a well-ventilated area. Ensure that the work environment remains clean.

Personal Protective Equipment (PPE):

<u>Eye Protection:</u> Safety glasses with side shields or chemical goggles are recommended when handling bulk quantities of this product.

<u>Skin Protection:</u> When handling bulk product, prevent skin contact by wearing chemical protective gloves e.g. PVC.

Respiratory Protection: Not required for the normal use of this product.

Other: When handling bulk quantities of this product, overalls, barrier cream and eye wash unit may be required.

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Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear, deep red liquid,

free of particulate

matter.

Upper / Lower

Flammability Limits:

Not available.

Odour: Not available.

Vapour Pressure:

Not available.

Not available.

Odour Threshold:

Not available.

Vapour Density:

pH: 3.

3.5 – 5.0 Relative Density /

Specific Gravity:

~ 1.005

Melting Point / Freezing

Point:

Not available.

Solubility:

Aqueous solution. Soluble in water.

Boiling Point and

Boiling Range:

Not available.

Partition Coefficient (n-octanol/water):

Not available.

Flash Point:

Not available.

Auto-Ignition Temperature:

Not available.

Evaporation Rate:

Not available.

Decomposition Temperature:

Not available.

Flammability:

Not available.

Viscosity:

Not available.

Section 10: STABILITY AND REACTIVITY

Reactivity: This product is unlikely to react or polymerise under normal storage conditions.

Chemical Stability: When stored appropriately this product should show no significant degradation within the expiry period shown on the label.

Conditions to Avoid: Extreme temperatures.

Incompatible Materials: Oxidising agents.

Hazardous Decomposition Products: Decomposition may produce toxic fumes of carbon dioxide (CO₂) and other pyrolysis products typical of burning organic material.

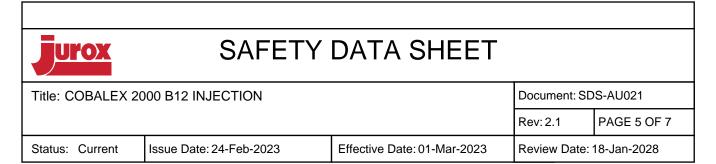
Section 11: TOXICOLOGICAL INFORMATION

Acute Toxicity:

<u>Ingestion:</u> No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the oral route.

<u>Inhalation:</u> No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the inhalation route.

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<u>Dermal:</u> No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the dermal route. Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.

Injection: No data for the mixture is available.

Hydroxocobalamin acetate: Intravenous LD₅₀: 2000 mg/kg (mouse).

Skin Corrosion / Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a skin irritant.

Serious Eye Damage / Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be an eye irritant.

Respiratory or Skin Sensitisation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a skin sensitiser or respiratory sensitiser.

Germ Cell Mutagenicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be mutagenic.

Carcinogenicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be carcinogenic.

Reproductive Toxicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a reproductive toxicant.

Specific Target Organ Toxicity (STOT): Single exposure: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a specific target organ toxicant after single exposure.

Specific Target Organ Toxicity (STOT): Repeated exposure: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a specific target organ toxicant after repeat exposure.

Aspiration Hazard: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be an aspiration hazard.

Narcotic Effects: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to have any narcotic effects.

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be an environmental toxicant.

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Hydroxocobalamin	No data available	No data available	No data available	No data available

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Section 13: DISPOSAL INFORMATION

Product Disposal: Dispose of product only by using according to label or at an approved landfill.

Container Disposal: Wrap with paper and place in garbage.

Section 14: TRANSPORT INFORMATION

Dangerous Goods Classification: Not considered a Dangerous Good for land, sea and air transport.

Hazchem Code: None specified.

Section 15: REGULATORY INFORMATION

Poisons Schedule: Not scheduled

APVMA Registration No: 67608

Section 16: OTHER INFORMATION

This information is based on data believed by Jurox Pty Limited to be accurate at the time of writing but is subject to change without notice. It is given in good faith, but no warranty expressed or implied is made as to its accuracy, completeness otherwise and no assumption of liability from howsoever arising is made by Jurox Pty Limited by reason of the provision of this information. Every person dealing with the materials referred to herein does so at his/her own risk absolutely and must make independent determinations of suitability and completeness of information from all sources to ensure their proper use.

Legend:

APVMA Australian Pesticides and Veterinary Medicines Authority

CAS No. Chemical Abstracts Service Registry Number.

GHS Globally Harmonized System of Classification and Labelling of Chemicals.

Hazchem Code Emergency action code of numbers and letters that provide information to emergency

services especially firefighters.

LD₅₀ The median lethal dose, being a statistically derived single dose of a substance that can

be expected to cause death in 50% of animals.

PPE Personal Protective Equipment.

PVC Polyvinyl chloride. SDS Safety Data Sheet.

STOT Specific Target Organ Toxicity.

References:

ChemIDplus Chemwatch

EPA New Zealand Chemical Classification and Information Database (CCID)

HSDB (Hazardous Substances Data Bank)

PubChem

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Revision History:

Date of Revision	Reason
28 November 2017	Addition of Jurox email address, minor updates to Sections 3, 4, 10, 12 and 16. Addition of hydroxocobalamin acetate LD ₅₀ (injection) information.
17 January 2023	Routine 5-year review. Minor updates throughout.
01 March 2023	Minor revision to update to Zoetis Customer Service and emergency phone numbers

END OF SDS

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