

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations Date of issue: 03/07/2017 Version: 1.0

SECTION 1: Identification	n		
1.1. Identification			
Product form		Mixtures	
Product name	:	Tanovea [™] -CA1 (rabacfosadine for injection)	
1.2. Recommended use and restrictions on use			
Recommended use		For intravenous use in dogs only	
Restrictions on use	:	Veterinarian use only. Prescription use only.	
1.3. Supplier			
VetDC, Inc. 320 East Vine Dr. Suite 218 Fort Collins, CO 80524 T 877-468-3832 <u>vet-dc.com</u>			
1.4. Emergency telephone	e number		
Emergency number	:	844-342-8129 (SafetyCall 24/7)	
SECTION 2: Hazard(s) ide			
2.1. Classification of the su	substance or mixtu	Jre	
GHS-US classification			
Germ cell mutagenicity, H3 Category 2	341	Suspected of causing genetic defects	
	360	May damage fertility or the unborn child	
Full text of H statements : see sec	ction 16		
2.2. GHS Label elements, i	including precaut	ionary statements	
GHS-US labelling			
Hazard pictograms (GHS-US)	:	GHS08	
Signal word (GHS-US)	:	Danger	
Hazard statements (GHS-US)	:	H341 - Suspected of causing genetic defects H360 - May damage fertility or the unborn child	
Precautionary statements (GHS-L	US) :	 P201 - Obtain special instructions before use P202 - Do not handle until all safety precautions have been read and understood P280 - Wear eye protection, protective clothing, protective gloves P308+P313 - If exposed or concerned: Get medical advice/attention P405 - Store locked up P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation 	
2.3. Other hazards which d	do not result in cla	assification	
No additional information available			
2.4. Unknown acute toxicity (GHS US)			
400/ of the printing consists of instruction to the territy (Oral)			

48% of the mixture consists of ingredient(s) of unknown acute toxicity (Oral) 48% of the mixture consists of ingredient(s) of unknown acute toxicity (Dermal) 48% of the mixture consists of ingredient(s) of unknown acute toxicity (Inhalation (Dust/Mist))

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

Safety Data Sheet

- - -

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

3.2. Mixtures			
Name	Product identifier	%	GHS-US classification
Rabacfosadine succinate	(CAS-No.) 1431856-99-3	40 - 50	Muta. 2, H341 Repr. 1B, H360
Citric acid	(CAS-No.) 77-92-9	1 - 5	Eye Irrit. 2A, H319

*Chemical name, CAS number and/or exact concentration have been withheld as a trade secret

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

Full text of hazard classes and H-statements : se	ee section 16
SECTION 4: First-aid measures	
4.1. Description of first aid measures	
First-aid measures general	 Never give anything by mouth to an unconscious person. IF exposed or concerned: Get medical advice/attention.
First-aid measures after inhalation	: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact	: Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 15 minutes, holding the eyelids apart. Get immediate medical advice/attention.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.
4.2. Most important symptoms and effect	cts (acute and delayed)
Symptoms/effects	: Suspected of causing genetic defects. May damage fertility or the unborn child.
Symptoms/effects after skin contact	: May cause slight irritation.
Symptoms/effects after eye contact	: May cause slight irritation.
4.3. Immediate medical attention and sp	pecial treatment, if necessary
Treat symptomatically and supportively.	,
SECTION 5: Fire-fighting measures	
5.1. Suitable (and unsuitable) extinguish	ning media
Suitable extinguishing media	: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.
5.2. Specific hazards arising from the cl	nemical
Fire hazard	: No particular fire or explosion hazard.
Reactivity	: No dangerous reactions known.
5.3. Special protective equipment and p	recautions for fire-fighters
Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.
SECTION 6: Accidental release mea	sures
6.1. Personal precautions, protective eq	uipment and emergency procedures
General measures	: Do not get in eyes, on skin, or on clothing. Use personal protective equipment as required.
6.1.1. For non-emergency personnel	
Protective equipment	: Refer to section 8.2.
Protective equipment Emergency procedures	: Refer to section 8.2. : Evacuate unnecessary personnel.
Emergency procedures	
Emergency procedures 6.1.2. For emergency responders	: Evacuate unnecessary personnel.
Emergency procedures 6.1.2. For emergency responders Protective equipment	: Evacuate unnecessary personnel.: Refer to section 8.2.
Emergency procedures 6.1.2. For emergency responders Protective equipment Emergency procedures	: Evacuate unnecessary personnel.
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Emergency procedures 6.1.2. For emergency responders Protective equipment Emergency procedures 6.2. Environmental precautions Prevent entry to sewers and public waters.	 Evacuate unnecessary personnel. Refer to section 8.2. Ventilate area.
Emergency procedures 6.1.2. For emergency responders Protective equipment Emergency procedures 6.2. Environmental precautions Prevent entry to sewers and public waters. 6.3. Methods and material for containment	 Evacuate unnecessary personnel. Refer to section 8.2. Ventilate area.
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Safety Data Sheet

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

6.4. Reference to other sections

Section 13: disposal information. Section 7: safe handling. Section 8: personal protective equipment.

SECTION 7: Handling and storage	
7.1. Precautions for safe handling	
Precautions for safe handling	: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Obtain special instructions before use. Use personal protective equipment as required. Do not handle until all safety precautions have been read and understood.
Hygiene measures	: Do not eat, drink or smoke when using this product. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.
7.2. Conditions for safe storage, including	ng any incompatibilities
Storage conditions	: Keep only in the original container.
Incompatible products	: Strong bases. Strong acids.
Incompatible materials	: Sources of ignition. Direct sunlight.
Storage temperature	: 2 - 8 °C
Storage area	: Store in a dark area. Store in a dry, cool area.

SECTION 8: Exposure controls/personal protection

8.1.	Control parameters
Rabact	fosadine succinate (1431856-99-3)
Not app	plicable
Citric a	acid (77-92-9)
Not app	plicable

8.2. Appropriate engineering controls

Appropriate engineering controls

: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure good ventilation of the work station.

Environmental exposure controls

: Prevent leakage or spillage. Prevent contaminated water run-off.

8.3. Individual protection measures/Personal protective equipment

Personal protective equipment:

Avoid all unnecessary exposure.

Hand protection:

Wear suitable gloves resistant to chemical penetration. PVC. Butyl rubber gloves. nitrile rubber gloves

Eye protection:

Chemical goggles or safety glasses

Skin and body protection:

Long sleeved protective clothing

Respiratory protection:

No respiratory protection needed under normal use conditions

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties		
9.1. Information on basic ph	ysical and chemical properties	
Physical state	: Solid	
Appearance	: Lyophilized powder / cake.	
Colour	: white Off-white	
Odour	: odourless	
Odour threshold	: No data available	

Safety Data Sheet

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

8 8 ,	3 2 2
pH	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Flammability (solid, gas)	: Non flammable.
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
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
Explosive limits	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity		
10.1. Reactivity		
No dangerous reactions known.		
0.2. Chemical stability		
Stable under normal conditions.		
10.3. Possibility of hazardous reactions		
Not established.		
10.4. Conditions to avoid		
Direct sunlight. Extremely high or low temperatures.		
10.5. Incompatible materials		
Strong acids. Strong bases.		
10.6. Hazardous decomposition products		
Carbon monoxide. Carbon dioxide.		
SECTION 11: Toxicological information		
11.1. Information on toxicological effects		
Likely routes of exposure	: Skin and eye contact	
Acute toxicity	: Not classified	
Citric acid (77-92-9)		
LD50 oral rat 11700 mg/kg		
ATE US (oral)	ATE US (oral) 11700.000 mg/kg	

ATE US (oral)	11700.000 mg/kg
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Suspected of causing genetic defects.
Carcinogenicity	: Not classified
Reproductive toxicity	: May damage fertility or the unborn child.
	. May damage fertility of the unborn child.
Specific target organ toxicity (single exposure)	: Not classified

Safety Data Sheet

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

Rabacfosadine succinate (1431856-99-3)	
LOAEL	>= 3 mg/kg bodyweight dog, intraveneous; Gastrointestinal tract, lymphoid tissues, bone marrow, kidney, prostrate, adrenal gland.
Specific target organ toxicity (repeated exposure)	: Not classified
Rabacfosadine succinate (1431856-99-3)	
LOAEL	>= 1 mg/kg bodyweight/day dog, intraveneous; Gastrointestinal tract, lymphoid tissues, bone marrow, kidney, testes, salivary gland, pancreas
Aspiration hazard	: Not classified
Symptoms/effects after skin contact	: May cause slight irritation.
Symptoms/effects after eye contact	: May cause slight irritation.
SECTION 12: Ecological information	
12.1. Toxicity	
Citric acid (77-92-9)	
LC50 fish 1	1516 g/l Lepomis macrochirus
EC50 Daphnia 1	120
12.2. Persistence and degradability	
Tanovea™-CA1 (rabacfosadine for injection	
Persistence and degradability	Not established.
Citric acid (77-92-9)	
Chemical oxygen demand (COD)	0.728 g O₂/g substance
Biodegradation	98 % after 48 hours
12.3. Bioaccumulative potential	
Tanovea™-CA1 (rabacfosadine for injection	
Bioaccumulative potential	Not established.
Bioaccumulative potential Citric acid (77-92-9)	Not established.
	Not established. -1.72
Citric acid (77-92-9) Log Pow	
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Safety Data Sheet

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

SECTION 15: Regulatory information

15.1. US Federal regulations

All components of this product are listed, or excluded from listing, on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

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.

Rabacfosadine succinate (1431856-99-3)	
EPA TSCA Regulatory Flag	Exempt from TSCA : Pharmaceutical/drug substance

15.2. International regulations

CANADA

Rabacfosadine succinate (1431856-99-3)

Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)

EU-Regulations

No additional information available

National regulations

Citric acid (77-92-9)

Listed on the AICS (Australian Inventory of Chemical Substances)

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	
SECTION 10. Other information	
Data sources	: ACGIH (American Conference of Government Industrial Hygienists).
	European Chemicals Agency (ECHA) C&L Inventory database. Accessed at http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database.
	Krister Forsberg and S.Z. Mansdorf, "Quick Selection Guide to Chemical Protective Clothing", Fifth Edition.
	OSHA 29CFR 1910.1200 Hazard Communication Standard.
	National Fire Protection Association. Fire Protection Guide to Hazardous Materials; 10th edition.
Other information	: None.
Full text of H-statements:	
H319	Causes serious eye irritation
H341	Suspected of causing genetic defects
H360	May damage fertility or the unborn child
Abbreviations and acronyms:	
	ATE: Acute Toxicity Estimate
	CAS (Chemical Abstracts Service) number
	GHS: Globally Harmonized System (of Classification and Labeling of Chemicals).

	GHS. Globally Harmonized System (of Classification and Labeling of Chemicals).
LOAEL	Lowest Observed Adverse Effect Level
	OSHA: Occupational Safety & Health Administration
	TSCA: Toxic Substances Control Act

Safety Data Sheet

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

NFPA health hazard	: 2 - Materials that, under emergency conditions, can cause temporary incapacitation or residual injury.	
NFPA fire hazard	: 1 - Materials that must be preheated before ignition can occur.	2 0
NFPA reactivity	: 0 - Normally stable, even under fire exposure conditions, and not reactive with water.	

SDS Prepared by:

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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