1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Baytril® solution for injection 10%

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : veterinary medicine
unfinished

1.3 Details of the supplier of the safety data sheet

Company
Bayer AG
CHS - SCR
D-51368 LEVERKUSEN
Tel.: +49 (0) 214 30 52482
Mail: bhc-md-oeko@bayer.com

1.4 Emergency telephone number

In case of emergency: +49 (0) 214 30 99300 (Central Emergency Response Center Bayer)

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2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS-Classification (according to EC 1272/2008):
Skin irritation, Category 2 (H315)
Serious eye damage, Category 1 (H318)

2.2 Label elements

GHS-Labelling (according to EC 1272/2008):

Danger

Hazard statements:

H315 Causes skin irritation.
H318 Causes serious eye damage.

Precautionary statements:

Prevention:
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ eye protection/ face protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of water.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Hazardous components which must be listed on the label:

71-36-3	n-Butanol
1310-58-3	Potassium hydroxide

2.3 Other hazards

Other hazards which do not result in classification:
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

This product is a mixture within the meaning of Regulation (EC) No. 1907/2006.

Aqueous solution

Hazardous components

n-Butanol
Concentration [Weight percent] >= 1 - < 3
CAS-No.: 71-36-3
CAS name: 1-Butanol
EINECS-No.: 200-751-6
Synonyms: butan-1-ol
Index-No.: 603-004-00-6

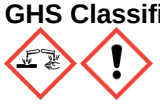
GHS Classification:

Flam. Liq. 3 H226
Acute Tox. 4 H302
Skin Irrit. 2 H315
Eye Dam. 1 H318
STOT SE 3 H336
STOT SE 3 H335

Potassium hydroxide

Concentration [Weight percent] >= 1 - < 2
CAS-No.: 1310-58-3
CAS name: Potassium hydroxide
EINECS-No.: 215-181-3
Synonyms: potassium hydroxide, potassium hydroxide (Solution)
Index-No.: 019-002-00-8

GHS Classification:



Met. Corr. 1 H290
Acute Tox. 4 H302
Skin Corr. 1A H314
Eye Dam. 1 H318
Aquatic Chronic 3 H412

Specific threshold concentration (GHS):

Skin Corr. 1A	H314	>= 5 %
Skin Corr. 1B	H314	2 - < 5 %
Skin Irrit. 2	H315	0,5 - < 2 %
Eye Irrit. 2	H319	0,5 - < 2 %

Enrofloxacin
Concentration [Weight percent] >= 1 - < 10
CAS-No.: 93106-60-6
CAS name: 3-Quinolinecarboxylic acid, 1,4-dihydro-1-cyclopropyl-7-(4-ethyl-1-piperazinyl)-6-fluoro-4-oxo-

Substances with a workplace exposure limit

For the full text of the H-Statements mentioned in this Section, see Section 16.

4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice: Take off all contaminated clothing immediately.

If inhaled: Remove to fresh air. Call a physician immediately.

In case of skin contact: After contact with skin, wash immediately with plenty of soap and water. If skin reactions occur, contact a physician.

In case of eye contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

If swallowed: If swallowed, seek medical advice immediately and show this container or label.

4.2 Most important acute symptoms/effects

Symptoms: No information available.

Risks: No information available.

4.3 Indication of any immediate medical attention and special treatment needed

No information available.

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable extinguishing media: High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: Fire may cause evolution of: Hydrogen cyanide (hydrocyanic acid) Hydrogen fluoride Nitrogen oxides (NOx) Carbon oxides

Further information: Prevent fire extinguishing water from contaminating surface water or the ground water system.

5.3 Advice for firefighters

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Use with adequate ventilation.

6.2 Environmental precautions

Do not flush into surface water or sanitary sewer system.

6.3 Methods and materials for containment and cleaning up

Methods for cleaning up: Suppress (knock down) gases/vapours/mists with a water spray jet. Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Place in closed containers. Label for proper disposal.

6.4 Reference to other sections

Additional advice: Keep away from/remove sources of ignition.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Handling:
Avoid formation of aerosol. Use with local exhaust ventilation. Avoid contact with skin, eyes and clothing.

Take measures to prevent the build up of electrostatic charge. Keep away from open flames, hot surfaces and sources of ignition.

7.2 Conditions for safe storage, including any incompatibilities

For storage suitable stores with adequate product-reception volume must be used. During handling local official regulations must be observed in order to avert impairment of water by the product.

Storage class in accordance to TRGS 510: 10 Combustible liquids not in Storage Class 3

7.3 Specific end use(s)

No statements available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Enrofloxacin	93106-60-6	Bayer OES	0,6 ml/m³	
Peak-limit: excursion factor (category)	4			
n-Butanol	71-36-3	AGW	100 ppm 310 mg/m3	DE TRGS 900
Peak-limit: excursion factor (category)	1;(I)			
Further information	Senate commission for the review of compounds at the work place dangerous for the health (MAK-commission)., When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child			

		AGW	100 ml/m³ 310 mg/m³	

Biological occupational exposure limits

Substance name	CAS-No.	Control parameters	Sampling time	Basis
n-Butanol	71-36-3	1-butanol: 2 mg/g Creatinine (Urine)	Before next shift	TRGS 903
		1-butanol: 10 mg/g Creatinine (Urine)	Immediately after exposure or after working hours	TRGS 903

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Potassium hydroxide	Workers	Inhalation	Short-term exposure, Acute systemic effects	1 mg/m³
	Consumer use	Inhalation	Short-term exposure, Acute systemic effects	1 mg/m³

8.2 Exposure controls

Personal protective measures:

Respiratory protection:
Recommended respiratory protection: full mask with filter ABEK-ST (ABEK-P3)

Hand protection:
Hand protection: protective gloves for chemicals made of Baypren, nitrile rubber or PVC wear
Breakthrough time not tested; dispose of immediately after contamination. Advice: The gloves should not be reused.

Eye protection:
Safety glasses

Hygiene measures:
Cleanliness Guidelines (GMP) for manufacturing of drugs must be observed!

Other protective measures:
Wear suitable protective equipment.
The personal protective equipment is applicable for the handling of bulk material without packaging and for incidents if an exposure by the active ingredient or hazardous components can be expected.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Form:	liquid	
Colour:	yellowish	
Odour:	weak Alcohol	
Melting point/range:	No statements available.	
Boiling point/boiling range:	ca. 100 °C	
Density:	1,024 g/cm³ at 20 °C	
Bulk density:	Not applicable	
Vapour pressure:	No statements available.	
Viscosity, dynamic:	No statements available.	
Viscosity, kinematic:	No statements available.	
Flow time:	No statements available.	
Surface tension:	No statements available.	
Water solubility:	No statements available.	
Solubility(ies):	No statements available.	
pH:	10 - 11,5 (undiluted)	
Corrosive to metal:	No statements available.	
Partition coefficient (n-octanol/water):	n-Butanol log Pow: 1	OECD 117
Flash point:	54,5 °C	
Flammability (liquid):	Does not sustain combustion.	Method: Data on a comparable substance
Explosion limits:	n-Butanol upper: 11,3 %(V) lower: 1,4 %(V)	

9.2 Other information

Miscibility with water:	in all proportions

10. STABILITY AND REACTIVITY

10.1 Reactivity
No statements available.

Reactions with water / air:
No statements available.

Ignition temperature:
n-Butanol
355 °C DIN 51794
Burning number:

Enrofloxacin
at 20 °C The product is flammable but not readily ignited.

Flammability (liquids):

Baytril® solution for injection 10%
Does not sustain combustion.
Method: Data on a comparable substance

10.2 Chemical stability
No statements available.

Thermal decomposition:
No data available

Dust explosion characteristic number:
Not applicable

Dust explosion class:
Not applicable

Impact sensitivity:

No data available

Hazardous reactions:

No data available

Explosive properties:

No statements available.

10.3 Possibility of hazardous reactions

deflagration ability:
No statements available.

Smoldering combustion:
No statements available.

10.4 Conditions to avoid
Do not allow product to come in contact with:
Exposure to light.
Heat
Protect from frost.

Minimum ignition energy:
No data available

Oxidizing properties:
No statements available.

10.5 Incompatible materials

Materials to avoid:
Oxidizing agents

10.6 Hazardous decomposition products
Hydrogen cyanide (hydrocyanic acid), Hydrogen fluoride, Nitrogen oxides (NOx), Carbon oxides

11. TOXICOLOGICAL INFORMATION

Toxicology Assessment:

Potassium hydroxide
Acute effects: Harmful if swallowed. Causes severe skin burns and eye damage.

11.1 Information on toxicological effects

Other information on toxicity:

n-Butanol
Liver and kidney injuries may occur.

After absorption of large quantities
Change in righting reflex
Liver disorders
drowsiness
Headache
Weakness

Potassium hydroxide
May cause blindness.
If ingested, severe burns of the mouth and throat, as well as a danger of perforation of the oesophagus and the stomach.

Acute oral toxicity:

Baytril® solution for injection 10%
Acute toxicity estimate (ATE) > 2.000 mg/kg
Method: Calculation method

n-Butanol
Acute toxicity estimate (ATE) 500 mg/kg
Method: Converted acute toxicity point estimate

Potassium hydroxide
LD50 Rat: 333 - 388 mg/kg
The component/mixture is moderately toxic after single ingestion.

Enrofloxacin
LD50 Rat: > 5.000 mg/kg
No adverse effect has been observed in acute toxicity tests.

Acute inhalation toxicity:

Enrofloxacin
LC50 Rat: > 2,937 mg/l, 4 h
dust/mist/aerosol
No adverse effect has been observed in acute toxicity tests.
An LC50/inhalation/4h/rat could not be determined because no mortality of rats was observed at the maximum achievable concentration.

Acute dermal toxicity:

Enrofloxacin
LD50 Rabbit: > 2.000 mg/kg
The component/mixture is minimally toxic after single contact with skin.

Acute toxicity (other routes of administration):
No statements available.

Corrosivity:
No statements available.

Skin irritation:

n-Butanol
Rabbit
Result: Mild skin irritation
Method: OECD 404

Potassium hydroxide
Rabbit
Classification: Causes severe skin burns and eye damage.
Result: Causes burns.

Enrofloxacin
Rabbit
Result: No skin irritation
Method: OECD 404

Eye irritation:

n-Butanol
Rabbit
Result: Risk of serious damage to eyes.
Method: OECD 405

Potassium hydroxide
Rabbit
Classification: Causes severe skin burns and eye damage.
Result: Irreversible effects on the eye

Enrofloxacin
Rabbit
Result: No eye irritation
Method: OECD 405

Sensitisation:

n-Butanol
test Type: Skin sensitization Guinea pig
Result: Did not cause sensitisation on laboratory animals.
Method: OECD 406

Potassium hydroxide
Guinea pig
Result: Does not cause skin sensitisation.

Enrofloxacin
test Type: Skin sensitization Guinea pig
Result: Did not cause sensitisation on laboratory animals.
Method: Buehler Test

Phototoxicity:
No statements available.

Subacute, subchronic and prolonged toxicity:
No statements available.

STOT - single exposure:

n-Butanol
May cause respiratory irritation.

Route of exposure: Inhalation
May cause drowsiness or dizziness.

STOT - repeated exposure:
No statements available.

Aspiration toxicity:

n-Butanol
May be harmful if swallowed and enters airways.

Genotoxicity in vitro:

n-Butanol
Ames test
Result: negative

Micronucleus test
Result: negative

In vitro gene mutation study in mammalian cells Hamster V79-cells
Result: No evidence of a genotoxic effect.

Method: OECD 476

Potassium hydroxide
Ames test
Result: negative

Bacterial mutagenicity Escherichia coli
Result: negative

Enrofloxacin
Ames test
Result: negative

Genotoxicity in vivo:

n-Butanol
Micronucleus test, Mouse
Result: No evidence of a genotoxic effect.
Method: OECD 474

Enrofloxacin
Micronucleus test, Mouse
Result: No indication of clastogenic effects.

Carcinogenicity:
No statements available.

Fertility:

n-Butanol
NOAEL (parental): 2000 ppm
NOAEL (F1): 2000 ppm
NOAEL (F2): 2000 ppm
Result: Animal testing did not show any effects on fertility.
Method: OECD Test Guideline 416

Developmental toxicity:
No statements available.

Human experience:

n-Butanol
May cause skin irritation and/or dermatitis.

Neurotoxicity:
No statements available.

Neurological symptoms:
No statements available.

Pharmaceutic effects:

Enrofloxacin
Antibiotic

12. ECOLOGICAL INFORMATION

Ecotoxicology Assessment

Potassium hydroxide
Acute aquatic toxicity: Neutralisation will reduce ecotoxic effects.

Enrofloxacin
Acute aquatic toxicity: slightly water endangering

12.1 Toxicity

Toxicity to fish:

n-Butanol
Acute Fish toxicity: LC50 1.730 mg/l
Test species: Pimephales promelas (fathead minnow) Duration of test: 96 h

Potassium hydroxide
Acute Fish toxicity: LC50 80 mg/l
Test species: Gambusia affinis (Mosquito fish) Duration of test: 96 h

Enrofloxacin
Acute Fish toxicity: LC0 > 10 mg/l
Test species: Salmo gairdneri Duration of test: 96 h

Acute Fish toxicity: LC0 > 9,6 mg/l
Test species: Lepomis macrochirus (Bluegill sunfish) Duration of test: 96 h

Toxicity to daphnia and other aquatic invertebrates:

n-Butanol
EC50 1.983 mg/l
Test species: Daphnia magna (Water flea) Duration of test: 48 h

Enrofloxacin
EC0 > 10 mg/l
Test species: Daphnia magna (Water flea) Duration of test: 48 h

Toxicity to algae:
No statements available.

Toxicity to bacteria:

Potassium hydroxide
EC50 22 mg/l
Test species: Photobacterium phosphoreum
Duration of test: 15 min

Enrofloxacin
EC0 0,003 mg/l
Test species: Pseudomonas putida

Toxicity to fish (Chronic toxicity):
No statements available.

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
No statements available.

Toxicity on soil-dwelling organisms:

Enrofloxacin
LC50
Test species: Eisenia fetida (earthworms) Duration of test: 28 d

Toxicity on other terrestrial non-mammal:
No statements available.

12.2 Persistence and degradability

Biodegradability:

n-Butanol
98 %, 28 d rapidly biodegradable
Method: OECD 301E

Potassium hydroxide

The methods for determining the biological degradability are not applicable to inorganic substances.

Biochemical Oxygen Demand (BOD):
No statements available.

Chemical Oxygen Demand (COD):
No statements available.

BSB in proportion to CSB:
No statements available.

Dissolved organic carbon (DOC):
No statements available.

Adsorbed organic bound halogens (AOX):
No statements available.

Theoretical biological oxygen requirement:
No statements available.

BSB in proportion to ThSB:
No statements available.

Total organic carbon (TOC):
No statements available.

Physico-chemical removability:
No statements available.

Stability in water:
No statements available.

Important degradation pathways:
No statements available.

Photodegradation:

Enrofloxacin
Water
half-life time (direct Photolysis): > 240 h

M-Factor:
No statements available.

12.3 Bioaccumulative potential

Bioaccumulation:

Potassium hydroxide

Bioaccumulation is unlikely.

Partition coefficient (n-octanol/water):

n-Butanol
log Pow: 1 OECD 117

12.4 Mobility in soil

Environmental distribution:
No statements available.

Surface tension:
No statements available.

Stability in soil:
No statements available.

12.5 Results of PBT and vPvB assessment

Baytril® solution for injection 10%
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

General advice:

Baytril® solution for injection 10%
Do not allow to enter surface waters or groundwater.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of as hazardous waste in compliance with local and national regulations.

Contaminated packaging: Contaminated, empty containers are to be treated in the same way as the contents.

14. TRANSPORT INFORMATION

ADR/RID	non-regulated
GGVS/GGVE	non-regulated
ADNR	non-regulated
IATA	non-regulated
IMDG	non-regulated

14.6 Special precautions for user

For personal protection see section 8.

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

not applicable

Other information : No dangerous cargo
Irritating to skin and eyes Keep separated from foodstuffs

15. REGULATORY INFORMATION

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

National legislation

Water contaminating class (Germany):
WGK 1 (slightly water endangering)
VwVwS (German Regulation) supplement 4

Major accidents regulations appendix I no.:
P5c

Guidelines and information sheets issued by the Chemical Industry Employers' Insurance Association:
M 053 /BGI 660 ("Protective measures when handling hazardous substances at work"), DGUV Information 213-083

Other regulations:
TRGS 500 Precaution: Least standards

15.2 Chemical safety assessment

No statements available.

16. OTHER INFORMATION

Full text of H-Statements mentioned in chapters 2 and 3

H226	Flammable liquid and vapour.
H290	May be corrosive to metals.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H412	Harmful to aquatic life with long lasting effects.

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

Further information

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.