

SECTION 1: IDENTIFICATION

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|---|---|
| 1.1 Product identifier | |
| Product name: | Tralieve 20mg Chewable Tablets for Dogs Tralieve 80mg Chewable Tablets for Dogs |
| Synonyms: | None |
| Proper Shipping name: | Not Available |
| Other means of identification: | None |
| 1.2 Relevant identified uses of the substances or mixture and uses advised against | |
| Recommended uses: | For the reduction of acute and chronic mild soft tissue and musculoskeletal pain |
| Uses advised against: | The product should not be used in: <ul style="list-style-type: none"> • Cases of hypersensitivity to the active substance or to any of the excipients • Conjunction with tricyclic antidepressants, monoamine oxidase inhibitors and serotonin reuptake inhibitors • Animals with epilepsy |
| 1.3 Details of the supplier of the substance or mixture | |
| Registered company name: | Le Vet Beheer B.V. |
| Address: | Wilgenweg 7 3421 TV Oudewater The Netherlands |
| Telephone: | +31 (0) 348 5656 |
| Fax: | +31 (0) 348 5454 |
| Email: | Not available |
| Website | www.dechra.com |
| 1.4 Emergency Telephone Numbers | |
| | +31 (0) 348 5656 |

SECTION 2: HAZARDS IDENTIFICATION

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|--|---------------|
| 2.1 Classification of the substance or mixture | |
| Not considered a hazardous mixture according to Reg. (EC) No 1272/2008 and their amendments. Not classified as Dangerous Goods for transport purposes. | |
| DSD Classification (EU): | Not Available |
| DPD Classification (EU)¹: | Not Available |

| | |
|---|----------------|
| Classification according to regulation (EC) No 1272/2008 [CLP] (EU)¹: | Not Applicable |
| 2.2 Label Elements | |
| Signal Word: | NOT APPLICABLE |
| Hazard Statement(s) | |
| Harmful if swallowed | |
| Additional Statement(s) | |
| Not Applicable | |
| Precautionary Statement(s) Prevention: | |
| Not Applicable | |
| Precautionary Statement(s) Response: | |
| Not Applicable | |
| Precautionary Statement(s) Storage: | |
| Not Applicable | |
| Precautionary Statement(s) Disposal: | |
| Not Applicable | |
| 2.3 Other Hazard Information | |
| REACH - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date. | |

SECTION 3: INFORMATION ON THE INGREDIENTS

3.1 Substances

See section below for composition of mixtures

3.2 Mixtures

| 1.CAS No 2.EC Number 3.Index Number 4.REACH Number | mg/ml | Name | Classification according to regulations (EC) No 1272/2008 [CLP] (EU) |
|---|----------------------------|------------------------|--|
| 1. 73806-49-2 2. Not Available 3. Not Available 4. Not Available | 20mg tablet 80mg tablet | Tramadol hydrochloride | Acute toxicity (oral) category 4; Acute aquatic hazard category 1; Specific target organ toxicity – repeated exposure Category 2; H302, H400, H373 ¹ |
| N/a | Proprietary | Other ingredients | N/a |

| | |
|----------------|----------------------------|
| Legend: | 1. Classified by Chemwatch |
|----------------|----------------------------|

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

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| Eye contact: | Due to the hypersensitivity and irritation potential of tramadol and its excipients, eye contact with this product should be avoided. In case of accidental contact of the product with the eyes rinse abundantly with fresh water. Seek medical attention if irritation persists. |
| Skin contact: | Due to the hypersensitivity and irritation potential of tramadol and its excipients, in case of accidental contact of the product with the skin rinse abundantly with fresh water. Seek medical attention if irritation persists. Remove contaminated clothes that are in direct contact with the skin. |
| Inhalation: | Due to physical form of this product, inhalation exposure is unlikely. However, if this product causes irritation to the mucous membranes, seek medical attention. |
| Ingestion: | Tramadol may cause sedation, nausea and dizziness after accidental ingestion, especially by children. To avoid accidental ingestion, particularly by a child, unused tablet parts should be returned to the open blister space and inserted back into the carton and kept in a safe place out of the sight and reach of children as they pose a health risk to small children due to accidental ingestion. In case of accidental ingestion, particularly by children, seek medical advice and show the package leaflet or the label to the physician. In case of accidental ingestion by adults: DO NOT DRIVE as sedation may occur. |

4.2 Most important symptoms and effects, both acute and delayed

See Section 11

4.3 Indication of immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIRE FIGHTING MEASURES

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| 5.1 Extinguishing media | |
| Suitable: | Water spray, carbon dioxide, dry chemical and foam, as appropriate for surrounding fire and materials. |
| Unsuitable: | None. |
| 5.2 Special hazards arising from the substance or mixture | |
| Fire incompatibility: | None known |
| 5.3 Special protective actions for fire-fighters: | |
| Firefighting: | Alert Fire Brigade and tell them location and nature of hazard. Wear full breathing apparatus and self-contained breathing apparatus. Prevent, by any means available, spillage from entering drains or water courses. |
| Fire / explosion hazard: | Non-combustible. Not considered a significant fire risk, however containers may burn. |

SECTION 6: ACCIDENTAL RELEASE MEASURES

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| 6.1 Personal precautions, protective equipment and emergency procedures | |
| For information on protective equipment, see section 8. | |
| 6.2 Environmental Precautions | |
| Do not allow product to reach sewage system or any water course. Inform respective authorities in case of seepage into water course or sewage system. Do not allow to enter sewers/ surface or ground water. | |
| 6.3 Methods and material for containment and cleaning up | |
| Minor Spills: | Clean up all spills immediately. Avoid contact with skin and eyes. Control personal contact with the substance, by using protective equipment. |
| Major Spills: | Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of the hazard. Prevent, by any means available, spillage from entering drains or water course. Large spills should be collected into an appropriate container for waste disposal. |

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

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| Safe Handling: | When handling, DO NOT eat, drink or smoke. Always wash hands with water after handling. Observe manufacturer's storage and handling recommendations. |
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| Other Information: | Keep out of the reach and sight of children. |
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7.2 Conditions for safe storage, including any incompatibilities

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| Suitable Container: | Shelf-life of the veterinary medicinal product as packaged for sale: 2 years. Shelf-life after first opening the immediate packaging: 3 days |
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| Storage incompatibility: | Unknown. |
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7.3 Specific end uses

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| Not available |
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SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

DERIVED NO EFFECT LEVEL - DNEL (EU)

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| Not Available |
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PREDICTED NO EFFECT LEVEL - PNEC (EU)

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| Not Available |
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OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA:

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|---------------|
| Not Available |
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EMERGENCY LIMITS:

| Ingredient | Material Name | TEEL-1 | TEEL-2 | TEEL-3 |
|------------|---------------|--------|--------|--------|
|------------|---------------|--------|--------|--------|

| | | | | |
|---------------|--|--|--|--|
| Not Available | | | | |
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| 8.2 Exposure controls | |
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| Appropriate engineering controls: | The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the particular risk. |
| Personal protection: | Not applicable |
| Eye and face protection: | Safety glasses with side shields / chemical goggles |
| Skin protection: | See hand protection below |
| Hands/ feet protection: | No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective gloves |
| Body protection: | Wear appropriate clothing |
| Other protection: | No special equipment needed when handling small quantities |
| Thermal hazards: | Not available |
| Respiratory protection: | Not applicable |
| 8.3 Environmental exposure controls | |
| See Section 12 | |

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Tralieve Chewable tables
Container: Aluminium – PVC/PE/PVDC blister. Cardboard box containing blisers of 10 tables.
Physical state: Tablet
Odour: Not available
Odour Threshold: Not available
pH (as supplied): Not available
Melting point / freezing point (degrees C): Tramadol hydrochloride:180-184°C
Initial boiling point and boiling range: Not available
Flash Point: Not available
Evaporation rate: Not available
Flammability: Not available
Upper/lower flammability or explosive limits: Not available
Vapour pressure: Not available
Relative Density (at degrees C): Not available
Solubility in water and solvents (mg/l): Tramadol: Miscible in water and methanol. Slightly soluble in acetone
Vapour density: Not available
Auto ignition temperature (degrees C): Not available
Decomposition temperature (degrees C): Not available
Viscosity: (degrees C): Not available
Explosive properties: Not available
Oxidising properties: Not available
Partition Coefficient: Not available
Molecular weight: Not available
Taste: Not available
Surface tension: Not available
Volative component: Not available
Gas group: Not available
pH as a solution: Not available
VOC g/L: Not available

9.2 Other information
 Not Available

10: REACTIVITY AND STABILITY

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|---|---|
| 10.1 Reactivity: | See Section 7 |
| 10.2 Chemical stability: | Product is considered stable. Hazardous polymerisation will not occur. |
| 10.3 Possibility of hazardous reactions: | See section 7. |
| 10.4 Conditions to avoid: | See Section 7. |

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| 10.5 Incompatible materials: | See section 7. |
| 10.6 Hazardous decomposition: | See Section 5. |

| SECTION 11: TOXICOLOGICAL INFORMATION | | |
|--|---|-------------------|
| Inhalation: | Due to the nature of the product, inhalation exposure is unlikely. | |
| Ingestion: | Care should be taken to avoid accidental ingestion. Tramadol may cause sedation, nausea and dizziness after accidental ingestion, especially by children. | |
| Skin contact: | Tramadol or its excipients may cause hypersensitivity and irritation. Care should be taken to avoid accidental skin contact. | |
| Eye contact: | Tramadol or its excipients may cause hypersensitivity and irritation. Care should be taken to avoid accidental eye contact. | |
| Chronic: | Tramazol is classed as an opioid and may typically induce euphoria and there are concerns of potential for abuse. | |
| Tralieve: | Acute toxicity | Irritation |
| | Not Available | Not Available |
| Tramadol hydrochloride: | Acute toxicity | Irritation |
| | Oral (rat) LD ₅₀ : 228 mg/kg* ¹ | Not available |
| <p><i>1. * Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS - Register of Toxic Effect of chemical Substances</i></p> | | |
| Acute toxicity: | | |
| Tramazol is classed as an opioid and may typically induce euphoria and there are concerns of potential for abuse. Fatal opioid overdose typically occurs due to bradypnea, hypoxemia and decreased cardiac output. A potentiation effect occurs when opioids are combined with ethanol, benzodiazepines or barbiturates which result in an increased risk for overdose to occur. | | |
| Skin corrosion/ irritation: | | |
| No data available | | |
| Serious eye damage/ irritation: | | |
| No data available | | |
| Respiratory or skin sensitization: | | |
| Tramadol or its excipients may cause hypersensitivity | | |

| SECTION 11: TOXICOLOGICAL INFORMATION | |
|---|--|
| Germ cell mutagenicity: | |
| Not available | |
| Carcinogenicity: | |
| Not available | |
| Reproductive toxicity: | |
| There is inadequate evidence available on the safety of tramadol in human pregnancy. Pregnant women and women of childbearing age should therefore take great care when handling this product and, in the event of exposure, seek medical advice immediately. | |
| STOT – single exposure: | |
| Not available | |
| STOT–repeated exposure: | |
| Not available | |
| Aspiration hazard: | |
| Not available | |

| SECTION 12: ECOLOGICAL INFORMATION | | | | | |
|---|--|--------------------|------------------|---------------|---------------|
| 12.1 Toxicity | | | | | |
| Ingredient | Endpoint | Test duration (hr) | Species | Value | Source |
| Tramadol hydrochloride | Not Available | Not Available | Not Available | Not Available | Not Available |
| Legend: | <i>Extracted from 1. Europe ECHA Registered Substances</i> | | | | |
| 12.2 Persistence and degradability | | | | | |
| Ingredient | Persistence: Water/Soil | | Persistence: Air | | |
| Tramadol hydrochloride | Not Available | | Not Available | | |
| 12.3 Bioaccumulative potential | | | | | |
| Ingredient | Bioaccumulation | | | | |
| Tramadol hydrochloride | Not available | | | | |
| 12.4 Mobility in Soil | | | | | |
| Ingredient | Mobility | | | | |
| Tramadol hydrochloride | Not available | | | | |

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| 12.5 Results of PBT and vPvB assessment |
| Not Available |
| 12.6 Other adverse effects |
| Not Available |

SECTION 13: DISPOSAL CONSIDERATIONS

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|--------------------------------------|--|
| 13.1 Waste treatment methods | |
| Product / packaging disposal: | <p>Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.</p> <p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area.</p> <p>Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001.</p> |
| Waste Treatment Options: | Not Available |
| Sewage Disposal Options: | Not Available |

SECTION 14: TRANSPORT INFORMATION

| | | |
|--|----------------|-----|
| Labels required: | None | |
| Marine pollutant: | NO | |
| Hazchem: | Not Applicable | |
| Land transport (ADR): | | |
| 14.1 UN Number | N/a | |
| 14.2 UN Proper Shipping Name | N/a | |
| 14.3 Transport hazard class(es) | Class | N/a |
| | Sub risk | N/a |
| 14.4 Packing group | N/a | |
| 14.5 Environmental hazards | N/a | |



| | | |
|---|----------------------|-----|
| 14.6 Special precautions for user | Special provisions | N/a |
| | Classification code | N/a |
| | Hazard Label | N/a |
| | Special provisions | N/a |
| | Limited quantity | N/a |
| 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | N/a | |
| Air transport (ICAO-IATA / DGR): | | |
| 14.1 UN Number | N/a | |
| 14.2 UN Proper Shipping Name | N/a | |
| 14.3 Transport hazard class(es) | ICAO/IATA Class | N/a |
| | ICAO / IATA Sub risk | N/a |
| | ERG Code | N/a |
| 14.4 Packing group | N/a | |
| 14.5 Environmental hazards | N/a | |

| | | |
|---|---|-----|
| 14.6 Special precautions for user | Special provisions | N/a |
| | Cargo only packing instructions | N/a |
| | Cargo only maximum qty/pack | N/a |
| | Passenger and cargo packaging instructions | N/a |
| | Passenger and cargo maximum qty/pack | N/a |
| | Passenger and cargo limited quantity packing instructions | N/a |
| | Passenger and cargo limited maximum qty/pack | N/a |
| 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | N/a | |
| Sea transport (IMDG-Code / GGVSee): | | |
| 14.1 UN Number | N/a | |
| 14.2 UN Proper Shipping Name | N/a | |
| 14.3 Transport hazard class(es) | IMDG Class | N/a |
| | IMDG Sub risk | N/a |
| 14.4 Packing group | N/a | |
| 14.5 Environmental hazards | N/a | |
| 14.6 Special precautions for user | EMS Number | N/a |
| | Special provisions | N/a |
| | Limited quantities | N/a |
| 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | N/a | |

| Inland waterways transport (ADN): | | |
|---|---------------------|-----|
| 14.1 UN Number | N/a | |
| 14.2 UN Proper Shipping Name | N/a | |
| 14.3 Transport hazard class(es) | N/a | N/a |
| 14.4 Packing group | N/a | |
| 14.5 Environmental hazard | N/a | |
| 14.6 Special precautions for user | Classification Code | N/a |
| | Special provisions | N/a |
| | Limited quantity | N/a |
| | Equipment required | N/a |
| | Fire cones number | N/a |
| 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | N/a | |

| SECTION 15: REGULATORY INFORMATION | | | |
|---|-----------------------------------|--------------------------------|--------------------------|
| 15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture | | | |
| TRAMADOL HYDROCHLORIDE (73806-49-2) IS FOUND ON THE FOLLOWING REGULATORY LISTS: | | | |
| Not applicable | | | |
| This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable-: 98/24/EC, 92/85/EC, 94/33/EC, 2008/98/EC, 2010/75/EU | | | |
| 15.2 Chemical Safety Assessment | | | |
| ECHA SUMMARY | | | |
| Ingredient | CAS number | Index Number | ECHA Dossier |
| Tramadol hydrochloride | 73806-49-2 | Not Available | Not Available |
| Harmonization (C&L Inventory) | Hazard Class and Category Code(s) | Pictograms Signal Word Code(s) | Hazard Statement Code(s) |
| 1 | Acute Tox. 4, Aquatic Chronic 2 | GHS09, GHS06, Dgr | H301, H411 |

| | | | |
|---|--|--|--|
| | | | |
| Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification | | | |

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|-------------------------------|--|
| Australia - AICS | No (Tramadol hydrochloride) |
| Canada - DSL | No (Tramadol hydrochloride) |
| Canada - NDSL | No (Tramadol hydrochloride) |
| China - IECSC | No (Tramadol hydrochloride) |
| Europe - EINEC / ELINCS / NLP | No (Tramadol hydrochloride) |
| Japan - ENCS | No (Tramadol hydrochloride) |
| Korea - KECI | No (Tramadol hydrochloride) |
| New Zealand - NZIoC | Yes |
| Philippines - PICCS | No (Tramadol hydrochloride) |
| USA - TSCA | No (Tramadol hydrochloride) |
| Legend: | <i>Yes = All ingredients are on the inventory No = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)</i> |

SECTION 16: OTHER INFORMATION

The SDS is written in accordance to guidelines specified by REACH, GHS and ECHA.

Full text Risk and Hazard codes:

| | |
|-------------|--|
| H301 | Toxic if swallowed. |
| H302 | Harmful if swallowed. |
| H315 | Causes skin irritation. |
| H317 | May cause an allergic skin reaction. |
| H319 | Causes serious eye irritation. |
| H411 | Toxic to aquatic life with long lasting effects |
| H412 | Harmful to aquatic life with long lasting effects. |

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

EN 166 Personal eye-protection
EN 340 Protective clothing
EN 374 Protective gloves against chemicals and micro-organisms
EN 13832 Footwear protecting against chemicals
EN 133 Respiratory protective devices

Definitions and abbreviations

PC – TWA: Permissible Concentration-Time Weighted Average
PC – STEL: Permissible Concentration-Short Term Exposure Limit
STEL: Short Term Exposure Limit
TEEL: Temporary Emergency Exposure Limit.
IDLH: Immediately Dangerous to Life or Health Concentrations

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