

Presponse® SQ, suspension for injection

Version Revision Date: SDS Number: Date of last issue: -

1.0 03/27/2023 000000039965 Date of first issue: 03/27/2023

SECTION 1. IDENTIFICATION

Product name : Presponse® SQ, suspension for injection

Synonyms : Mannheimia Haemolytica Toxoid with Metastim®. USDA Code

8699.01

with: Mannheimia Haemolytica Toxoid

Manufacturer or supplier's details

Company name of supplier : Boehringer Ing. Pharma GmbH & Co.KG

Address : Binger Straße 173

Ingelheim 55216

Germany

Telephone : +498007790900

Prepared by : EHS-Services@Boehringer-Ingelheim.com

Emergency telephone num-

ber

Int. Emergency Telephone number: +1 703-527-3887

German Emergency Telephone number: +49800 1817059

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Safety Data Sheet only for the professional user., For veteri-

nary use only, Refer to the product insert for complete instruc-

tions on usage

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

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

This drug is not subject to the labelling requirements under the Globally Harmonized System (GHS)

The pharmacological effect of the medicament has to be considered (see package leaflet).

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS



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Substance / Mixture : Mixture

Chemical nature : Mixture

Components

No hazardous ingredients

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

(show the package insert where possible).

First Aid responders should pay attention to self-protection

and use the recommended protective clothing

Remove from exposure, lie down.

Take off immediately all contaminated clothing.

Victim to lie down in the recovery position, cover and keep him

warm.

If inhaled : Move to fresh air.

In case of skin contact : Wash off immediately with plenty of water.

In case of eye contact : Rinse immediately with plenty of water for at least 15 minutes.

Keep eye wide open while rinsing.

If swallowed : Rinse mouth.

Drink plenty of water.

Most important symptoms and effects, both acute and

delayed

No information available.

Notes to physician : Observe the summary of product characteristics of proprietary

medicinal products
Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Water Dry chemical Foam

Carbon dioxide (CO2)

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

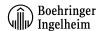
fighting

In case of fire and/or explosion do not breathe fumes.

Product itself is non-combustible; fire extinguishing method of

surrounding areas must be considered.

Hazardous combustion prod- : Carbon oxides



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ucts

Further information 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

In the event of fire, wear self-contained breathing apparatus.

Complete suit protecting against chemicals

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Wear personal protective equipment.

Ensure adequate ventilation.

High risk of slipping due to leakage/spillage of product.

Environmental precautions Do not flush into surface water or sanitary sewer system.

Methods and materials for

containment and cleaning up

Pick up and transfer to properly labelled containers.

Absorb with liquid-binding material (sand, diatomite, acid

binders, universal binders). Clean with disinfectants.

SECTION 7. HANDLING AND STORAGE

Advice on protection against

fire and explosion

No special protective measures against fire required.

The product is not flammable.

Advice on safe handling Provide sufficient air exchange and/or exhaust in work rooms.

Conditions for safe storage Refer to the product insert for instructions on storage.

Materials to avoid Keep away from food, drink and animal feedingstuffs.

Observe joint storage prohibition.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures Local exhaust

Emergency sprinkling nozzle

Personal protective equipment

Respiratory protection General and local exhaust ventilation is recommended to

maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazard-



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ous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate

protection.

Hand protection

Material : Nitrile rubber

Remarks : The break through time depends amongst other things on the

material, the thickness and the type of glove and therefore

has to be measured for each case.

Eye protection : Safety glasses with side-shields

(Not necessary when using full face mask)

Skin and body protection : Laboratory: laboratory coat; Factory: disposable Overall.

Protective measures : Handle in accordance with good industrial hygiene and safety

practice.

Avoid contact with skin, eyes and clothing.

Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warran-

ty given by the manufacturer for the safe function.

Hygiene measures : General industrial hygiene practice.

Wash hands and face before breaks and immediately after

handling the product.

Keep working clothes separately.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : suspension

Colour : light red, red

Odour : No data available

pH : 6.8 - 7.2

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : No data available

Flammability (solid, gas) : Not applicable

Self-ignition : No data available



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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 : No data available

Relative density : No data available

Density : No data available

Bulk density : Not applicable

Solubility(ies)

Water solubility : 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 : No data available

Viscosity, kinematic : No data available

Explosive properties : Not tested

Oxidizing properties : No data available

Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : No decomposition if stored and applied as directed.

Possibility of hazardous reac-

tions

No dangerous reaction known under conditions of normal use.

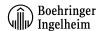
Conditions to avoid : No data available

Incompatible materials : No data available

Hazardous decomposition

products

No data available



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SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC 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.

OSHANo component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No component of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available



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Mobility in soil

No data available

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Pro-

tection of Stratospheric Ozone - CAA Section 602 Class I

Substances

Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Packs that cannot be cleaned should be disposed of in the

same manner as the contents.

Uncontaminated packaging can be recycled.

SECTION 14. TRANSPORT INFORMATION

International Regulations

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

National Regulations

49 CFR

Not regulated as a dangerous good

Special precautions for user

Not applicable

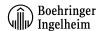
SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

SARA 304 Extremely Hazardous Substances Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the RQ



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SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

formaldehyde 50-00-0 >= 0 - < 0.1 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

formaldehyde 50-00-0 >= 0 - < 0.1 % Sodium phosphate, diba- 7782-85-6 >= 0 - < 0.1 %

sic, heptahydrate

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

formaldehyde 50-00-0

Pennsylvania Right To Know

water 7732-18-5 formaldehyde 50-00-0 Sodium phosphate, dibasic, heptahydrate 7782-85-6 thiomersal 54-64-8

Maine Chemicals of High Concern

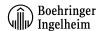
Product does not contain any listed chemicals

Vermont Chemicals of High Concern

thiomersal 54-64-8 formaldehyde 50-00-0

Washington Chemicals of High Concern

thiomersal 54-64-8 formaldehyde 50-00-0



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California Prop. 65

WARNING: This product can expose you to chemicals including formaldehyde, which is/are known to the State of California to cause cancer, and

thiomersal, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

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

TCSI : Not in compliance with the inventory

TSCA : Product contains substance(s) not listed on TSCA inventory.

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.

PEG-PPG-PEG

Ethylenediaminetetraacetic acid tetrasodium salt

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

NZIoC : On the inventory, or in compliance with the inventory

TECI: Not in compliance with the inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

Further information

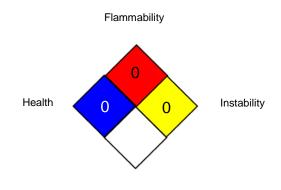


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NFPA 704:



Special hazard

HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ -Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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



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Sources of key data used to

Sheet

compile the Safety Data

data.

Revision Date 03/27/2023

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.

The specifications are based on own tests and/or literature

US / EN