SAFETY DATA SHEET

Product Name: ICON – F Injection

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER	
Product name:	ICON - F Injection
ACVM approval code:	A011186
Recommended use:	For the treatment and control of gastrointestinal nematodes, lungworms, liver fluke, eyeworms, warbles, mites and lice of beef and non-lactating dairy cattle.
Company name:	Alleva Animal Health Limited
Address:	1/116a Harris Road, East Tamaki, Auckland, 2013, New Zealand
Telephone:	0064-9-4181405
Emergency telephone number:	National Poisons Centre: 0800 764 766 (0800 POISON) Fire Service, Ambulance: Dial 111
Date of Preparation	2 September 2021 v3
Restrictions of Use	Refer to Section 15

SECTION 2: HAZARDS IDENTIFICATION

This substance is hazardous according to the EPA Hazardous Substances (Classification) Notice 2020

EPA Approval Code: Veterinary Medicines (Non-Dispersive Closed System Application) – HSR100758

Pictograms:

Toxic Chronic Ecotoxic

Signal Word: WARNING

GHS Classification and Category	Hazard Code	Hazard Statement

Acute oral toxicity Cat. 4	H302	Harmful if swallowed.
Germ cell mutagenicity Cat. 2	H341	Suspected of causing genetic defects.
Reproductive toxicity Cat. 2	H361	Suspected of damaging fertility or the unborn child.
Effects on or via lactation	H362	May cause harm to breast-fed children.
Specific target organ toxicity – repeated exposure Cat. 2	H373	May cause damage to organs through prolonged or repeated exposure.
Hazardous to the aquatic environment chronic Cat. 1	H410	Very toxic to aquatic life with long lasting effects.
Hazardous to soil organisms	H423	Hazardous to soil organisms
Hazardous to terrestrial vertebrates	H433	Hazardous to terrestrial vertebrates
Hazardous to terrestrial invertebrates	H441	Hazardous to terrestrial invertebrates

Prevention Code **Prevention Statement**

P102	Keep out of reach of children.
P103	Read label before use.
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe fumes, vapours or spray.
P263	Avoid contact during pregnancy or while nursing.
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P273	Avoid release to the environment.
P281	Use personal protective equipment as required.

Response Code **Response Statement**

P101	If medical advice is needed, have product container or label at hand.
P314	Get medical advice/attention if you feel unwell.
P330	Rinse mouth.
P391	Collect spillage.
P301 + P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P308 + P313	IF exposed or concerned: Get medical advice/ attention.

Storage Code **Storage Statement**

P405	Store locked up.

Disposal Code **Disposal Statement**

P501	Dispose of according to Local Regulations or Authorities

SECTION 3: COMPOSITION

Product Components:		
Name	**CAS**	**Proportion**
Ivermectin	70288-86-7	10g/L
Clorsulon	60200-06-8	100g/L
Glycerol Formal	5464-28-8	400g/L
Propylene Glycol	57-55-6	to 100%

SECTION 4: FIRST AID MEASURES

Necessary first aid measures:	**Skin Contact:** Wash thoroughly with soap and water. Remove contaminated clothing and wash before reuse. Get medical attention if irritation develops. **Eye Contact:** In case of contact, immediately flush eye with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists. **Ingestion:** If swallowed,rinse mouth, do NOT induce vomiting, get medical attention if needed. **Inhalation:** In case of accidental overexposure, get to fresh air. If irritation occurs or persists, get medical attention.
Most important symptoms and effects, both acute and delayed	Symptoms: Harmful if swallowed. Suspected of causing genetic defects. Suspected of damaging fertility or the unborn child. May cause harm to breast-fed children. May cause damage to the kidneys through prolonged or repeated exposure.
Notes for Medical Personnel:	In case of symptomatic effect provide treatment to maintain life functions.

SECTION 5: FIRE FIGHTING MEASURES

Type of hazard:	Product is not self-igniting and does not present an explosion hazard.
Fire hazard properties:	Carbon monoxide and carbon dioxide may be generated.
Extinguishing media and methods:	Use water spray or all-purpose dry chemical.
Hazchem code:	**3YE**

Recommended protective clothing:	Fire fighters should wear full protective gear and self-contained breathing apparatus. Cool sealed drums with water to prevent rupture due to thermal expansion. Contain run-off. Keep non-involved persons away.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Wear suitable protective clothing as detailed in Section 8. Restrict access to contaminated area.
Environmental Precautions:	Contain the spill and prevent further dispersion. Prevent contamination of water courses and sewers.
Procedure for Spills:	Absorb small spills on spill pillows or other suitable absorbing material and place in a sealed container for disposal. Dike large spills and transfer to an appropriate container for disposal. Contact emergency response personnel for large spills.
Procedure for Disposal:	Avoid contamination of any water supply with product or empty container.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:	• Keep out of reach of children. • Read label before use. • Do not handle until all safety precautions have been read and understood. • Do not breathe fumes, vapours or spray. • Avoid contact during pregnancy or while nursing. • Wash hands thoroughly after handling. • Do not eat, drink or smoke when using this product. • Avoid release to the environment. • Use personal protective equipment as required.
Conditions for safe storage:	• Keep out of reach of children. • Protect contents from light

	• Keep container closed when not in use. • Keep away from incompatible materials listed in Section 10.

SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION

WORKPLACE EXPOSURE STANDARDS (provided for guidance only)

	TWA		STEL	
Substance	**ppm**	**mg/m³**	**ppm**	**mg/m³**

No substance has exposure limits

Workplace Exposure Standard – Time Weighted Average (WES-TWA). The time-weighted average exposure standard designed to protect the worker from the effects of long-term exposure. Workplace Exposure Standard – Short-Term Exposure Limit (WESSTEL). The 15-minute average exposure standard. Applies to any 15- Minute period in the working day and is designed to protect the worker against adverse effects of irritation, chronic or irreversible tissue change, or narcosis that may increase the likelihood of accidents. The WES-STEL is not an alternative to the WES-TWA; both the short-term and time-weighted average exposures apply. Workplace Exposure Standards and Biological Exposure Indices NOV 2020 12TH EDITION.

Engineering controls:	No specialised ventilation required under normal conditions of use.
Personal protection: 	**Respiratory protection:** No respirator is required under normal conditions of use. **Hand protection:** Latex gloves or gloves of equal or greater protection are recommended. **Eye protection:** Safety glasses are recommended if there is a potential for direct eye contact.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Clear, slightly yellow coloured solution.
Odour	Practically odourless.
Odour Threshold	Not applicable
pH	Not applicable
Boiling Point	Not applicable
Melting Point	Not applicable
Freezing Point	Not applicable
Flash Point	81^0C
Flammability	Not applicable
Upper and Lower Exposure Limits	Not applicable

Vapour Pressure	Not applicable
Vapour Density	Not applicable
Density	Not applicable
Solubilities	Not applicable
Partition Coefficient:	Not applicable
Auto-ignition Temperature	Not applicable
Decomposition Temperature	Not applicable
Kinematic Viscosity	Not applicable
Particle Characteristics	Not applicable

SECTION 10: STABILITY AND REACTIVITY

Stability of the substance:	Stable when protected from light.
Conditions to avoid:	Avoid direct sunlight.
Material to avoid:	None known.
Hazardous decomposition products:	Carbon monoxide and carbon dioxide may be generated if heated to decomposition.

SECTION 11: TOXICOLOGICAL INFORMATION

Acute effects:	
Swallowed	Harmful if swallowed. Pure ivermectin is considered highly toxic in acute animal studies. The acute oral toxicity studies of ivermectin have shown clear differences among species in sensitivity to ivermectin toxicity. Rodents are uniquely sensitive compared to other species in which the compound has been tested. It is therefore inappropriate to base human risk assessment on the response of mice. Ivermectin is used at a therapeutic dose of 200mcg/kg in a variety of species, including human. Ivermectin can be excreted in milk. If overexposed to ivermectin, symptoms may include decreased activity, slow rate of breathing, dilation of pupils, muscle tremors, and incoordination.

	Glycerol formula is practically non-toxic in animal studies.
Dermal	Not applicable
Inhalation	Not applicable
Eye	Under normal conditions of use, no eye contact with the solution is expected. Direct contact of the solution with the eyes can cause irritation. Glycerol formula is moderately irritating to the eyes. Clorsulon is a slight to moderate ocular irritant.
Skin	Not a skin irritant. Ivermectin and Clorsulon are non-irritating in animal studies. Although skin absorption of the formulation of this formulation of ivermectin has not been established, it has been shown that less than 1% of the closely related compound abamectin is absorbed through the skin of the rhesus monkeys when it is applied as emulsifiable concentrate or suspended in alcohol. Glycerol formula may be absorbed through the skin. Propylene glycol was reported to be a skin sensitizer.
Chronic and long-term effects:	
Reproductive **Systemic**	Suspected of damaging fertility or the unborn child.
Carcinogenicity	Not applicable.
Germ Cell Mutagenicity	Suspected of causing genetic defects. May cause harm to breast-fed children.
STOT/RE	May cause damage to kidneys through prolonged or repeated exposure.
Chronic	Unknown for product mixture. When this product is used according to the directions, prolonged exposure of man is not expected. Ivermectin has tested negative in several mutagenicity studies. Ivermectin was administered to dogs daily for 3 months and to monkeys daily for 2 weeks. In dogs there was no effect up to 500mcg/kg/day and in immature rhesus monkeys there was no effect at the maximum dosage used 1.2mg/kg/day. At higher doses in dogs there was dilation of the pupils, and at still higher doses tremor and anorexia were noted.

	Glycerol formula was well tolerated in chronic toxicity studies in rabbits, rats and dogs up to very high doses (288mg/kg/day). However, in fetotoxicity studies in rodents the no effect level was set at 10mg/kg/day. The equivalent figure in teratogenicity studies was 75mg/kg/day. Clorsulon is negative in several bacterial and mammalian cell mutation studies. In studies in mice, chromosome damage and bone marrow toxicity were seen at high doses

SECTION 12: ENVIRONMENTAL INFORMATION

Ecotoxicity effects:	

Hazardous to the aquatic environment chronic Cat. 1
Hazardous to soil organisms
Hazardous to terrestrial vertebrates
Hazardous to terrestrial invertebrates

Persistence and degradability	No data available
Bioaccumulation	No data available
Mobility in Soil	No data available
Other adverse effects	No data available

Ivermectin photodegrades rapidly in the environment and is metabolized in the soil. Water solubility is limited and it binds to soil very tightly. It does not bioconcentrate in fish and is not taken up from soil into plants.

Do not allow to enter waterways.

SECTION 13: DISPOSAL CONSIDERATIONS

Product disposal:	Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Disposal must be made according to official regulations.

SECTION 14: TRANSPORT INFORMATION

This product is classified as a Dangerous Good for transport in NZ: NZS 5433:2012

Road and Rail Transport

UN No:	3082
Class-primary	9
Packing Group	III
Proper Shipping Name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (ivermectin)

Air Transport

UN No:	3082
Class-primary	9
Packing Group	III
Proper Shipping Name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (ivermectin)

Marine Transport

UN No:	3082
Class-primary	9
Packing Group	III
Proper Shipping Name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (ivermectin)

NOT RESTRICTED UNDER SPECIAL PROVISION A197 (375): These substances when transported in single or combination packagings containing a net quantity per single or inner packaging of 5 L or less for liquids or having a net mass of 5 kg or less for solids, are not subject to any other provisions of these Regulations provided the packagings meet the general provisions of 5.0.2.4.1, 5.0.2.6.1.1 and 5.0.2.8.

SECTION 15: REGULATORY INFORMATION

Regulatory status:	**EPA Approval No:** Veterinary Medicines (Non-Dispersive Closed System Application) – HSR100758. **Registered pursuant to the ACVM Act 1997** **ACVM Approval No:** A011186 See www.foodsaftely.govt.nz for registration conditions.
HSW (HS) Regulations 2017	**Trigger Quantity**
Certified Handler	Not required
Location Certificate	Not required

Tracking Trigger Quantities	Not required
Signage Trigger Quantities	100L/Kg
Emergency Response Plan	100L/Kg
Secondary Containment	100L/Kg
Restriction of Use	None
Hazardous Property Controls Notice 2017	
HPC Notice Part 4 Clause 47	Equipment for class 9 substances must be appropriate
HPC Notice Part 4 Clause 48	Records of application of class 9 pesticides and plant growth regulators
HPC Notice Part 3	Hazardous substances in a place other than a workplace.

SECTION 16: OTHER INFORMATION

Glossary

CAT Category
EC50 Median effective concentration.
EEL Environmental Exposure Limit.
EPA Environmental Protection Authority
HSNO Hazardous Substances and New Organisms.
HSW Health and Safety at Work.
LC50 Lethal concentration that will kill 50% of the test organisms inhaling or ingesting it.
LD50 Lethal dose to kill 50% of test animals/organisms.
LEL Lower explosive level.
OSHA American Occupational Safety and Health Administration.
TEL Tolerable Exposure Limit.
TLV Threshold Limit Value-an exposure limit set by responsible authority.
UEL Upper Explosive Level
WES Workplace Exposure Limit

References:

1. EPA Hazardous Substances (Safety Data Sheets) Notice 2017
2. Workplace Exposure Standards and Biological Exposure Indices Nov 2020 12th edition.
3. Assigning a hazardous substance to a HSNO Approval (Aug 2013).
4. Transport of Dangerous goods on land NZS 5433:2012
5. HSW (Hazardous Substances) Regulations 2017

This Safety Data Sheet summarises our best knowledge of the health and safety hazard information of the product and how to safely handle and use the product in the workplace. ALLEVA Animal Health Limited makes no warranty with respect hereto and disclaims all liability from reliance thereon.

Each user should read this SDS and consider the information in the context of how the product will be handled and used in the workplace including
in conjunction with other products.
PLEASE READ ALL LABELS CAREFULLY BEFORE USING PRODUCT.

Issued Date: 2 September 2021 Review Date: 2 September 2026