SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Halofuginone Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
   Company : MSD
             20 Spartan Road
             1619 Spartan, South Africa
   Telephone : +27119239300
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   +1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Eye irritation, Category 2
   Long-term (chronic) aquatic hazard, Category 3
   H319: Causes serious eye irritation.
   H412: Harmful to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms :
   Signal word : Warning
   Hazard statements :
   H319 Causes serious eye irritation.
   H412 Harmful to aquatic life with long lasting effects.
   Precautionary statements :
   Prevention:
   P264 Wash skin thoroughly after handling.
   P273 Avoid release to the environment.
   P280 Wear eye protection/ face protection.
   Response:
2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumula-
tive and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or
higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactic acid</td>
<td>50-21-5</td>
<td>200-018-0</td>
<td></td>
<td></td>
<td></td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
<tr>
<td>Halofuginone</td>
<td>82186-71-8</td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 2; H300 Acute Tox. 2; H330 Acute Tox. 1; H310 Skin Irrit. 2; H315 Eye Dam. 1; H318 Skin Sens. 1B; H317 Rep. 2; H361f STOT RE 1; H372 (Blood) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 10 M-Factor (Acute aquatic toxicity): 10</td>
<td>&gt; 0.025 - &lt; 0.1</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-
vice immediately. When symptoms persist or in all cases of doubt seek medical advice.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment.
4.2 Most important symptoms and effects, both acute and delayed

Risks: Causes serious eye irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides

5.3 Advice for firefighters

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

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling: Do not get on skin or clothing. Avoid inhalation of vapour or mist. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-
Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types: Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Occupational Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
</tr>
<tr>
<td>Halofuginone</td>
</tr>
</tbody>
</table>

Further information: DSEN, Skin

| Wipe limit                  | 50 µg/100 cm² | Internal |

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactic acid</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>592 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>592 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>296 mg/m³</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

Engineering measures

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted.

Use closed processing systems or containment technologies.

If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.
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Personal protective equipment

Eye protection: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection

Material: Chemical-resistant gloves
Remarks: Consider double gloving.

Skin and body protection:

Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Organic vapour type (A)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: liquid
Colour: yellow
Odour: odourless
Odour Threshold: No data available
pH: 2,1 - 3
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: No data available
Evaporation rate: No data available
Flammability (solid, gas): Not applicable
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
Density: No data available
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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, kinematic: No data available

Explosive properties
- Not explosive

Oxidizing properties
- The substance or mixture is not classified as oxidizing.

9.2 Other information
- Flammability (liquids): No data available
- Molecular weight: No data available
- Particle size: No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
- Not classified as a reactivity hazard.

10.2 Chemical stability
- Stable under normal conditions.

10.3 Possibility of hazardous reactions
- Hazardous reactions: Can react with strong oxidizing agents.

10.4 Conditions to avoid
- Conditions to avoid: None known.

10.5 Incompatible materials
- Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
- No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
- Information on likely routes of exposure:
  - Inhalation
  - Skin contact
  - Ingestion
  - Eye contact
Acute toxicity
Not classified based on available information.

Components:

Lactic acid:
Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg
Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: Based on data from similar materials

Halofuginone:
Acute oral toxicity : LD50 (Rat): 30 mg/kg
LD50 (Mouse): 5 mg/kg

Acute inhalation toxicity : LC50 (Rat): 0,053 mg/l
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): 16 mg/kg
Acute toxicity estimate: 16 mg/kg
Method: Calculation method

Skin corrosion/irritation
Not classified based on available information.

Components:

Lactic acid:
Species : Rabbit
Result : Skin irritation
Remarks : Based on data from similar materials

Halofuginone:
Species : Rabbit
Result : Skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

Lactic acid:
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Species: Chicken eye
Remarks: Based on data from similar materials
Result: Irreversible effects on the eye

Halofuginone:
Result: Severe irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Lactic acid:
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

Halofuginone:
Exposure routes: Dermal
Species: Guinea pig
Result: Sensitiser

Germ cell mutagenicity
Not classified based on available information.

Components:

Lactic acid:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Halofuginone:
Genotoxicity in vitro: Test Type: Ames test
Result: positive
Test Type: Mouse Lymphoma
Result: negative

Test Type: Chromosomal aberration
Test system: human lymphoblastoid cells
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Genotoxicity in vivo:
Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

Test Type: Cytogenetic assay
Species: Rat
Application Route: Oral
Result: negative

Test Type: DNA Repair
Species: Mouse
Application Route: Oral
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Lactic acid:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative
Remarks: Based on data from similar materials

Halofuginone:
Species: Mouse
Application Route: Oral
NOAEL: 0.24 mg/kg body weight
Result: negative

Species: Rat
Application Route: Oral
Exposure time: 63 weeks
NOAEL: 0.36 mg/kg body weight
Result: negative

Species: Rat
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
</table>

**Application Route**: Oral  
**Exposure time**: 26 Months  
**NOAEL**: 0,09 - 0,18 mg/kg body weight  
**Result**: negative

**Reproductive toxicity**
Not classified based on available information.

### Components:

**Lactic acid**:
- **Effects on foetal development**: Test Type: Embryo-foetal development  
  Species: Mouse  
  Application Route: Ingestion  
  Result: negative

**Halofuginone**:
- **Effects on fertility**: Test Type: Fertility  
  Species: Mouse  
  Application Route: Oral  
  Fertility: NOAEL: 0,126 mg/kg body weight  
  Result: No effects on fertility

  Test Type: Fertility  
  Species: Dog  
  Application Route: Oral  
  Fertility: LOAEL: 0,067 mg/kg body weight  
  Result: Effects on fertility

  Test Type: Three-generation reproduction toxicity study  
  Species: Mouse  
  Application Route: Oral  
  General Toxicity F1: LOAEL: 0,063 mg/kg body weight  
  Symptoms: Reduced body weight  
  Result: No effects on fertility and early embryonic development were detected.

- **Effects on foetal development**: Test Type: Embryo-foetal development  
  Species: Rat  
  Application Route: Oral  
  General Toxicity Maternal: LOAEL: 0,34 mg/kg body weight  
  Embryo-foetal toxicity: NOAEL: 0,67 mg/kg body weight  
  Result: No embryo-foetal toxicity, No teratogenic effects

  Test Type: Embryo-foetal development  
  Species: Rabbit  
  Application Route: Oral  
  General Toxicity Maternal: NOAEL: 0,025 mg/kg body weight  
  Embryo-foetal toxicity: NOAEL: 0,076 mg/kg body weight  
  Result: No embryo-foetal toxicity, No teratogenic effects

**Reproductive toxicity - Assessment**: Some evidence of adverse effects on sexual function and fertility, based on animal experiments.
STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Components:

Halofuginone:
Target Organs: Blood
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Lactic acid:
Species: Rat
NOAEL: > 100 mg/kg
Application Route: Ingestion
Exposure time: 13 Weeks
Remarks: Based on data from similar materials

Species: Rat
LOAEL: 886 mg/kg
Application Route: Skin contact
Exposure time: 13 Weeks

Halofuginone:
Species: Mouse
NOAEL: 0,07 mg/kg
LOAEL: 0,16 mg/kg
Application Route: Oral
Exposure time: 4 Weeks
Target Organs: Blood

Species: Rat
NOAEL: 0,13 mg/kg
LOAEL: 0,88 mg/kg
Application Route: Oral
Exposure time: 13 Weeks
Target Organs: Liver

Species: Dog
NOAEL: 0,067 mg/kg
LOAEL: 0,134 mg/kg
Application Route: Oral
Exposure time: 13 Weeks
Target Organs: Blood

Species: Dog
NOAEL: 0,075 mg/kg
LOAEL: 0,16 mg/kg
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Version: 3.12
Revision Date: 27.08.2021
SDS Number: 845726-00015
Date of last issue: 09.04.2021
Date of first issue: 26.08.2016

Application Route: Oral
Exposure time: 26 Weeks
Target Organs: Blood

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Halofuginone:
General Information: No human information is available.
Inhalation: Remarks: May cause irritation of respiratory tract.
Skin contact: Remarks: May cause skin irritation and/or dermatitis.
May cause sensitisation by skin contact.
Can be absorbed through skin.
Eye contact: Remarks: May irritate eyes.

SECTION 12: Ecological information

12.1 Toxicity

Components:

Lactic acid:
Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms: EC50: > 10 - 100 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

Halofuginone:
Toxicity to fish:
LC50 (Oncorhynchus mykiss (rainbow trout)): 1.8 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

LC50 (Cyprinus carpio (Carp)): 0.3 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.12 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): 0.02 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants:
EC50 (Chlorella pyrenoidosa (algae)): 46 mg/l
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

M-Factor (Acute aquatic toxicity): 10
M-Factor (Chronic aquatic toxicity): 10

12.2 Persistence and degradability

Components:
Lactic acid:
Biodegradability: Result: Not readily biodegradable.
Remarks: Based on data from similar materials

Halofuginone:
Biodegradability: Result: Not readily biodegradable.

12.3 Bioaccumulative potential

Components:
Lactic acid:
Partition coefficient: n-octanol/water: log Pow: -0.62

Halofuginone:
Partition coefficient: n-octanol/water: log Pow: 1.18

12.4 Mobility in soil

Components:
Halofuginone:
Distribution among environmental compartments: log Koc: 3.87
Method: FDA 3.08
12.5 Results of PBT and vPvB assessment

**Product:**
- **Assessment:** 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

**Product:**
- **Endocrine disrupting potential:** The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

**Product:** Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

**Contaminated packaging:** Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number
- Not regulated as a dangerous good

14.2 UN proper shipping name
- Not regulated as a dangerous good

14.3 Transport hazard class(es)
- Not regulated as a dangerous good

14.4 Packing group
- Not regulated as a dangerous good

14.5 Environmental hazards
- Not regulated as a dangerous good

14.6 Special precautions for user
- Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
- **Remarks:** Not applicable for product as supplied.
SECTION 15: Regulatory information

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

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

- AICS: not determined
- DSL: not determined
- IECSC: not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

- H300: Fatal if swallowed.
- H310: Fatal in contact with skin.
- H315: Causes skin irritation.
- H317: May cause an allergic skin reaction.
- H318: Causes serious eye damage.
- H330: Fatal if inhaled.
- H361f: Suspected of damaging fertility.
- H372: Causes damage to organs through prolonged or repeated exposure.
- H400: Very toxic to aquatic life.
- H410: Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

- Acute Tox.: Acute toxicity
- Aquatic Acute: Short-term (acute) aquatic hazard
- Aquatic Chronic: Long-term (chronic) aquatic hazard
- Eye Dam.: Serious eye damage
- Repr.: Reproductive toxicity
- Skin Irrit.: Skin irritation
- Skin Sens.: Skin sensitisation
- STOT RE: Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentra-
Further information

Classification of the mixture:

Eye Irrit. 2 H319 Calculation method
Aquatic Chronic 3 H412 Calculation method

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.