

Safety Data Sheet

acc. to OSHA HCS

1: Identification

- **1.1 Product identifier**
- **Trade name:** Imiquimod
- **Product Code:** 106803
- **CAS Number:**
99011-02-6
- **EC number:**
619-387-8
- **1.2 Relevant identified uses of the substance or mixture and uses advised against** No further relevant information available.
- **Application of the substance / the mixture** Pharma Active ingredients
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Fagron Inc
2400 Pilot Knob Road
St. Paul, MN 55120
www.fagron.us
QA@fagron.us
- **Information department:**
Tel.: 800-423-6967
Fax: 800-339-1596
- **1.4 Emergency telephone number:**
Emergency Telephone:
US: 1-800-535-5053
International: 1-352-323-3500

2: Hazard(s) identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS06 Skull and crossbones

Acute Tox. 2 H300 Fatal if swallowed.



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2A H319 Causes serious eye irritation.

STOT SE 3 H335 May cause respiratory irritation.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** The substance is classified and labeled according to the CLP regulation.
- **Hazard pictograms** GHS06, GHS07
- **Signal word** Danger
- **Hazard statements**
H300 Fatal if swallowed.
H315 Causes skin irritation.

(Contd. on page 2)

Trade name: Imiquimod

(Contd. of page 1)

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

· **Precautionary statements**

P261 Avoid breathing dust/fume/gas/mist/vapors/spray

P280 Wear protective gloves.

P280 Wear eye protection / face protection.

P301+P310 If swallowed: Immediately call a poison center/doctor.

P321 Specific treatment (see on this label).

P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3: Composition/information on ingredients

· **3.1 Chemical characterization: Substances**

· **CAS No. Description**

99011-02-6 Imiquimod

· **Identification number(s)**

· **EC number:** 619-387-8

4: First-aid measures

· **4.1 Description of first aid measures**

· **General information:**

Immediately remove any clothing soiled by the product.

In case of irregular breathing or respiratory arrest provide artificial respiration.

· **After inhalation:** In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

· **After eye contact:** Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:** Do not induce vomiting; immediately call for medical help.

· **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

· **4.3 Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5: Fire-fighting measures

· **5.1 Extinguishing media**

· **Suitable extinguishing agents:**

CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

· **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

· **5.3 Advice for firefighters**

· **Protective equipment:** No special measures required.

USA

(Contd. on page 3)



Trade name: Imiquimod

(Contd. of page 2)

6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **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:**
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7: Handling and storage

- **7.1 Precautions for safe handling** Thorough dedusting.
- **Information about protection against explosions and fires:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Store in cool, dry conditions in well sealed receptacles.
- **7.3 Specific end use(s)** No further relevant information available.

8: Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **8.1 Control parameters**
- **Components with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
- **Breathing equipment:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

(Contd. on page 4)

USA

Trade name: Imiquimod

(Contd. of page 3)

· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
 Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**



Tightly sealed goggles

9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· Form:	Powder
· Color:	White
· Odor:	Odorless
· Odour threshold:	Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

· Melting point/Melting range:	292-294 °C (558-561 °F)
· Boiling point/Boiling range:	Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Product is not flammable.

· **Ignition temperature:**

· **Decomposition temperature:** Not determined.

· **Auto igniting:** Not determined.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

· **Lower:** Not determined.

(Contd. on page 5)

USA

Trade name: Imiquimod

(Contd. of page 4)

Upper:	Not determined.
· Vapor pressure:	Not applicable.
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with Water:	Not determined.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· 9.2 Other information	No further relevant information available.

10: Stability and reactivity

- 10.1 Reactivity
- 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions: No dangerous reactions known.
- 10.4 Conditions to avoid: No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: No dangerous decomposition products known.

11: Toxicological information

- 11.1 Information on toxicological effects
- Acute toxicity:
- Primary irritant effect:
 - on the skin: Irritant to skin and mucous membranes.
 - on the eye: Irritating effect.
- Sensitization: No sensitizing effects known.
- Additional toxicological information:
- Carcinogenic categories
- IARC (International Agency for Research on Cancer) Substance is not listed.
- NTP (National Toxicology Program) Substance is not listed.
- OSHA-Ca (Occupational Safety & Health Administration) Substance is not listed.

12: Ecological information

- 12.1 Toxicity
- Aquatic toxicity: No further relevant information available.

(Contd. on page 6)

USA



Safety Data Sheet

acc. to OSHA HCS

Trade name: Imiquimod

(Contd. of page 5)

- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation:** Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14: Transport information

- | | |
|---|-----------------|
| · 14.1 UN-Number
· DOT, ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name
· DOT, ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es)
· DOT, ADR, ADN, IMDG, IATA
· Class | Void |
| · 14.4 Packing group
· DOT, ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards:
· Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | - |

15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.

(Contd. on page 7)

USA



Trade name: Imiquimod

(Contd. of page 6)

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16: Other information

This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered to be dependable and is accurate to the best of the Company's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. The Company cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

· Department issuing SDS:

Fagron US

Quality Assurance

· **Contact:** QA@fagron.us

· **Date of preparation / last revision** 10/26/2015 / -

· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

Acute Tox. 2: Acute toxicity, Hazard Category 2

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

· *** Data compared to the previous version altered.**

USA