

Creation Date 14-May-2014

Revision Date 15-Oct-2015

Revision Number 2

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identification

Product Description: Abacavir sulfate
Cat No. : 458860000; 458860010; 458860250
CAS-No 188062-50-2
Molecular Formula C14 H18 N6 O . 1/2 H2 S O4

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Laboratory chemicals. For research use only.
Uses advised against No Information available

1.3. Details of the supplier of the safety data sheet

Company Acros Organics BVBA
 Janssen Pharmaceuticaaan 3a
 2440 Geel, Belgium
E-mail address begel.sdsdesk@thermofisher.com

1.4. Emergency telephone number

For information **US** call: 001-800-ACROS-01 / **Europe** call: +32 14 57 52 11
 Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99
CHEMTREC Tel. No.**US**:001-800-424-9300 / **Europe**:001-703-527-3887

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

CLP Classification - Regulation (EC) No 1272/2008

The toxicological properties have not been fully investigated.

Physical hazards

Based on available data, the classification criteria are not met

Health hazards

| | |
|-----------------------------------|------------|
| Serious Eye Damage/Eye Irritation | Category 1 |
| Skin Sensitization | Category 1 |
| Germ Cell Mutagenicity | Category 2 |
| Carcinogenicity | Category 2 |
| Reproductive Toxicity | Category 2 |

Environmental hazards

| | |
|--------------------------|------------|
| Chronic aquatic toxicity | Category 3 |
|--------------------------|------------|

2.2. Label elements

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Signal Word

Danger

Hazard Statements

- H361d - Suspected of damaging the unborn child
- H341 - Suspected of causing genetic defects
- H351 - Suspected of causing cancer
- H317 - May cause an allergic skin reaction
- H318 - Causes serious eye damage
- H412 - Harmful to aquatic life with long lasting effects

Precautionary Statements

- P202 - Do not handle until all safety precautions have been read and understood
- P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
- P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
- P310 - Immediately call a POISON CENTER or doctor/ physician
- P280 - Wear protective gloves/ protective clothing/ eye protection/ face protection

2.3. Other hazards

No information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

| Component | CAS-No | EC-No. | Weight % | CLP Classification - Regulation (EC) No 1272/2008 |
|------------------|-------------|--------|----------|---|
| Abacavir Sulfate | 188062-50-2 | | >95 | Muta. 2 (H341) Carc. 2 (H351) Repr. 2 (H361d) Skin Sens. 1 (H317) Eye Dam. 1 (H318) Aquatic Chronic 3 (H412) |

Full text of Hazard Statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

| | |
|-----------------------------------|---|
| Eye Contact | Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. |
| Skin Contact | Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. |
| Ingestion | Clean mouth with water and drink afterwards plenty of water. |
| Inhalation | Move to fresh air. |
| Protection of First-aiders | Ensure that medical personnel are aware of the material(s) involved, take precautions to |

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protect themselves and prevent spread of contamination.

4.2. Most important symptoms and effects, both acute and delayed

Causes eye burns. May cause allergic skin reaction. . Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain or flushing

4.3. Indication of any immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Extinguishing media which must not be used for safety reasons

No information available.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors.

Hazardous Combustion Products

Carbon monoxide (CO), Carbon dioxide (CO₂), Nitrogen oxides (NO_x), Sulfur oxides.

5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation.

6.2. Environmental precautions

Do not flush into surface water or sanitary sewer system. See Section 12 for additional ecological information. Avoid release to the environment. Collect spillage.

6.3. Methods and material for containment and cleaning up

6.4. Reference to other sections

Refer to protective measures listed in Sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Ensure adequate ventilation.

7.2. Conditions for safe storage, including any incompatibilities

Keep locked-up. Keep container tightly closed. To maintain product quality: Keep refrigerated.

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7.3. Specific end use(s)

Use in laboratories

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies

Biological limit values

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Monitoring methods

BS EN 14042:2003 Title Identifier: Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents.

MDHS14/3 General methods for sampling and gravimetric analysis of respirable and inhalable dust

Derived No Effect Level (DNEL) No information available

| Route of exposure | Acute effects (local) | Acute effects (systemic) | Chronic effects (local) | Chronic effects (systemic) |
|-------------------|-----------------------|--------------------------|-------------------------|----------------------------|
| Oral | | | | |
| Dermal | | | | |
| Inhalation | | | | |

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Engineering Measures

Ensure that eyewash stations and safety showers are close to the workstation location.

Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source

Personal protective equipment

Eye Protection

Goggles (European standard - EN 166)

Hand Protection

Protective gloves

| Glove material | Breakthrough time | Glove thickness | EU standard | Glove comments |
|----------------|-------------------|-----------------|-------------|-----------------------|
| Natural rubber | See manufacturers | - | EN 374 | (minimum requirement) |
| Nitrile rubber | recommendations | | | |
| Neoprene | | | | |
| PVC | | | | |

Skin and body protection

Long sleeved clothing

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves.

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(Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatibility, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

| | |
|--|--|
| Respiratory Protection | When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained properly |
| Large scale/emergency use | Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced Recommended Filter type: Particulates filter conforming to EN 143 |
| Small scale/Laboratory use | Use a NIOSH/MSHA or European Standard EN 149:2001 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. Recommended half mask:- Particle filtering: EN149:2001 When RPE is used a face piece Fit Test should be conducted |
| Hygiene Measures | Handle in accordance with good industrial hygiene and safety practice. |
| Environmental exposure controls | Prevent product from entering drains. |

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

| | | |
|--|---------------------------------|--|
| Appearance | White | |
| Physical State | Solid | |
| Odor | No information available | |
| Odor Threshold | No data available | |
| pH | No information available | |
| Melting Point/Range | 232 - 237 °C / 449.6 - 458.6 °F | |
| Softening Point | No data available | |
| Boiling Point/Range | No information available | |
| Flash Point | No information available | Method - No information available |
| Evaporation Rate | Not applicable | Solid |
| Flammability (solid,gas) | No information available | |
| Explosion Limits | No data available | |
| Vapor Pressure | No data available | |
| Vapor Density | Not applicable | Solid |
| Specific Gravity / Density | No data available | |
| Bulk Density | No data available | |
| Water Solubility | Soluble in water | |
| Solubility in other solvents | No information available | |
| Partition Coefficient (n-octanol/water) | | |
| Component | log Pow | |
| Abacavir Sulfate | +1.20 | |
| Autoignition Temperature | | |
| Decomposition Temperature | No data available | |
| Viscosity | Not applicable | Solid |
| Explosive Properties | No information available | |
| Oxidizing Properties | No information available | |

9.2. Other information

| | |
|--------------------------|----------------------------|
| Molecular Formula | C14 H18 N6 O . 1/2 H2 S O4 |
| Molecular Weight | 335.37 |

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SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

None known, based on information available

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Hazardous Polymerization Hazardous Reactions

No information available.

No information available.

10.4. Conditions to avoid

Avoid dust formation.

10.5. Incompatible materials

Strong oxidizing agents. Strong reducing agents. Strong bases.

10.6. Hazardous decomposition products

Carbon monoxide (CO). Carbon dioxide (CO₂). Nitrogen oxides (NO_x). Sulfur oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Product Information

Caution - contains a substance not yet fully tested

(a) acute toxicity;

Oral

No data available

Dermal

No data available

Inhalation

No data available

(b) skin corrosion/irritation;

No data available

(c) serious eye damage/irritation;

Category 1

(d) respiratory or skin sensitization;

Respiratory

No data available

Skin

Category 1

(e) germ cell mutagenicity;

No information available

Category 2

(f) carcinogenicity;

Category 2

There are no known carcinogenic chemicals in this product

(g) reproductive toxicity;

Category 2

(h) STOT-single exposure;

No data available

(i) STOT-repeated exposure;

No data available

Target Organs

No information available.

(j) aspiration hazard;

Not applicable

Solid

Other Adverse Effects

The toxicological properties have not been fully investigated.

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Symptoms / effects, both acute and delayed Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain or flushing

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity effects

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. The product contains following substances which are hazardous for the environment.

12.2. Persistence and degradability

Persistence

Soluble in water, Persistence is unlikely, based on information available.

Degradation in sewage treatment plant

Contains substances known to be hazardous to the environment or not degradable in waste water treatment plants.

12.3. Bioaccumulative potential

Bioaccumulation is unlikely

| Component | log Pow | Bioconcentration factor (BCF) |
|------------------|---------|-------------------------------|
| Abacavir Sulfate | +1.20 | No data available |

12.4. Mobility in soil

The product is water soluble, and may spread in water systems Will likely be mobile in the environment due to its water solubility. Highly mobile in soils

12.5. Results of PBT and vPvB assessment

No data available for assessment.

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

Persistent Organic Pollutant

This product does not contain any known or suspected substance

Ozone Depletion Potential

This product does not contain any known or suspected substance

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from Residues / Unused Products

Waste is classified as hazardous. Dispose of in accordance with the European Directives on waste and hazardous waste. Dispose of in accordance with local regulations.

Contaminated Packaging

Dispose of this container to hazardous or special waste collection point.

European Waste Catalogue (EWC)

According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.

Other Information

Do not dispose of waste into sewer. Waste codes should be assigned by the user based on the application for which the product was used. Do not empty into drains. Do not let this chemical enter the environment.

SECTION 14: TRANSPORT INFORMATION

IMDG/IMO

Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

ADR

Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

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IATA Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

14.5. Environmental hazards No hazards identified

14.6. Special precautions for user No special precautions required

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable, packaged goods

SECTION 15: REGULATORY INFORMATION

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

International Inventories X = listed The product is classified and labeled according to EC directives or corresponding national laws The product is classified and labeled in accordance with Directive 1999/45/EC

National Regulations

Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment.

Take note of Dir 94/33/EC on the protection of young people at work

Take note of Dir 92/85/EC on the protection of pregnant and breastfeeding women at work

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

15.2. Chemical safety assessment

A Chemical Safety Assessment/Report (CSA/CSR) has not been conducted

SECTION 16: OTHER INFORMATION

Full Text of H-/EUH-Statements Referred to Under Section 3

H341 - Suspected of causing genetic defects

H351 - Suspected of causing cancer

H361d - Suspected of damaging the unborn child

H317 - May cause an allergic skin reaction

H318 - Causes serious eye damage

H412 - Harmful to aquatic life with long lasting effects

Legend

CAS - Chemical Abstracts Service

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

IECSC - Chinese Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

ENCS - Japanese Existing and New Chemical Substances

AICS - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

WEL - Workplace Exposure Limit

ACGIH - American Conference of Governmental Industrial Hygienists

DNEL - Derived No Effect Level

RPE - Respiratory Protective Equipment

LC50 - Lethal Concentration 50%

NOEC - No Observed Effect Concentration

TWA - Time Weighted Average

IARC - International Agency for Research on Cancer

PNEC - Predicted No Effect Concentration

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50%

POW - Partition coefficient Octanol:Water

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PBT - Persistent, Bioaccumulative, Toxic

vPvB - very Persistent, very Bioaccumulative

ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road

ICAO/IATA - International Civil Aviation Organization/International Air Transport Association

IMO/IMDG - International Maritime Organization/International Maritime Dangerous Goods Code

MARPOL - International Convention for the Prevention of Pollution from Ships

OECD - Organisation for Economic Co-operation and Development

ATE - Acute Toxicity Estimate

BCF - Bioconcentration factor

VOC - Volatile Organic Compounds

Key literature references and sources for data

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

Training Advice

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Use of personal protective equipment, covering appropriate selection, compatibility, breakthrough thresholds, care, maintenance, fit and standards.

First aid for chemical exposure, including the use of eye wash and safety showers.

Creation Date 14-May-2014

Revision Date 15-Oct-2015

Revision Summary Update to Format, 1, 2, 3.

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer

The information provided on 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 guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as 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 material or in any process, unless specified in the text.

End of Safety Data Sheet