

Scientific Documentation

Budesonide, Micronized, USP

Not appropriate for regulatory submission.

Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp
769 Jersey Avenue
New Brunswick, NJ 08901
Phone 732.214.1300



Table of Contents

Product Specification
Certificate of Analysis
Safety Data Sheet (SDS)
Certification of Current Good Manufacturing Practices (cGMP)
Manufacturing Process Flowchart
Technical Statements
Elemental Impurities Statement
Residual Solvents Statement
General Label Information – Sample Label

Specification for Budesonide, Micronized, USP (B4040)

Item Number	B4040
Item	Budesonide, Micronized, USP
CAS Number	51333-22-3
Molecular Formula	C ₂₅ H ₃₄ O ₆
Molecular Weight	430.59
MDL Number	
Synonyms	16,17-Butylidenebis[oxy]-11,21-dihydroxypregna-1,4-diene-3,20-dione

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS, BOTH EPIMERS)	98.0	102.0 %
ASSAY (DRIED BASIS, EPIMER A)	40.0	51.0 %
LOSS ON DRYING		0.3 %
ORGANIC IMPURITIES:		
16a-HYDROXPREDNISOLONE		0.2 %
BUDESONIDE ACETALDEHYDE ACETAL (EPIMERS)		0.10 %
BUDESONIDE D-HOMO ANALOG		0.10 %
DESONIDE		0.10 %
BUDESONIDE GLYOXAL (EPIMERS)		0.07 %
BUDESONIDE RELATED COMPOUND E		0.10 %
BUDESONIDE RELATED COMPOUND L		0.2 %
BUDESONIDE RELATED COMPOUND G (EPIMERS)		0.10 %
BUDESONIDE 21-ACETATE (EPIMERS)		0.10 %
BUDESONIDE 21-BUTYRATE		0.10 %
ANY OTHER INDIVIDUAL IMPURITY		0.10 %
TOTAL SPECIFIED IMPURITIES		0.4 %
TOTAL UNSPECIFIED IMPURITIES		0.4 %
ELEMENTAL IMPURITIES	AS REPORTED	
MICROBIAL LIMITS:		

Test	Specification	
	Min	Max
TOTAL AEROBIC MICROBIAL COUNT (TAMC)		10 ³ cfu/g
TOTAL MOLDS AND YEASTS COUNT (TMYC)		10 ² cfu/g
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION B	SPECTRUM MATCHES STANDARD	
APPEARANCE		
EXPIRATION DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS	AS REPORTED	

Spectrum Chemical Mfg Corp

<i>Corporate Headquarters:</i>	<i>West Coast Facility:</i>
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

Certificate Of Analysis

Item Number	B4040	Lot Number	4ME0004
Item	Budesonide, Micronized, USP	Manufacturer Lot	BD210603M
CAS Number	51333-22-3	Manufacturer Code	13105
Molecular Formula	C ₂₅ H ₃₄ O ₆	Molecular Weight	430.59

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS, BOTH EPIMERS)	98.0	102.0 %	101.0 %
ASSAY (DRIED BASIS, EPIMER A)	40.0	51.0 %	41.9 %
LOSS ON DRYING		0.3 %	0.3 %
ORGANIC IMPURITIES:			.
16a-HYDROXPREDNISOLONE		0.2 %	0.0 %
BUDESONIDE ACETALDEHYDE ACETAL (EPIMERS)		0.10 %	0.0 %
BUDESONIDE D-HOMO ANALOG		0.10 %	0.0 %
DESONIDE		0.10 %	0.0 %
BUDESONIDE GLYOXAL (EPIMERS)		0.07 %	0.0 %
BUDESONIDE RELATED COMPOUND E		0.10 %	0.0 %
BUDESONIDE RELATED COMPOUND L		0.2 %	0.0 %
BUDESONIDE RELATED COMPOUND G (EPIMERS)		0.10 %	0.0 %
BUDESONIDE 21-ACETATE (EPIMERS)		0.10 %	0.0 %
BUDESONIDE 21-BUTYRATE		0.10 %	0.0 %
ANY OTHER INDIVIDUAL IMPURITY		0.10 %	0.0 %
TOTAL SPECIFIED IMPURITIES		0.4 %	0.0 %
TOTAL UNSPECIFIED IMPURITIES		0.4 %	0.0 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
MICROBIAL LIMITS:			.
TOTAL AEROBIC MICROBIAL COUNT (TAMC)		10 ³ cfu/g	<10 ³ cfu/g
TOTAL MOLDS AND YEASTS COUNT (TMYC)		10 ² cfu/g	<10 ² cfu/g

TEST	SPECIFICATION		RESULT
	MIN	MAX	
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION B	SPECTRUM MATCHES STANDARD		SPECTRUM MATCHES STANDARD
APPEARANCE			WHITE POWDER
EXPIRATION DATE			19-JUN-2024
DATE OF MANUFACTURE			20-JUN-2021
RESIDUAL SOLVENTS	AS REPORTED		.
CLASS 2 (solvent) / ACETONITRILE			<410 ppm
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm
CLASS 2 (solvent) / METHYLENE CHLORIDE			<600 ppm
CLASS 3 (solvent) / ACETONE			<5000 ppm
CLASS 3 (solvent) / ETHANOL			<5000 ppm
MONOGRAPH EDITION			USP 2023

Certificate of Analysis Results Entered By:

SVANGOOR
Swetha Vangoor
18-MAY-23 12:44:59

Spectrum Chemical Mfg Corp
777 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS
Allison Williams
18-MAY-23 12:46:56

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Hubei Gedian Humanwell Pharmaceutical Co., Ltd at No. 25, Juxian Road, Gedian Economic Development District,, Ezhou, Hubei 436070, China (CHN). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

SAFETY DATA SHEET

spectrum®



Revision date 11-February-2020

Revision Number 1

1. Identification

Product identifier

Product Name Budesonide, Micronized, USP

Other means of identification

Product Code(s) B4040

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use No information available

Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Address

Spectrum Chemical Mfg. Corp.
14422 South San Pedro St.
Gardena, CA 90248
(310) 516-8000

Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification

Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2B
Reproductive toxicity	Category 2

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Warning

Hazard statements

Causes skin irritation
Causes eye irritation
Suspected of damaging fertility or the unborn child



Appearance Powder

Physical state Solid

Odor Odorless

Precautionary Statements - Prevention

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Wear protective gloves/protective clothing/eye protection/face protection

Wash face, hands and any exposed skin thoroughly after handling

Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention

Specific treatment (see .? on this label)

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

If eye irritation persists: Get medical advice/attention

IF ON SKIN: Wash with plenty of water and soap

If skin irritation occurs: Get medical advice/attention

Take off contaminated clothing and wash it before reuse

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

May be harmful if swallowed.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Budesonide	51333-22-3	100	*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures

Description of first aid measures

General advice

Show this safety data sheet to the doctor in attendance.

Inhalation

Remove to fresh air. Get medical attention immediately if symptoms occur.

Eye contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Skin contact

Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

Ingestion

Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Call a physician.

Self-protection of the first aider Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Symptoms No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. Fire-fighting measures

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

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing media Do not scatter spilled material with high pressure water streams.

Specific hazards arising from the chemical No information available.

Explosion data

Sensitivity to mechanical impact none.

Sensitivity to static discharge none.

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required.

Other information Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Take off contaminated clothing and wash before reuse.

Conditions for safe storage, including any incompatibilities

Storage Conditions Store locked up. Keep containers tightly closed in a dry, cool and well-ventilated place.

8. Exposure controls/personal protection

Control parameters

Exposure Limits

The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

Appropriate engineering controls

Engineering controls

Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection

If splashes are likely to occur, wear safety glasses with side-shields. None required for consumer use.

Hand protection

Wear suitable gloves. Impervious gloves.

Skin and body protection

Wear suitable protective clothing. Long sleeved clothing.

Respiratory protection

No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations

Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product. Wear suitable gloves and eye/face protection. Avoid contact with skin, eyes or clothing.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Solid
Appearance	Powder
Color	white
Odor	Odorless
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	no data available	None known
Melting point / freezing point	227 °C / 440.6 °F	None known
Boiling point / boiling range	no data available	None known
Flash point	no data available	None known
Evaporation rate	no data available	None known
Flammability (solid, gas)	no data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	no data available	None known
Water solubility	No data available	None known
Solubility(ies)	no data available	None known
Partition coefficient	1.6	None known
Autoignition temperature	no data available	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known

Other information

Explosive properties	No information available
Oxidizing properties	No information available
Softening point	No information available
Molecular weight	No information available
VOC Content (%)	No information available
Liquid Density	No information available
Bulk density	No information available

10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	Strong acids. Strong bases. Strong oxidizing agents.
Hazardous decomposition products	Spontaneous polymerisation.

11. Toxicological information**Information on likely routes of exposure****Product Information**

.

Inhalation	Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.
Eye contact	Specific test data for the substance or mixture is not available. Irritating to eyes. (based on components). Causes eye irritation.
Skin contact	Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components).
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. May be harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	Redness. May cause redness and tearing of the eyes.
-----------------	---

Acute toxicity**Numerical measures of toxicity**

3200 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Budesonide 51333-22-3	> 3200 mg/kg (Rat)	-	-

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	Classification based on data available for ingredients. Irritating to skin.
Serious eye damage/eye irritation	Classification based on data available for ingredients. Irritating to eyes.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.

Reproductive toxicity	Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. Suspected of damaging fertility or the unborn child.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

12. Ecological information

Ecotoxicity	The environmental impact of this product has not been fully investigated.
Persistence and degradability	No information available.
Bioaccumulation	Inherently biodegradable.
Other adverse effects	No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
Contaminated packaging	Do not reuse empty containers.

14. Transport information

<u>DOT</u>	not regulated
<u>TDG</u>	not regulated
<u>MEX</u>	not regulated
<u>ICAO (air)</u>	not regulated
<u>IATA</u>	not regulated
<u>IMDG</u>	not regulated
<u>RID</u>	not regulated
<u>ADR</u>	not regulated
<u>ADN</u>	not regulated

15. Regulatory information

International Inventories

TSCA	Not listed
-------------	------------

*Contact supplier for details. One or more substances in this product are either not listed on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise exempted from inventory listing requirements

DSL/NDSL	Does not Comply
EINECS/ELINCS	Complies
ENCS	This product complies with encls:
IECSC	This product does not comply with china:
KECL	Does not Comply
PICCS	Does not Comply
AICS	This product does not comply with AICS

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA

Health hazards 2

Flammability 0

Instability 0

Physical and chemical properties -

HMIS**Health hazards** 2 ***Flammability** 0**Physical hazards** 0**Personal protection** X*Chronic Hazard Star Legend*** = Chronic Health Hazard***Key or legend to abbreviations and acronyms used in the safety data sheet****Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGl(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications

Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

World Health Organization

Revision date 11-February-2020**Revision Note** No information available.**Disclaimer**

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.

End of Safety Data Sheet



Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
B4040	Budesonide, Micronized, USP

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

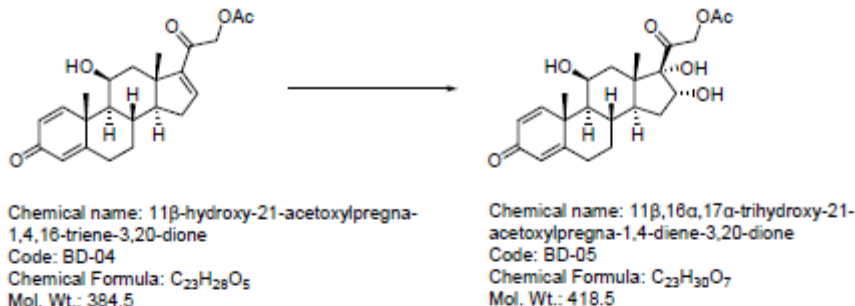
Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

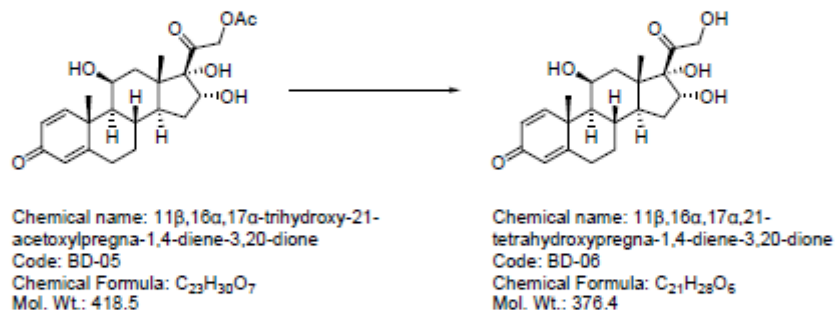
Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart Budesonide, Micronized, USP (Cat#B4040)

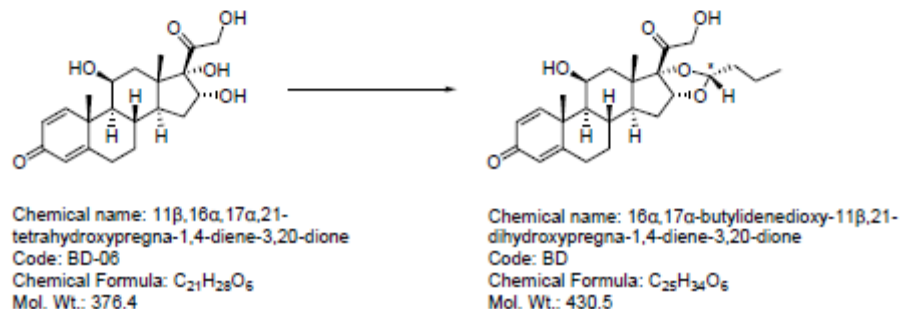
Step 1 Oxidation reaction



Step 2 Alcoholysis reaction



Step 3 Condensation reaction



CORPORATE HEADQUARTERS

769 Jersey Avenue
New Brunswick, NJ 08901
PHONE 732.214.1300
FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843

B4040, Budesonide, Micronized, USP

Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 36 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- | | |
|---------------------|-----------------|
| • Aflatoxins | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • Preservatives |



RE: Elemental Impurities - Budesonide, Micronized, USP (Cat # B4040)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue
New Brunswick, NJ 08901
PHONE 732.214.1300
FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843



RE: Residual Solvents - Budesonide, Micronized, USP (Cat# B4040)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Acetonitrile	2	< 410 ppm
Methanol	2	< 3000 ppm
Methylene Chloride	2	< 600 ppm
Acetone	3	< 5000 ppm
Ethanol	3	< 5000 ppm
N-Butyraldehyde	Other	< 150 ppm

No Class 1 solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue
New Brunswick, NJ 08901
PHONE 732.214.1300
FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843

Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.



Exp. Date: 00-00-0000

WARNING

- Causes skin and eye irritation
- Suspected of damaging fertility or the unborn child
- May be harmful if swallowed.
- Obtain special instructions before use
- Do not handle until all safety precautions have been read and understood
- Wear protective gloves, protective clothing, eye protection, face protection
- Wash face, hands and any exposed skin thoroughly after handling.

FIRST AID: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF eye irritation persists: Get medical attention. IF ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical attention. If exposed or concerned: Get medical attention.

KEEP FROM CHILDREN



B4040

SIZ SY

Budesonide

(16,17-Butylidenebis[oxy]-
11,21-dihydroxypregna-1,4-diene-3,20-dione)

Micronized, USP

CAS 51333-22-3

CAUTION: For manufacturing, processing, repacking, or for prescription compounding. Rx only.
Read and understand the label and Safety Data Sheet (SDS) prior to use.

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

$C_{25}H_{34}O_6$ F.W. 430.59

Manufacturer/Supplier Code ?
Manufacturer Lot Number ?

Assay (Dried Basis, Both Epimers) 98.0-102.0%
Assay (Dried Basis, Epimer A) 40.0-51.0%

Loss on Drying MAXIMUM LIMITS 0.3%

Organic Impurities:

16 α -Hydroxyprednisolone	0.2%
Budesonide Acetaldehyde Acetal (Epimers)	0.10%
Budesonide D-homo Analog	0.10%
Desonide	0.10%
Budesonide Glyoxal (Epimers)	0.07%
Budesonide Related Compound E	0.10%
Budesonide Related Compound L	0.2%
Budesonide Related Compound G (Epimers)	0.10%
Budesonide 21-Acetate (Epimers)	0.10%
Budesonide 21-Butyrate	0.10%
Any Other Individual Impurity	0.10%
Total Specified Impurities	0.4%
Total Unspecified Impurities	0.4%
Elemental Impurities	As reported
Residual Solvents	To pass test

MICROBIAL LIMITS

Total Aerobic Microbial Count	10 ² cfu/g
Total Molds and Yeasts Count	10 ² cfu/g

Repackaged by Spectrum as:

G 1/J16HS-A ? Lot No. XQ####

Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.
New Brunswick, NJ 08901
732.214.1300

West Coast Facility:

14422 S. San Pedro St.
Gardena, CA 90248
310.516.8000