

**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : SDA40B/200PF/DNB TBA/147600  
CAS Number: 64-17-5  
Chemical characterization : Alcohol  
Chemical Name : Ethyl Alcohol  
Synonyms : 200 Proof Ethyl Alcohol, Anhydrous, Denatured Ethanol

Use of the Substance/Mixture : For excipient use only, Manufacture of pharmaceutical mixtures, Other consumer uses

Recommended restrictions on use : Alcoholic Beverage

Company : Equistar Chemicals, LP  
LyondellBasell Tower, Suite 300  
1221 McKinney St.  
P.O. Box 2583  
Houston Texas 77252-2583

Telephone : Customer Service  
888 777-0232  
Product Safety  
800 700-0946

Emergency telephone : CHEMTREC USA 800-424-9300  
EQUISTAR 800-245-4532

E-mail address : product.safety@lyb.com

**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Flammable liquids	Category 2
Eye irritation	Category 2A
Specific target organ systemic toxicity - single exposure	Category 3

GHS Classification Scale (1= severe hazard; 4= slight hazard)

**Label elements**

Hazard symbols :



Signal Word : Danger

Hazard Statements : H225 Highly flammable liquid and vapor.  
H319 Causes serious eye irritation.  
H335 May cause respiratory irritation.

H336 May cause drowsiness or dizziness.

**Precautionary Statements**

**: Prevention**

P210 Keep away from heat/sparks/open flames/hot surfaces.  
- No smoking.  
P233 Keep container tightly closed.  
P241 Use explosion-proof electrical/ ventilating/ lighting/ equipment.  
P243 Take precautionary measures against static discharge.  
P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.  
P264 Wash hands thoroughly after handling.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response**

P370 + P378 In case of fire: Use dry chemical, carbon dioxide, water spray, or alcohol-resistant foam.  
P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.  
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

**Storage**

P403 + P235 Store in a well-ventilated place. Keep cool.

**Other hazards**

Hazards Not Otherwise Classified (HNOC)  
Prolonged or repeated contact may cause skin to become dry or cracked.

**3. Composition/information on ingredients**

**Mixtures**

**Ingredients**

Chemical Name	CAS-No.	Weight %
Ethyl alcohol	64-17-5	99.88 %
TERT-BUTYL ALCOHOL	75-65-0	0.12 %
Denatonium Benzoate	3734-33-6	0.0 %

**SECTION 4. FIRST AID MEASURES**

**First aid procedures**

- General advice** : Take proper precautions to ensure your own health and safety before attempting rescue and providing first aid. For specific information refer to the Emergency Overview in Section 2 of this SDS.  
Show this material safety data sheet to the doctor in attendance.
- If inhaled** : Remove person to fresh air. If signs/symptoms continue, get medical attention.  
Give oxygen or artificial respiration as needed.
- In case of skin contact** : Immediately flush affected area with plenty of water while removing contaminated clothing. Wash contaminated clothing before reuse. If irritation persists, get medical attention.
- In case of eye contact** : Thoroughly flush the eyes with large amounts of clean low-pressure water for at least 15 minutes, occasionally lifting the upper and lower eyelids. If irritation persists, seek medical attention.  
Remove contact lenses.  
Do not use eye ointment unless directed to by a physician.
- If swallowed** : Do not induce vomiting. Risk of damage to lungs exceeds poisoning risk.  
Drink plenty of water.  
If vomiting does occur, have victim lean forward to reduce risk of aspiration.  
If victim is drowsy or unconscious, place on the left side with head down.  
Never give anything by mouth to an unconscious person.  
Obtain emergency room treatment immediately.

**Notes to physician**

- Symptoms** : Ingestion of the liquid or exposure to high airborne concentrations can cause central nervous system (CNS) effects ranging from excitation, dizziness, drowsiness, and headache to deep anesthesia, respiratory arrest, and death in cases of severe over-exposure.  
Repeated or prolonged contact with skin may cause defatting and drying of the skin which may result in dermatitis.
- Treatment** : Treat symptomatically.  
Treatment of overexposure should be directed at the control of symptoms and the clinical condition of the patient.  
There is no specific antidote.  
Gastric lavage can be used if done shortly after ingestion. GI decontamination with charcoal is not effective unless other toxic co-ingestants are involved.

**SECTION 5. FIRE-FIGHTING MEASURES****Flammable properties**

- Flash point : 55 - 61 °F (13 - 16 °C)  
Method: ASTM D 56
- Autoignition temperature : 685 °F (363 °C)  
at 1,013 hPa (760 mm Hg)
- Lower explosion limit : 3.3 vol%
- Upper explosion limit : 19 vol%

**Fire fighting**

- Suitable extinguishing media : SMALL FIRE: Use dry chemicals, CO<sub>2</sub>, water spray or alcohol-resistant foam  
LARGE FIRE: Use water spray, water fog or alcohol-resistant foam

**Protective equipment and precautions for firefighters**

- Specific hazards during fire fighting : Extremely flammable well below ambient temperatures.  
Vapor forms explosive mixture with air and may cause a flash fire.  
Eliminate all sources of ignition.  
Prevent entry into waterways, sewers, basements or confined areas.  
Ethanol vapors are heavier than air and may travel a considerable distance to a source of ignition and flash back.  
Alcohols burn with a pale blue flame which may be extremely hard to see under normal lighting conditions. Personnel may only be able to feel the heat of the fire without seeing flames.  
Extreme caution must be exercised in fighting alcohol fires.  
When exposed to ignition source in air, vapors can burn in open or explode if confined.  
Fight fire from maximum distance or use unmanned hose holders or monitor nozzles.  
Heat may build enough pressure to rupture closed containers/spreading fire/increasing risk of burns/injuries.  
Cool containers with flooding quantities of water until well after fire is out.  
Withdraw immediately in case of rising sound from venting safety devices or discoloration of tank.  
Always stay away from tanks engulfed in fire.  
Move containers from fire area if it can be done without risk.  
Sustained fire attack on vessels may result in a Boiling Liquid Expanding Vapour Explosion (BLEVE).  
Prevent fire extinguishing water from contaminating surface water or the ground water system.  
When fighting a fire, notify environmental authorities if liquid enters sewers or public waters.  
Fire residues and contaminated fire extinguishing water must

be disposed of in accordance with local regulations.

Special protective equipment for fire-fighters : Wear positive pressure self-contained breathing apparatus (SCBA).  
Structural firefighter's protective clothing will only provide limited protection.

## SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions : Clean-up to be performed only by trained and properly equipped personnel.  
Wear recommended personal protective equipment.  
Eliminate all sources of ignition.  
Ensure adequate ventilation.  
Evacuate personnel to safe areas.

Environmental precautions : If necessary, all contaminated waste water must be treated in a municipal or industrial wastewater treatment plant before release to surface water.

Chemical removal by air and water pollution control devices must meet the minimum efficiency requirements needed to reduce exposures to an acceptable level.  
The discharge of treatment plant effluent to rivers and oceans must achieve the dilution ratio needed to reduce exposures to an acceptable level.  
The size and capacity of wastewater treatment plants must meet the minimum requirements needed to reduce exposures to an acceptable level.  
Waste management practices such as incineration, recycling, reuse must be enforced as needed to reduce exposures to an acceptable level.

External treatment and disposal of waste should comply with applicable local and/or national regulations.  
The maximum allowable site tonnage and the days of use should be below the number needed to maintain exposures at an acceptable level.

Methods for containment / Methods for cleaning up : Highly flammable liquid and vapor.  
Eliminate all sources of ignition.  
All equipment used when handling this product must be grounded.  
Do not touch or walk through spilled material.  
Stop leak if you can do it without risk.  
Prevent entry into waterways, sewers, basements or confined areas.  
A vapor suppressing foam may be used to reduce vapors.  
Absorb or cover with dry earth, sand or other non-combustible material and transfer to containers.  
Use clean non-sparking tools to collect absorbed material.  
For large spills:  
Contain spill with dike to prevent entry into sewers or waterways.

Water spray may reduce vapor; but may not prevent ignition in closed spaces.

## SECTION 7. HANDLING AND STORAGE

### Handling

Advice on safe handling : Wear recommended personal protective equipment.  
Eliminate all sources of ignition.  
Use only in area provided with appropriate exhaust ventilation.  
Take necessary action to avoid static electricity discharge (which might cause ignition of organic vapors).  
Use only non-sparking tools.  
Avoid contact with incompatible agents.  
Open and handle container with care.  
Keep in properly labeled containers.  
Metal containers involved in the transfer of this material should be grounded and bonded. Keep containers tightly closed and in a well-ventilated place. Store away from oxidizers and other combustible material by a distance of at least 20 feet. Metal containers used to store this material should be grounded.  
Ensure all equipment is electrically grounded before beginning transfer operations.  
Handle empty containers with care; vapor/residue may be extremely flammable.  
Do not pressurize or expose empty containers to open flame, sparks, or heat.  
Isolate, vent, drain, wash and purge systems or equipment before maintenance or repair.  
Observe precautions pertaining to confined space entry.

Advice on protection against fire and explosion : Take precautionary measures against static discharges.  
Keep away from heat and sources of ignition.

### Storage

Requirements for storage areas and containers : Flammable materials should be stored in a separate safety storage cabinet or room.  
Store only in tightly closed, properly vented containers away from heat, sparks, open flame and strong oxidizing agents.  
Store this product in a dry location where it can be protected from the elements.  
Keep in a well-ventilated place.  
Metal containers involved in the transfer of this material should be grounded and bonded. Keep containers tightly closed and in a well-ventilated place. Store away from oxidizers and other combustible material by a distance of at least 20 feet. Metal containers used to store this material should be grounded.  
Ensure that all relevant regulations regarding explosive atmospheres, and handling and storage facilities of flammable products are followed.  
Store closed drums with bung in up position.

**8. Exposure controls/personal protection****Control parameters****Ingredients with workplace control parameters****Occupational Exposure Limits**

Ingredients	CAS-No.	Type	Limit Value	Basis Revision Date	Additional Information
Ethyl alcohol	64-17-5	STEL	1,000 ppm	US (ACGIH) 2012	
Ethyl alcohol	64-17-5	IDLH	3,300 ppm	NIOSH September 2007	
<b>Remarks: 10% LEL</b>					
Ethyl alcohol	64-17-5	TWA	1,000 ppm 1,900 mg/m <sup>3</sup>	US (OSHA) June 23, 2006	
TERT-BUTYL ALCOHOL	75-65-0	TWA	100 ppm	US (ACGIH) 2012	
TERT-BUTYL ALCOHOL	75-65-0	IDLH	1,600 ppm	NIOSH September 2007	
TERT-BUTYL ALCOHOL	75-65-0	TWA	100 ppm 300 mg/m <sup>3</sup>	US (OSHA) June 23, 2006	

Consult local authorities for acceptable exposure limits.

**Exposure controls****Engineering measures**

General room or local exhaust ventilation is usually required to meet exposure limit(s).  
Electrical equipment should be grounded and conform to applicable electrical code.

**Personal protective equipment**

Respiratory protection : When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

Hand protection : Wear chemical resistant gloves such as:  
Glove material butyl rubber; material thickness .5mm; break through time ≥ 480 min. Gloves must be replaced after 8 hours of wear.

Glove material fluoroelastomer; material thickness 0.4 mm; break through time ≥ 480 min. Gloves must be replaced after

- 8 hours of wear.  
Gloves should be discarded and replaced if there is any indication of degradation or chemical breakthrough.
- Eye and face protection : Use splash goggles when eye contact due to splashing or spraying liquid is possible.
- Skin and body protection : When skin contact is possible, protective clothing including gloves, apron, sleeves, boots, head and face protection should be worn.
- Hygiene measures : Selection of appropriate personal protective equipment should be based on an evaluation of the performance characteristics of the protective equipment relative to the task(s) to be performed, conditions present, duration of use, and the hazards and/or potential hazards that may be encountered during use.  
Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.  
Use good personal hygiene practices.  
Wash hands before eating, drinking, smoking, or using toilet facilities.  
Take off contaminated clothing and wash before reuse.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES****Appearance**

- Physical state : liquid
- Color : Colorless liquid/invisible vapor.
- Odor : Sweet.  
Alcohol-like.

**Safety data**

- Flash point : 55 - 61 °F (13 - 16 °C)  
Method: ASTM D 56
- Lower explosion limit : 3.3 vol%
- Upper explosion limit : 19 vol%
- Flammability (solid, gas) : Not applicable
- Oxidizing properties : The substance or mixture is not classified as oxidizing.
- Autoignition temperature : 685 °F (363 °C)  
at 1,013 hPa (760 mm Hg)



Decomposition temperature	: not determined
pH	: Not applicable.
Melting point/freezing point	: -173.4 °F (-114.1 °C)
Boiling point/boiling range	: 173.3 °F (78.5 °C)
Vapor pressure	: 59.45 hPa (44.59 mm Hg) at 68 °F (20 °C)
Density	: 0.789 g/cm3 at 68 °F (20 °C)
Water solubility	: completely soluble
Partition coefficient: n-octanol/water	: log Pow: -0.35 at 68 °F (20 °C)
Viscosity, dynamic	: No Data Available.
Viscosity, kinematic	: 1.08 mm2/s at 104 °F (40 °C)
Relative vapor density	: 1.6 (Air = 1.0)
Explosive properties	: Not explosive
Remarks - Other information	: No additional information available.

**SECTION 10. STABILITY AND REACTIVITY**

Reactivity	: Will not occur.
Chemical stability	: Stable under recommended storage conditions.
Conditions to avoid	: Avoid contact with strong oxidizers, excessive heat, sparks or open flame.
Materials to avoid	: Contact with acetyl chloride or other oxidizing agents may result in a violent reaction.
Hazardous decomposition products	: Not expected to decompose under normal conditions.
Thermal decomposition	: Carbon monoxide is expected to be the primary hazardous combustion product.
Hazardous reactions	: Not expected to occur.

**SECTION 11. TOXICOLOGICAL INFORMATION**

- Product Summary** : The below given information is based on the assessment of the product including impurities.
- Acute toxicity**
- Acute oral toxicity** : Based on acute toxicity values, not classified.  
Short term overexposure May cause drunkenness, depression of the central nervous system and death.
- : LD50: 7,678.4 mg/kg  
Species: Rat
- Method: Acute toxicity estimate
- Acute inhalation toxicity** : Based on acute toxicity values, not classified.  
Short term overexposure may cause irritation of eyes, nose and throat and central nervous system (CNS) effects such as headache, dizziness, drowsiness and an inability to concentrate.
- : LC50: 123.8 mg/l  
Species: Rat
- Method: Acute toxicity estimate
- Acute dermal toxicity** : Based on acute toxicity values, not classified.
- : LD50: 15,670.6 mg/kg  
Species: Rabbit
- Method: Acute toxicity estimate
- Skin corrosion/irritation** : Based on skin irritation values, not classified.
- Serious eye damage/eye irritation** : Classified  
Causes serious eye irritation.
- Respiratory or skin sensitization** : Respiratory sensitization  
Not classified  
No study available.
- : Skin sensitization  
Not classified  
No adverse effect observed.

**Chronic toxicity**

Component Name	NTP	IARC	OSHA
Ethyl alcohol		1	Present

**Carcinogenicity** : Not classified  
 Ethanol possesses properties that indicate a carcinogenicity hazard for human health but these are manifest only at doses associated with consumption of alcoholic beverages. In the context of an industrial chemical, these hazards do not warrant concern as these are not likely to result from the manufacture and use of ethanol and ethanol containing products.

Contains:  
 t-Butyl Alcohol  
 Contains a substance that has a positive carcinogenicity study.  
 The weight of evidence for the carcinogenicity of this substance does not meet the criteria for classification.

**Germ cell mutagenicity** : Not classified  
 No adverse effect observed.

**Reproductive toxicity**

**Effects on fertility /  
 Effects on or via lactation** : Not classified  
 Ethanol possesses properties that indicate a lactation hazard for human health but these are manifest only at doses associated with consumption of alcoholic beverages. In the context of an industrial chemical, these hazards do not warrant concern as these are not likely to result from the manufacture and use of ethanol and ethanol containing products.

**Effects on Development** : Not classified  
 Ethanol possesses properties that indicate a developmental hazard for human health but these are manifest only at doses associated with consumption of alcoholic beverages. In the context of an industrial chemical, these hazards do not warrant concern as these are not likely to result from the manufacture and use of ethanol and ethanol containing products.

Contains:  
 t-Butyl Alcohol  
 Embryo/fetal toxicity and/or developmental delay was observed in animals following repeated oral or inhalation exposures to high concentrations of t-Butyl Alcohol that produced slight maternal toxicity in the dams. No

teratogenicity was observed in the embryos/fetuses as well.

- Target Organ Systemic Toxicant - Single exposure** : Target Organs: Respiratory system, Central nervous system  
Classified, May cause respiratory irritation., May cause drowsiness or dizziness.
- Target Organ Systemic Toxicant - Repeated exposure** : Based on repeated exposure toxicity values, not classified.,  
Repeated exposure to high oral doses may damage the liver.
- Aspiration hazard** : Based on physico-chemical values or lack of human evidence,  
not classified.

## 12. ECOLOGICAL INFORMATION

### Ecotoxicology Assessment

- Acute aquatic toxicity** : Based on acute aquatic toxicity values, not classified.
- Chronic aquatic toxicity** : Not classified, based on readily biodegradability and low acute toxicity.
- Toxicity to fish** :  
Test substance: Based on Ethanol  
Acute toxicity to fish is very low.
- Toxicity to daphnia and other aquatic invertebrates** : Test substance: Based on Ethanol  
Acute toxicity to freshwater and marine invertebrates is very low.
- Toxicity to algae** : Test substance: Based on Ethanol  
Acute toxicity to aquatic plants very low.
- Toxicity to bacteria** : Test substance: Based on Ethanol  
Low toxicity to sewage microbes.
- Toxicity to fish (Chronic toxicity)** : No Data Available.
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)** : Test substance: Based on Ethanol  
Chronic toxicity expected to be low.

### Persistence and degradability

**Biodegradability** : 74 %  
Test substance: Based on Ethanol  
Rapidly degradable.  
: (After 5 days in a ready biodegradability test)

**Bioaccumulative potential**

**Bioaccumulation** : This material is not expected to bioaccumulate.

**Mobility in soil**

**Distribution among environmental compartments** : Stability in water  
no data available

: Stability in soil  
no data available

**Additional advice Environmental fate and pathways** : No additional information available.

**Results of PBT and vPvB assessment**

Not applicable.

**Other adverse effects**

**Additional ecological information** : No additional information available.

**SECTION 13. DISPOSAL CONSIDERATIONS**

Further information : Contaminated products/soil/water may be Resource Conservation and Recovery Act (RCRA)hazardous waste/Occupational Safety and Health Administration (OSHA) hazardous material due to low flash point (see 40 Code of Federal Regulations (CFR) 261 and 29 CFR 1910). Empty containers should be taken to an approved waste handling site for recycling or disposal.Comply with applicable local, state or international regulations concerning solid or hazardous waste disposal and/or container disposal.

**SECTION 14. TRANSPORT INFORMATION**

**DOT**  
UN number : 1170  
Description of the goods : Ethanol solutions  
Class : 3  
Packing group : II

**SDA40B/200PF/DNB TBA/147600**

Gen. Variant: SDS\_US\_GHS

Version 1.0

Revision Date 10/02/2014

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SDS No.: 872

Labels : 3

For further information see Title 49, Code of Federal Regulations, parts 172 and 173.

**SECTION 15. REGULATORY INFORMATION**

All components of this product are listed or are exempt from listing on the TSCA 8(b) inventory. If identified components of this product are listed under the TSCA 12(b) Export Notification rule, they will be listed below.

**SARA 302/304**

This product contains no known chemicals regulated under SARA 302/304.

**SARA 311/312**

Based upon available information, this material is classified as the following health and/or physical hazards according to Section 311 & 312:

Fire Hazard.

Immediate (Acute) Health Hazard.

Delayed (Chronic) Health Hazard.

**SARA 313**

This material does not contain any chemical components with known CAS numbers that exceed the De Minimis reporting levels established by SARA Title III, Section 313 and 40 CFR 372.

ComponentReporting Threshold

TERT-BUTYL ALCOHOL

1.0%

**State Reporting**

This material contains the following chemical substance at very low levels which is regulated under California Proposition 65. However, it is the responsibility of the California business owner to develop his or her own regulatory compliance plan. Contact Product Safety for further information at [product.safety@lyb.com](mailto:product.safety@lyb.com).

Substance	CASRN	Type of Toxicity			
		Carcinogen	Developmental	Repro-Male	Repro-Female
Acetaldehyde	75-07-0	X			

This product contains the following chemicals regulated by New Jersey's Worker and Community Right to Know Act:

64-17-5 Ethyl alcohol

75-65-0 TERT-BUTYL ALCOHOL

This product contains the following chemicals regulated by Massachusetts' Right to Know Law:

64-17-5 Ethyl alcohol

75-65-0 TERT-BUTYL ALCOHOL

This product contains the following chemicals regulated by Pennsylvania's Right to Know Act:

64-17-5 Ethyl alcohol  
75-65-0 TERT-BUTYL ALCOHOL

#### Other international regulations

#### Global Inventory Status

The ingredients of this product are compliant with the following chemical inventory requirements or exemptions.

\*Additional Explanatory Status Statements follow the table, as necessary.

Country/Region	Inventory	Status Description
Australia	AICS	Compliant
Canada	DSL	Compliant
China	IECSC	Compliant
Europe	REACH	See REACH Compliance Statement
Japan	ENCS	Compliant
Korea	KECI	Compliant
New Zealand	NZIoC	Compliant
Philippines	PICCS	Compliant
United States of America	TSCA	Compliant

#### REACH status

If the product has been purchased from any company of the LyondellBasell group of companies registered in the European Union, we confirm that all substances in this preparation have been pre-registered or, where required under REACH, registered, and that we have the intention to proceed with their registration in accordance with the deadlines set forth in REACH. (Regulation (EU) No. 1907/2006)

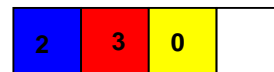
Contact [product.safety@lyb.com](mailto:product.safety@lyb.com) for additional global inventory information.

## SECTION 16. OTHER INFORMATION

#### Further information

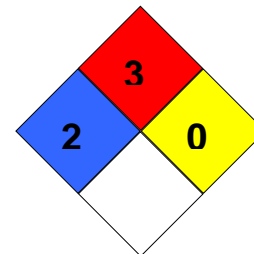
#### HMIS Classification

: Health Hazard: 2  
Flammability: 3  
Physical hazards: 0



#### NFPA Classification

: Health Hazard: 2  
Fire Hazard: 3  
Instability: 0



**Other Information**

HMIS rating scale (0 = minimal hazard; 4 = severe hazard)

NFPA rating scale (0 = minimal hazard; 4 = severe hazard)

**Material safety datasheet sections which have been updated:**

Updated format ; First Edition September 30 2014

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**Disclaimer**

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Information is correct to the best of our knowledge at the date of the SDS publication.

It is not a specification sheet nor should any displayed data be construed as a specification.

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This product(s) may not be used in:

(i) any U.S. FDA Class I, Health Canada Class I, and/or European Union Class I medical devices, without prior notification to Seller for each specific product and application; or (ii) the manufacture of any of the following, without prior written approval by Seller for each specific product and application: U.S. FDA Class II Medical Devices; Health Canada Class II or Class III Medical Devices; European Union Class II Medical Devices; film, overwrap and/or product packaging that is considered a part or component of one of the aforementioned medical devices; packaging in direct contact with a pharmaceutical active ingredient and/or dosage form that is intended for inhalation, injection, intravenous, nasal, ophthalmic (eye), digestive, or topical (skin) administration; tobacco related products and applications, electronic cigarettes and similar devices, and pressure pipe or fittings that are considered a part or component of a nuclear reactor. Additionally, the product(s) may not be used in: (i) U.S. FDA Class III Medical Devices; Health Canada Class IV Medical Devices; European Class III Medical Devices; (ii) applications involving permanent implantation into the body; (iii) life-sustaining medical applications; and (iv) lead, asbestos or MTBE related applications. All references to U.S. FDA, Health Canada, and European Union regulations include another country's equivalent regulatory classification.

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