

# SAFETY DATA SHEET



## Molnupiravir Capsule Formulation

Version  
8.0

Revision Date:  
2025/06/20

SDS Number:  
6199209-00015

Date of last issue: 2025/04/14  
Date of first issue: 2020/08/24

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Molnupiravir Capsule Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065

Telephone : +1-908-740-4000

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

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

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### 2. HAZARDS IDENTIFICATION

#### GHS Classification

Specific target organ toxicity - : Category 1 (Gastrointestinal tract)  
repeated exposure (Oral)

#### GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H372 Causes damage to organs (Gastrointestinal tract) through prolonged or repeated exposure if swallowed.

Precautionary statements :

#### Prevention:

P260 Do not breathe dust.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

#### Response:

P314 Get medical advice/ attention if you feel unwell.

#### Disposal:

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P501 Dispose of contents/ container to an approved waste disposal plant.

### Other hazards which do not result in classification

May form explosive dust-air mixture during processing, handling or other means.

Dust contact with the eyes can lead to mechanical irritation.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 60 -<= 100
Molnupiravir	2492423-29-5	>= 60 -<= 100

### 4. FIRST AID MEASURES

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

If inhaled : If inhaled, remove to fresh air.  
Get medical attention if symptoms occur.

In case of skin contact : In case of contact, immediately flush skin with plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.

In case of eye contact : Thoroughly clean shoes before reuse.  
If in eyes, rinse well with water.  
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention if symptoms occur.  
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : Causes damage to organs through prolonged or repeated exposure if swallowed.  
Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

### 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

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Specific hazards during fire-fighting	: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Carbon oxides Metal oxides
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.
Special protective equipment for firefighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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## 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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.

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## 7. HANDLING AND STORAGE

Technical measures	: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding
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Local/Total ventilation	and bonding, or inert atmospheres.
Advice on safe handling	<ul style="list-style-type: none"><li>: Use only with adequate ventilation.</li><li>: Do not get on skin or clothing.</li><li>Do not breathe dust.</li><li>Do not swallow.</li><li>Avoid contact with eyes.</li><li>Wash skin thoroughly after handling.</li></ul>
	Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
	Minimize dust generation and accumulation.
	Keep container closed when not in use.
	Keep away from heat and sources of ignition.
	Take precautionary measures against static discharges.
	Do not eat, drink or smoke when using this product.
Conditions for safe storage	Take care to prevent spills, waste and minimize release to the environment.
Materials to avoid	<ul style="list-style-type: none"><li>: Keep in properly labelled containers.</li><li>Store in accordance with the particular national regulations.</li><li>: Do not store with the following product types:</li></ul>
	Strong oxidizing agents

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Cellulose	9004-34-6	NAB	10 mg/m <sup>3</sup>	ID OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Molnupiravir	2492423-29-5	TWA	20 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	200 µg/100cm <sup>2</sup>	Internal

### 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. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

### Personal protective equipment

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

Filter type : Particulates type  
Hand protection

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

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: powder
Colour	: white to off-white
Odour	: No data available
Odour Threshold	: No data available
pH	: No data available
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flash point	: Not applicable
Evaporation rate	: Not applicable
Flammability (solid, gas)	: May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	: Not applicable
Upper explosion limit / Upper	: No data available

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### flammability limit

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Density : No data available

### Solubility(ies)

Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

### Viscosity

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

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

Molecular weight : No data available

### Particle characteristics

Particle size : No data available

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## 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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## 11. TOXICOLOGICAL INFORMATION

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Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

### Acute toxicity

Not classified based on available information.

#### Components:

##### **Cellulose:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

##### **Molnupiravir:**

Acute oral toxicity : LD0 (Rat): 2,000 mg/kg  
LD0 (Dog): 2,000 mg/kg

### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### **Molnupiravir:**

Species : reconstructed human epidermis (RhE)  
Method : EpiDerm  
Result : Mild skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

##### **Molnupiravir:**

Species : Bovine cornea  
Result : No eye irritation  
Method : Bovine cornea (BCOP)

### Respiratory or skin sensitisation

#### **Skin sensitisation**

Not classified based on available information.

#### **Respiratory sensitisation**

Not classified based on available information.

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### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### **Cellulose:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Result: negative

#### **Molnupiravir:**

Genotoxicity in vitro : Test Type: Ames test  
Result: positive

Test Type: Micronucleus test  
Test system: human lymphoblastoid cells  
Result: negative

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

Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Rat  
Cell type: Bone marrow  
Result: equivocal

Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Transgenic rat  
Application Route: Oral  
Result: negative

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

### **Carcinogenicity**

Not classified based on available information.

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### Components:

#### **Cellulose:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 72 weeks  
Result : negative

### **Reproductive toxicity**

Not classified based on available information.

### Components:

#### **Cellulose:**

Effects on fertility : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on foetal development : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative

#### **Molnupiravir:**

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: > 200 mg/kg body weight  
Symptoms: Effects on embryofoetal and postnatal development  
Result: No effects on fertility and early embryonic development were detected.  
Remarks: Not classified due to data which are conclusive although insufficient for classification.

### **STOT - single exposure**

Not classified based on available information.

### **STOT - repeated exposure**

Causes damage to organs (Gastrointestinal tract) through prolonged or repeated exposure if swallowed.

### Components:

#### **Molnupiravir:**

Exposure routes : Oral  
Target Organs : Gastrointestinal tract  
Assessment : Causes damage to organs through prolonged or repeated exposure.

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### Repeated dose toxicity

#### Components:

##### **Cellulose:**

Species : Rat  
NOAEL : >= 9,000 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

##### **Molnupiravir:**

Species : Rat  
LOAEL : 2,000 mg/kg  
Exposure time : 7 d  
Target Organs : Stomach

Species : Dog  
LOAEL : 300 mg/kg  
Exposure time : 7 d  
Target Organs : Gastrointestinal tract  
Symptoms : tachycardia, decreased activity, decrease in appetite, Diarrhoea, Vomiting

Species : Rat  
NOAEL : 500 mg/kg  
Exposure time : 28 d

Species : Dog  
NOAEL : 6 mg/kg  
LOAEL : 17 mg/kg  
Exposure time : 28 d  
Target Organs : Gastrointestinal tract  
Symptoms : decreased activity, Gastrointestinal tract damage, decrease in appetite

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

##### **Molnupiravir:**

General Information : Symptoms: Headache, Gastrointestinal disturbance  
Remarks: The most common side effects are:  
Symptoms: Back pain

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## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

##### **Cellulose:**

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials

##### **Molnupiravir:**

Toxicity to algae/aquatic plants : EC10 (Raphidocelis subcapitata (freshwater green alga)): 89 mg/l  
End point: Growth  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : EC10 (Pimephales promelas (fathead minnow)): 5.8 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : EC10 (Daphnia magna (Water flea)): > 8.8 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211  
Remarks: No toxicity at the limit of solubility

Toxicity to microorganisms : EC10: 143.1 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition of activated sludge  
Method: OECD Test Guideline 209

#### **Ecotoxicology Assessment**

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

### **Persistence and degradability**

#### Components:

##### **Cellulose:**

Biodegradability : Result: Readily biodegradable.

##### **Molnupiravir:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 81 %  
Exposure time: 28 d  
Method: OECD Test Guideline 314

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### Bioaccumulative potential

#### Components:

##### **Molnupiravir:**

Partition coefficient: n-octanol/water : log Pow: -0.534  
pH: 7

### Mobility in soil

#### Components:

##### **Molnupiravir:**

Distribution among environmental compartments : OECD Test Guideline 106  
log Koc: 1.45

### Other adverse effects

No data available

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## 13. DISPOSAL CONSIDERATIONS

#### **Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.  
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.

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## 14. TRANSPORT INFORMATION

#### **International Regulations**

##### **UNRTDG**

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Environmentally hazardous : no

##### **IATA-DGR**

UN/ID No. : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable

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Packing instruction (passenger aircraft) : Not applicable

### IMDG-Code

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
EmS Code : Not applicable  
Marine pollutant : Not applicable

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Special precautions for user

Not applicable

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## 15. REGULATORY INFORMATION

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

**Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.**

**Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health**

Hazardous substances that must be registered : Not applicable

**Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances**

Hazardous substances approved for use : Not applicable  
Prohibited substances : Not applicable  
Restricted substances : Not applicable

**Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials**

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

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### 16. OTHER INFORMATION

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#### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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

Date format : yyyy/mm/dd

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
ID OEL : Indonesia. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average  
ID OEL / NAB : Long term exposure limit

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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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.

ID / EN