

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 07-Nov-2023 Revision Number 1

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Name 80 Kg each Lattice® NTC-80

Product Code(s) NTC80-INDR080

Pure substance/mixture Mixture

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

Recommended use Pharmaceutical excipient

Uses advised against None under normal use conditions

1.3. Details of the supplier of the safety data sheet

Supplier

International Flavors and Fragrances, Inc Wallingstown Little Island Cork, Ireland

+353 21 451 7200 (General Information - Cork, Ireland)

E-mail address

sds.genencor@iff.com

1.4. Emergency telephone number

See section 16 for more information

Emergency Telephone - §45 - (E	C)1272/2008					
Poison control centre phone	Italy:					
number	Telephone numbers of the main poison control centers (CAV) active 24/24h:					
	CAV "Osp. Pediatrico Bambino Gesù", Piazza Sant'Onofrio 4, 00165 Roma, Tel.					
	0668593726					
	Az. Osp. Univ. Foggia, Via le Luigi Pinto 1, 71122 Foggia, Tel. 800183459					
	Az. Osp. "A. Cardarelli", Via A. Cardarelli 9, 80131 Napoli, Tel. 081-5453333					
	CAV Policlinico "Umberto I", Via le del Policlinico 155, 00161 Roma, Tel. 06-49978000					
	CAV Policlinico "A. Gemelli" Largo Agostino Gemelli 8, 00168 Roma, Tel. 06-3054343					
	Osp. "Careggi" U.O. Tossicologia Medica, Largo Brambilla 3, 50134 Firenze, Tel.					
	055-7947819					
	CAV Centro Nazionale di Informazione Tossicologica, Via Salvatore Maugeri 10, 27100					
	Pavia, Tel. 0382-24444					
	Osp. Niguarda Ca' Granda, Piazza Ospedale Maggiore 3, 20162 Milano, Tel. 02-66101029					
	Azienda Ospedaliera Papa Giovanni XXII, Piazza OMS 1, 24127 Bergamo, Tel. 800883300					
	Azienda Ospedaliera Integrata Verona, Piazzale Aristide Stefani 1, 37126 Verona, Tel.					
	800011858					
	Austria: +43 (0) 14064343					

Belgium: +32 (0) 70245245 Bulgaria: +359 2 9154 233 Croatia: +3851 2348 342

Cyprus: 1401 (only from within Cyprus) Czech Republic: +420 224 919 293

Denmark: +45 8212 1212 Estonia: +372 7943 794

Finland: +0800 147 111 (only from within Finland)

France: + 33 (0)1 45 42 59 59 Germany: +49 (0) 55119240 Greece: +30 2107793777 Hungary: +36-80-201-199

Iceland: +543 1000 (only from within Iceland)

Ireland: +353 (0) 18379964 Latvia: +371 67042473 Liechtenstein: +41 442 515 151 Lithuania: +370 (85) 2362052 Luxembourg: (+352) 8002 5500

Malta: +2122 4071 (only from within Malta)

the Netherlands: +31 (0)88 755 8000 (only for medical professionals)

Norway: +22 59 13 00 (only from within Norway)

Poland: +48 (22) 6 19 08 97 Portugal: +351 800 250 250 Romania: +40213183606 Slovakia: +421 2 5477 4166 Slovenia: +386 (0) 1 522 50 50 Spain: +34 91 562 04 20

Sweden: +010-456 6700 (only from within Sweden for less urgent cases; urgent cases:

112)

Switzerland: +41 442 515 151

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture Regulation (EC) No 1272/2008

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.2. Label elements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.3. Other hazards

WARNING. May form combustible dust concentrations in air. The components in this formulation do not meet the criteria for classification as PBT or vPvB.

SECTION 3: Composition/information on ingredients

- 3.1 Substances Not applicable
- 3.2 Mixtures

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Microcrystalline Cellulose 9004-34-6	85 - 90	No data available	232-674-9	Not classified	-	-	-
Sodium carboxymethylcellulo se 9004-32-4	10 - 15	No data available		Not classified	-	-	-

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg		Inhalation LC50 - 4 hour - vapour - mg/L	
Microcrystalline Cellulose 9004-34-6	-	> 2 g/kg (Rabbit) > 2000 mg/kg (Rabbit)	5.8	No data available	No data available
Sodium carboxymethylcellulose 9004-32-4	= 27000 mg/kg (Rat)	>2 g/kg (Rabbit)	5.8	No data available	No data available

SECTION 4: First aid measures

4.1. Description of first aid measures

General advice When in doubt or if symptoms are observed, get medical advice.

Inhalation IF INHALED: Remove person to fresh air and keep comfortable for breathing. If

experiencing respiratory symptoms: Call a POISON CENTER or doctor.

Eye contact 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.

Skin contact IF ON SKIN: Wash with plenty of water and soap. If skin irritation occurs: Get medical

advice/attention.

Ingestion IF SWALLOWED: Never give anything by mouth to an unconscious person. Drink plenty of

water. Get medical attention if symptoms occur.

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

Symptoms Get medical attention if irritation or other symptoms occur.

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

Note to doctors Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media Foam. Dry powder. Water spray. Carbon dioxide (CO2).

Unsuitable extinguishing media Keep product and empty container away from heat and sources of ignition. Do not use

water jetstream.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

chemical

Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition

source is a potential dust explosion hazard.

Hazardous combustion products Smoke production.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters

Positive pressure self-contained breathing apparatus (SCBA) and structural firefighters'

protective clothing will provide adequate protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions

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. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Use personal

protection recommended in Section 8. Sweep up to prevent slipping hazard.

For emergency responders

Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautionsClean contaminated objects and areas thoroughly observing environmental regulations.

6.3. Methods and material for containment and cleaning up

Methods for containment Sweep up and shovel into suitable containers for disposal. Avoid dust formation. Dispose of

in accordance with local regulations.

Methods for cleaning up

Use industrial vacuum cleaners approved for combustible dust and area electrical

classification.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling Avoid generation of dust and aerosols. Avoid contact with eyes, skin and clothing. Minimise

dust generation and accumulation. Combustible dust clouds may be created where operations produce fine material (dust). Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may

contribute to secondary explosions. Handling and processing operations should be

conducted in accordance with 'best practices' (e.g. NFPA- 654).

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice. Regular cleaning of

equipment, work area and clothing is recommended. Avoid contact with eyes, skin and

clothing. Wear suitable gloves and eye/face protection.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep/store only in original container. Keep container tightly closed in a dry and

well-ventilated place.

7.3. Specific end use(s)

Specific use(s) See section 1 for more information.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure LimitsBased on data available for ingredients

Chemical name	European Union	United Kingdom	France	Spain	Germany TRGS
Microcrystalline Cellulose	-	TWA: 10 mg/m ³	TWA: 10 mg/m ³	TWA: 10 mg/m ³	-
9004-34-6		TWA: 4 mg/m ³			
		STEL: 20 mg/m ³			
		STEL: 12 mg/m ³			

Chemical name	Italy MDLPS	Portugal	Netherlands	Finland	Denmark
Microcrystalline Cellulose	=	TWA: 10 mg/m ³	-	TWA: 2 mg/m ³	TWA: 1 mg/m ³
9004-34-6					STEL: 2 mg/m ³

Chemical name	Austria	Switzerland	Poland	Norway	Ireland
Microcrystalline Cellulose	-	TWA: 3 mg/m ³	TWA: 3 mg/m ³	-	TWA: 10 mg/m ³
9004-34-6		_			STEL: 30 mg/m ³

Chemical name	Belgium	Sweden	Croatia	Türkiye	Greece
Microcrystalline Cellulose 9004-34-6	TWA: 10 mg/m ³	NGV: 2 mg/m ³	TWA: 10 mg/m ³ TWA: 4 mg/m ³ STEL: 20 mg/m ³	ZAOD: 15 mg/m³ (Toplam toz) ZAOD: 5 mg/m³ (Solunabilir toz)	TWA: 5 mg/m ³

8.2. Exposure controls

Engineering controls Ensure adequate ventilation. Avoid generation of dust and aerosols.

Personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Hand protection Wear protective gloves.

Skin and body protection Wear protective gloves and protective clothing.

Respiratory protection If exposure limits are likely to be exceeded or if irritation or other symptoms are

experienced, NIOSH/MSHA or EN 136 approved respiratory protection should be worn.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice. Regular cleaning of

equipment, work area and clothing is recommended. Avoid contact with eyes, skin and

clothing. Wear suitable gloves and eye/face protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance Powder
Physical state Solid
Colour Off-white
Odour Odourless

Odour threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

6.0 - 8.0None known pН **Melting point / freezing point** No data available None known Initial boiling point and boiling rangeNo data available None known Flash point No data available None known **Evaporation rate** No data available None known Flammability (solid, gas) No data available Not applicable Flammability Limit in Air None known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Vapour pressureNo data availableNone knownRelative vapour densityNo data availableNone knownRelative densityNo data availableNone known

Bulk density
No data available
Liquid Density
No data available

Water solubilityNo data availableNone knownSolubility(ies)No data availableNone knownPartition coefficientNo data availableNone knownAutoignition temperatureNo data availableNone knownDecomposition temperatureNone known

Kinematic viscosity

No data available

None known

No data available

None known

No data available

None known

Particle characteristics

Particle Size Not applicable
Particle Size Distribution Not applicable

9.2. Other information

Softening point No data available

9.2.1. Information with regards to physical hazard classes

Not applicable

Explosive properties No data available.

9.2.2. Other safety characteristics None known

Sensitivity to mechanical impact No

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity Not expected.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact No. Sensitivity to static discharge Yes.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions
None under normal processing.

Hazardous polymerisation Hazardous polymerisation does not occur.

10.4. Conditions to avoid

Conditions to avoid Heat, flames and sparks. May form combustible dust concentrations in air.

10.5. Incompatible materials

Incompatible materials Keep away from heat, flames and sparks.

10.6. Hazardous decomposition products

Hazardous decomposition products No hazardous decomposition products known.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Product Information

Acute toxicity

InhalationNo information or data specific to the product on this toxicological (health) effect is available.

Eye contact No information or data specific to the product on this toxicological (health) effect is available.

Skin contactNo information or data specific to the product on this toxicological (health) effect is available.

Ingestion No information or data specific to the product on this toxicological (health) effect is available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Get medical attention if irritation or other symptoms occur.

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

Respiratory or skin sensitisation No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicityNo information available.

STOT - single exposure No information available.

STOT - repeated exposureNo information available.

Aspiration hazard No information available.

Numerical measures of toxicity

<u>Component Information</u> Classification based on data available for ingredients

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Microcrystalline Cellulose	> 5 g/kg (Rat)	> 2 g/kg (Rabbit) > 2000 mg/kg (Rabbit)	> 5800 mg/m³ (Rat) 4 h
Sodium carboxymethylcellulose	= 27000 mg/kg (Rat)	>2 g/kg (Rabbit)	>5800 mg/m³ (Rat) 4 h

Microcrystalline Cellulose 9004-34-6

Eye irritation May cause irritation **Skin irritation** May cause skin irritation

Respiratory irritation
Sensitisation
Not expected
Reproductive effects
Not expected
Mutagenic effects
Not expected
Systemic Toxicity
Not expected
Carcinogenicity
Not expected
Teratogenicity
Not expected
Not expected

Sodium carboxymethylcellulose 9004-32-4

Eye irritation May cause slight irritation

Skin irritation Not expected Not expected Respiratory irritation Sensitisation Not expected Reproductive effects Not expected Not expected **Mutagenic effects** Not expected **Systemic Toxicity** Carcinogenicity Not expected **Teratogenicity** Not expected

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties This product does not contain any known or suspected endocrine disruptors.

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity Based on data available for ingredients.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium	ErC50: >500 mg/l	LC50: 1,414 mg/l (zebra	-	EC50: 1,414 mg/l
carboxymethylcellulose	(Selenastrum	fish)		(Daphnia magna)
9004-32-4	capricornutum)	·		

12.2. Persistence and degradability

Persistence and degradability Based on data available for ingredients.

Chemical name	Biodegradation
Sodium carboxymethylcellulose	Not readily biodegradable (0% after 28 days).
9004-32-4	

12.3. Bioaccumulative potential

Bioaccumulative potential Based on data available for ingredients

Component Information Based on data available for ingredients

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment Based on data available for ingredients

12.6. Endocrine disrupting properties

Endocrine disrupting properties This product does not contain any known or suspected endocrine disruptors.

Component Information

Microcrystalline Cellulose (9004-34-6)

12.7. Other adverse effects

Other adverse effects No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused products

Dispose of wastes in an approved waste disposal facility. Dispose of contents and container in accordance with local, regional, national, and international regulations as applicable.

Contaminated packaging Dispose of empty containers and wastes safely. Dispose of waste product or used

containers according to local regulations.

SECTION 14: Transport information

<u>IATA</u>

14.1 UN number or ID number
14.2 Extended Proper Shipping
Not regulated
Not regulated

Name

14.3 Transport hazard class(es)
 14.4 Packing group
 14.5 Environmental hazards
 Not regulated Not regulated Not applicable

14.6 Special Precautions for Users

Special Provisions None

IMDG

14.1 UN number or ID number
 14.2 EPNM
 14.3 Transport hazard class(es)
 14.4 Packing group
 14.5 Environmental hazards
 Not regulated Not regulated Not applicable

14.6 Special Precautions for Users

Special Provisions None

14.7 Maritime transport in bulk No information available according to IMO instruments

RID

14.1 UN number Not regulated14.2 Extended Proper Shipping Not regulated

Name

14.3 Transport hazard class(es)
 14.4 Packing group
 14.5 Environmental hazards
 Not regulated Not regulated Not applicable

14.6 Special Precautions for Users

Special Provisions None

<u>ADR</u>

14.1 UN number or ID number
14.2 UN proper shipping name
14.3 Transport hazard class(es)
14.4 Packing group
14.5 Environmental hazards

Not regulated
Not regulated
Not regulated
Not regulated
Not applicable

14.6 Special Precautions for Users

Special Provisions None

SECTION 15: Regulatory information

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

International Inventories: Based on data available for ingredients

Chemical name	AICS	DSL/NDSL	EINECS/ELIN CS	ENCS	IECSC	KECL	PICCS
Microcrystalline Cellulose 9004-34-6	Х	X	Х	1	Х	Х	Х
Sodium carboxymethylcellulo se 9004-32-4	Х	Х	-	X	X	X	X

National regulations

Water hazard class (WGK) Based on data available for ingredients

Chemical name	CAS No.	WGK Classification (AwSV)
Microcrystalline Cellulose	9004-34-6	nicht wassergefährdend (nwg) (non-hazardous to water)
Sodium carboxymethylcellulose	9004-32-4	Klasse (class) 1

France Occupational Illnesses (R-463-3, France) Based on data available for ingredients

Chemical name	French RG number
Microcrystalline Cellulose	RG 66
9004-34-6	

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV). This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII).

15.2. Chemical safety assessment

Chemical Safety Report No information available

SECTION 16: Other information

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

AICS - Australian Inventory of Chemical Substances

Further information ATEX Directive 1999/92/EC, Workplace Requirements for Explosive Atmospheres

ATEX Directive 94/9/EC, Equipment for use in Explosive Atmospheres

Use CHEMTREC instead of Emergency Phone Number Belgium: 32-28083237 Bulgaria: 359-32570104 Croatia: 385-17776920

Czech Republic: 420-228880039

Denmark: 45-69918573 Estonia: 372-6681294 Finland: 358-942419014 France: 33-975181407 Germany: 0800-181-7059 Greece: 30-2111768478 Hungary: 36-18088425 Iceland: 354 539 0655 India: 000-800-100-7141

Ireland: 353-19014670 Israel: 972-37630639 Italy: 39-0245557031 Latvia: 371-66165504

Lithuania: 370-52140238 Luxembourg: 352-20202416 Macedonia: 389 2 551 7456 Netherlands: 31-858880596 Nigeria: 234 1 227 8883 Poland: 48-223988029 Portugal: 351-308801773 Romania: 40-37-6300026 Russia: 8-800-100-6346 Saudi Arabia: 966-8111095861 Slovakia: 421-233057972 Slovenia: 38-618888016 South Africa: 0-800-983-611 Spain: 34-931768545 Sweden: 46-852503403 Switzerland: 41-435082011 Ukraine: 380-947101374

United Kingdom: 44-870-8200418 and 44-2038073798

Revision date 07-Nov-2023

Reason for revision ***Indicates updated section

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

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