SAFETY DATA SHEET

EXVELIA PS 20

Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II, as amended by Commission Regulation (EU) 2020/878

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Version : 1

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

1.1 Product identifier

Product name : EXVELIA PS 20
Chemical name : Sorbitan monolaurate, ethoxylated
EC number : Polymer
REACH Registration number : Exempt from REACH: Polymer.
CAS number : 9005-64-5
INCI Name : Polysorbate 20
Other means of identification : Ethoxylated sorbitan monolaurate; Polysorbate 20 (Ph. Eur.)

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

Identified uses
Manufacture of pharmaceutical products.

Uses advised against	**Reason**
Not determined.	-

1.3 Details of the supplier of the safety data sheet

PCC Exol SA, Sienkiewicza 4, 56-120 Brzeg Dolny, Poland
Phone: +48 71 794 2127

e-mail address of person responsible for this SDS : kch@pcc.eu

1.4 Emergency telephone number

National advisory body/Poison Center

Telephone number : Not available.

Supplier

Telephone number : Telephone: +48 71 794 2555, +48 71 794 2441 (available 24h/day) or +48 71 794 2690 (fax) or the closest local Fire Brigade

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition : Polymer

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Not classified.

The product is not classified as hazardous according to Regulation (EC) 1272/2008 as amended.

See Section 16 for the full text of the H statements declared above.

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Hazard pictograms : Not applicable.

Signal word : No signal word.

Hazard statements : Not applicable.

Precautionary statements

Prevention : Wear protective gloves or clothing and eye or face protection:

Response : Not applicable.

Storage : Not applicable.

Disposal : Not applicable.

Supplemental label elements : Not applicable.

2.3 Other hazards

Results of PBT and vPvB assessment :

PBT	P	B	T	vPvB	vP	vB
No	N/A	No	No	No	N/A	No

Other hazards which do not result in classification : The product does not contain components included in the list established in accordance with Article 59(1) for having endocrine disrupting properties, and identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration ≥ 0.1% (w/w).

SECTION 3: Composition/information on ingredients

3.1 Substances : Mono-constituent substance

Product/ingredient name	Identifiers	%	Classification	Specific Conc. Limits, M-factors and ATEs	Type
Sorbitan monolaurate, ethoxylated	REACH #: Polymer CAS: 9005-64-5	>97	Not classified. **See Section 16 for the full text of the H statements declared above.**	-	[1]

There are no additional ingredients present which, within the current knowledge of the supplier, are classified and contribute to the classification of the substance and hence require reporting in this section.

Type

[1] Constituent

Occupational exposure limits, if available, are listed in Section 8.

SECTION 4: First aid measures

4.1 Description of first aid measures

Eye contact : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.

Skin contact : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion : Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training. Put on appropriate personal protective equipment (see Section 8).

4.2 Most important symptoms and effects, both acute and delayed

Over-exposure signs/symptoms

Eye contact	:	No specific data.
Inhalation	:	No specific data.
Skin contact	:	No specific data.
Ingestion	:	No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician	:	Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
Specific treatments	:	No specific treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media	:	Extinguish fire with dispersed water jets, foam and dry powder or carbon dioxide extinguisher.
Unsuitable extinguishing media	:	Avoid heavy hose streams.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture	:	In a fire or if heated, a pressure increase will occur and the container may burst.
Hazardous combustion products	:	Decomposition products may include the following materials: carbon dioxide carbon monoxide (CO)

5.3 Advice for firefighters

Special protective actions for fire-fighters	:	Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
Special protective equipment for fire-fighters	:	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	:	No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.
For emergency responders	:	If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

6.2 Environmental precautions	:	Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Methods and materials for containment and cleaning up

Small spill	:	Stop leak if without risk. Move containers from spill area. Absorb with an inert material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Large spill	:	Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via a licensed waste disposal contractor. Do not absorb in sawdust or other combustible material.
6.4 Reference to other sections	:	See Section 1 for emergency contact information. See Section 8 for information on appropriate personal protective equipment. See Section 13 for additional waste treatment information. See Section 15 for additional Regulatory information.

SECTION 7: Handling and storage

The information in this section contains generic advice and guidance.

7.1 Precautions for safe handling

Protective measures	:	Put on appropriate personal protective equipment (see Section 8).
Advice on general occupational hygiene	:	Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Shelf life: 12 months from the date of manufacture. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use. The product maintains its quality parameters for 1 year if stored in original, tightly closed containers. It is recommended that the ambient temperature during long-term storage is between 5°C and 25°C, and the extremely acceptable range is between 0°C and 30°C. Storage at higher temperatures is only possible for a short time.
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7.3 Specific end use(s)

Recommendations	:	No additional information.
Industrial sector specific solutions	:	No additional remark.

SECTION 8: Exposure controls/personal protection

The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

8.1 Control parameters

Occupational exposure limits

Not established exposure limit value.

Biological exposure indices

No exposure indices known.

Recommended monitoring procedures	:	Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

Not available.

PNECs

Not available.

8.2 Exposure controls

Appropriate engineering controls : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical product, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Wear suitable gloves tested to EN374. In case of long-term direct exposure, protective gloves made of nitrile or nitrile rubber with a thickness > 0.2 mm, and a penetration time ≥ 30 min. should be used. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

9.1 Information on basic physical and chemical properties

Appearance

Physical state : Liquid.

Color : light yellow to brown

Odor : Characteristic. [Slight]

Odor threshold : Lack of data.

Melting point/freezing point : -10°C approx.

Initial boiling point and boiling range : Lack of data.

Flammability : Lack of data.

Lower and upper explosion limit : Lack of data.

Flash point : Open cup: >250°C (>482°F)

Auto-ignition temperature : Lack of data.

Decomposition temperature : Lack of data.

pH : 6 to 7 [Conc. (% w/w): 1%]

Viscosity : Dynamic (room temperature): 400 mPa·s
Kinematic (room temperature): Lack of data.
Kinematic (40°C): Lack of data.

Solubility(ies) :

Media	Result
cold water	Easily soluble
methanol	Easily soluble

Solubility in water : Lack of data.

Partition coefficient: n-octanol/water : Lack of data.

Vapor pressure : Lack of data.

Evaporation rate : Lack of data.

Relative density : Lack of data.

Density : 1,103 g/cm³ [25°C (77°F)]

Vapor density : Lack of data.

Particle characteristics

Median particle size : Not applicable.

9.2 Other information

9.2.1 Information with regard to physical hazard classes

Explosive properties : Product does not contain substances which possess explosive properties.

Oxidizing properties : Lack of data.

9.2.2 Other safety characteristics

Evaporation rate : Lack of data.

SECTION 10: Stability and reactivity

10.1 Reactivity : No specific test data related to reactivity available for this product or its ingredients.

10.2 Chemical stability : Shelf life: 12 months from the date of manufacture.

10.3 Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.

10.4 Conditions to avoid : The product maintains its quality parameters for 1 year if stored in original, tightly closed containers. It is recommended that the ambient temperature during long-term storage is between 5°C and 25°C, and the extremely acceptable range is between 0°C and 30°C. Storage at higher temperatures is only possible for a short time.

10.5 Incompatible materials : No specific data.

10.6 Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

Source toxicological data have not been identified for the product. The information given herein has been developed based on data and ecotoxicology of components and similar substances.

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

Acute toxicity

Product/ingredient name	Result
Sorbitan monolaurate, ethoxylated	**Rat - Oral - LD50** >2000 mg/kg

Conclusion/Summary [Product] : No known significant effects or critical hazards.

Acute toxicity estimates
Not applicable

Skin corrosion/irritation

Conclusion/Summary [Product] : No known significant effects or critical hazards.

Serious eye damage/eye irritation

Conclusion/Summary [Product] : No known significant effects or critical hazards.

Respiratory corrosion/irritation

Conclusion/Summary [Product] : No known significant effects or critical hazards.

Respiratory or skin sensitization

Skin
Conclusion/Summary [Product] : No known significant effects or critical hazards.

Respiratory
Conclusion/Summary [Product] : No known significant effects or critical hazards.

Germ cell mutagenicity

Conclusion/Summary [Product] : No known significant effects or critical hazards.

Carcinogenicity

Conclusion/Summary [Product] : No known significant effects or critical hazards.

Reproductive toxicity

Conclusion/Summary [Product] : No known significant effects or critical hazards.

Specific target organ toxicity (single exposure)
No known significant effects or critical hazards.

Specific target organ toxicity (repeated exposure)
No known significant effects or critical hazards.

Aspiration hazard
No known significant effects or critical hazards.

Information on the likely routes of exposure
Routes of entry not anticipated: Oral, Dermal, Inhalation, Eyes.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.
Inhalation : No specific data.
Skin contact : No specific data.

Ingestion : No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects : No specific data.

Potential delayed effects : No specific data.

Long term exposure

Potential immediate effects : No specific data.

Potential delayed effects : No specific data.

Potential chronic health effects

Conclusion/Summary [Product] : No known significant effects or critical hazards.

General : No known significant effects or critical hazards.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Reproductive toxicity : No known significant effects or critical hazards.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

Conclusion/Summary [Product] : The product does not contain components included in the list established in accordance with Article 59(1) for having endocrine disrupting properties, and identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration ≥ 0.1% (w/w).

11.2.2 Other information

No additional information.

SECTION 12: Ecological information

12.1 Toxicity

Conclusion/Summary [Product] : No known significant effects or critical hazards.

12.2 Persistence and degradability

Product/ingredient name	Result
Sorbitan monolaurate, ethoxylated	>60% [28 days] - Readily

Conclusion/Summary [Product] : Biodegradation data source has not been precisely determined for this product. The information provided is compiled based on the data of similar substances. DID list

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
Sorbitan monolaurate, ethoxylated	-	-	Readily

12.3 Bioaccumulative potential

Product/ingredient name	$LogP_{ow}$	BCF	Potential
Sorbitan monolaurate, ethoxylated	<1	<500	Low

12.4 Mobility in soil

Soil/Water partition coefficient

Product/ingredient name	logKoc	Koc
Sorbitan monolaurate, ethoxylated	-1,7	0,02

Results of PMT and vPvM assessment

Product/ingredient name	PMT	P	M	T	vPvM	vP	vM
Sorbitan monolaurate, ethoxylated	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Mobility : Not tested
This product may move with surface or groundwater flows because its water solubility is: Soluble in water in any proportion.

Conclusion/Summary : The product does not meet the criteria to be considered as a PMT or vPvM.

12.5 Results of PBT and vPvB assessment

Regulation (EC) No. 1907/2006 [REACH]

According to the results of its assessment, this substance is not a PBT or a vPvB.

Regulation (EC) No. 1272/2008 [CLP]

Product/ingredient name	PBT	P	B	T	vPvB	vP	vB
Sorbitan monolaurate, ethoxylated	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Conclusion/Summary Regulation (EC) No. 1272/2008 [CLP] : The product does not meet the criteria to be considered as a PBT or vPvB.

12.6 Endocrine disrupting properties

Conclusion/Summary [Product] : The product does not contain components included in the list established in accordance with Article 59(1) for having endocrine disrupting properties, and identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration ≥ 0.1% (w/w).

12.7 Other adverse effects

No known significant effects or critical hazards.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Methods of disposal : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional or local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor.

Hazardous waste : Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC.

European waste catalogue (EWC)

Waste code	Waste designation
16 03 06	organic wastes other than those mentioned in 16 03 05

Packaging

Methods of disposal : The generation of waste should be avoided or minimized wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Type of packaging	European waste catalogue (EWC)	
Barrel	15 01 02	plastic packaging
Tank	15 01 02	plastic packaging
Container	15 01 02	plastic packaging

Special precautions : This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number or ID number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
14.2 UN proper shipping name	-	-	-	-
14.3 Transport hazard class(es)	-	-	-	-
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.

14.6 Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

14.7 Maritime transport in bulk according to IMO instruments : Not regulated.

SECTION 15: Regulatory information

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

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorization

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

No listed substance

Other EU regulations

DIRECTIVE 2008/68/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 September 2008 on the inland transport of dangerous goods (ADR, ADN, RID)
IATA /International Air Transport Association/ Dangerous Goods Regulations (ICAO/IATA DGR)
International Maritime Dangerous Goods Code (IMDG CODE)

REGULATION (EC) No 648/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 on detergents
REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products

Explosives precursors (1148/2019/EU) : Not applicable.

Ozone depleting substances (EU 2024/590)

Not listed.

Prior Informed Consent (PIC) (EU 2012/649)

Not listed.

Persistent Organic Pollutants (EU 2019/1021)

Not listed.

Seveso Directive

This product is not controlled under the Seveso Directive.

National regulations

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

15.2 Chemical Safety Assessment : Not applicable.

SECTION 16: Other information

Changes to the Safety Data Sheet : Not applicable.

Abbreviations and acronyms : ADN = European Provisions concerning the International Carriage of Dangerous Goods by Inland Waterway
ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road
AOX = Adsorbable Organically Bound Halogens
ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
CAS = Chemical Abstracts Service
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
CMR = Carcinogen, Mutagen or Reproductive toxicant
CSA = Chemical Safety Assessment
DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level
EC number = EINECS or ELINCS number
EC50 = Half maximal effective concentration
ES = Exposure Scenario
EUH statement = CLP-specific Hazard statement
EWC = European Waste Catalogue
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
H statement = CLP/GHS Hazard statement
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IC50 = Half maximal inhibitory concentration
IMDG = International Maritime Dangerous Goods
LC50 = Median lethal concentration
LD50 = Median lethal dose
LogPow = logarithm of the octanol/water partition coefficient
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
N/A = Not available
OECD = Organisation for Economic Co-operation and Development
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
R phrase = DSD/DPD Risk phrase
REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation [Regulation (EC) No. 1907/2006]
RID = The Regulations concerning the International Carriage of Dangerous Goods by Rail
RRN = REACH Registration Number
STOT = Specific Target Organ Toxicity
SVHC = Substances of Very High Concern
UN = United Nations
VOC = Volatile Organic Compound
vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP]

Classification	Justification
Not classified.	Expert judgment

Full text of abbreviated H statements

Not applicable.

Full text of classifications [CLP]

Not applicable.

Training advice : Ensure operatives are trained to minimise exposures.

Notice to reader

The information contained herein is accurate to the latest knowledge and describes the product from the point of view of help and environmental protection as well as safe handling. The information presented in this SDS refers to the technical product only and will not apply to any processed product. Final determination of the suitability of any materials for the chosen application(s) is the sole responsibility of the user"