

# Regalis®



A water dispersible granule formulation containing 10% w/w prohexadione-calcium.

A growth regulator for the control of shoot growth in apples.

### Risk and Safety Information

To avoid risks to human health and the environment, comply with the instructions for use.

**1** kg

MAPP No. 12414  
PCS No. 03321

Supplied in UK by:  
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 **BASF**  
The Chemical Company

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## SAFETY PRECAUTIONS

### Operator protection

WHEN USING DO NOT EAT, DRINK OR SMOKE.

### Storage and disposal

KEEP OUT OF REACH OF CHILDREN.  
KEEP AWAY FROM FOOD, DRINK AND ANIMAL FEEDINGSTUFFS.  
THIS MATERIAL AND ITS CONTAINER must be disposed of in a safe way.  
KEEP IN ORIGINAL CONTAINER, tightly closed in a safe place.  
RINSE CONTAINER THOROUGHLY by using an integrated pressure rinsing device or manually rinsing three times. Add washings to sprayer at time of filling and dispose of safely.

The (COSHH) Control of Substances Hazardous to Health Regulations may apply to the use of this product at work – UK only.

This label is compliant with the CPA Voluntary Initiative Guidance – UK only.



This product is approved under the Plant Protection Product Regulations – UK only.  
This product is approved under SI No 159 of 2012 ( Ireland only)'

### IMPORTANT INFORMATION

FOR USE ONLY AS A HORTICULTURAL PLANT GROWTH REGULATOR, as directed below:

Crops	Maximum Individual Dose	Maximum Total Dose	Latest Time of Application
Apples	1.25 kg/ha	2.5 kg/ha	55 days before harvest

**READ THE LABEL BEFORE USE. USING THIS PRODUCT IN A MANNER THAT IS INCONSISTENT WITH THE LABEL MAY BE AN OFFENCE. FOLLOW THE CODE OF PRACTICE FOR USING PLANT PROTECTION PRODUCTS.**

## **DIRECTIONS FOR USE**

**IMPORTANT:** This information is approved as part of the Product Label. All instructions within this section must be read carefully in order to obtain safe and successful use of this product.

Regalis is a growth regulator for the control of shoot growth in apples.

### **1. Restrictions/Warnings**

For professional use only.

Do not apply Regalis together with calcium based foliar fertilizers.  
Avoid spray drift onto neighbouring crops and other non-target plants.

### **2. Crops**

#### **2.1 Apples**

##### Time and Rate of Application

For a standard orchard, apply one application of Regalis at 1.25 kg/ha at the start of active shoot growth (BBCH 31 stage), when there are 3 to 5 fully expanded leaves per shoot (this growth stage usually coincides with the end of flowering). Apply a second application of 1.25 kg/ha after an interval of 3 to 5 weeks, depending on growth conditions.

Alternatively, apply the first application of 1.25 kg/ha from the start of active shoot growth (3–5 leaves per shoot) and follow this with four reduced rate applications of 0.31 kg/ha at 2 week intervals, ensuring that the minimum pre-harvest interval of 55 days is adhered to.

##### Water volume

Apply in 300 to 1000 litres of water per hectare, depending on tree size and canopy development, using a sufficient water volume to ensure good coverage.

### **3. Integrated pest management**

When used according to the instructions, this product is not harmful to *Typhlodromus pyri*, *Aphidius rhopalosiphi*, *Aleochara bilineata*, *Pardosa spp.*, *Poecilus cupreus*, *Chrysopa carnea* and *Anthocoris nemoralis*.

### **4. Mixing and spraying**

Half fill the spray tank with clean water and start the agitation. Pour in the required amount of product. Rinse any empty containers thoroughly and add rinsings to the spray tank. Add the remainder of the water and continue agitation until spraying is completed.

Apply as a FINE to MEDIUM spray (BCPC definition).

### **5. Compatibility**

UK only:- Regalis can be used in tank-mix with Kumulus DF. Ensure all label conditions are followed, including restrictions on 'sulphur shy' varieties (e.g, cox).

Ireland:- Information on compatibilities may be available. Contact your supplier or BASF Ireland Ltd. (Tel 01 825 5701) for up to date information.

**The following does not form part of the product label under the Plant Protection Products Regulations (UK only) or S.I. No. 159 of 2012 (IE only).**

With many products there is a general risk of resistance developing to the active ingredients. For this reason a change in activity cannot be ruled out. It is generally impossible to predict with certainty how resistance may develop because there are so many crop and use connected ways of influencing this. We therefore have to exclude liability for damage or loss attributable to any such resistance that may develop. To help minimise any loss in activity the BASF recommended rate should in all events be adhered to.

Numerous, particularly regional or regionally attributable, factors can influence the activity of the product. Examples include weather and soil conditions, crop plant varieties, crop rotation, treatment times, application amounts, admixture with other products, appearance of organisms resistant to active ingredients and spraying techniques. Under particular conditions a change in activity or damage to plants cannot be ruled out. The manufacturer or supplier is therefore unable to accept any liability in such circumstances. All goods supplied by us are of high grade and we believe them to be suitable, but as we cannot exercise control over their mixing or use or the weather conditions during and after application, which may affect the performance of the material, all conditions and warranties, statutory or otherwise, as to the quality or fitness for any purpose of our goods are excluded and no responsibility will be accepted by us for any damage or injury whatsoever arising from their storage, handling, application or use; but nothing should be deemed to exclude or restrict any liability upon us which cannot be excluded or restricted under the provisions of the Unfair Contract Terms Act 1977 or any similar applicable law.

**Section 6 of the Health and Safety at Work Act  
Additional Product Safety Information**

The product label provides information on a specific pesticidal use of the product; do not use otherwise, unless you have assessed any potential hazard involved, the safety measures required and that the particular use has "off-label" approval or is otherwise permitted under the Plant Protection Product Regulations.

The information on this label is based on the best available information including data from test results.

## **Safety Data Sheet**

### **1. Identification of the substance/mixture and of the company/undertaking**

**Product identifier**

**REGALIS**

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

Relevant identified uses: crop protection product, growth regulator

**Details of the supplier of the safety data sheet**

Company:

BASF SE  
67056 Ludwigshafen  
GERMANY

Contact address:

BASF plc  
PO Box 4, Earl Road, Cheadle Hulme, Cheadle, Cheshire  
SK8 6QG, UNITED KINGDOM

Telephone: +44 161 485-6222

E-mail address: product-safety-north@basf.com

**Emergency telephone number**

International emergency number: Telephone: +49 180 2273-112

## 2. Hazards Identification

### Label elements

Globally Harmonized System, EU (GHS)

Hazard Statement:

EUH401

To avoid risks to human health and the environment, comply with the instructions for use.

The product does not require a hazard warning label in accordance with GHS criteria.

According to Directive 67/548/EEC or 1999/45/EC  
Classification/labelling in accordance with UK regulations.

R-phrase(s)

R52/53

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

S-phrase(s)

S2

Keep out of the reach of children.

S13

Keep away from food, drink and animal feeding stuffs.

S20/21

When using do not eat, drink or smoke.

S35

This material and its container must be disposed of in a safe way.

S57

Use appropriate container to avoid environmental contamination.

### Classification of the substance or mixture

According to Regulation (EC) No 1272/2008 [CLP]

No need for classification according to GHS criteria for this product.

According to Directive 67/548/EEC or 1999/45/EC

Possible Hazards:

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

### Other hazards

According to Regulation (EC) No 1272/2008 [CLP]

See section 12 – Results of PBT and vPvB assessment.

If applicable information is provided in this section on other hazards which do not result in classification but which may contribute to the overall hazards of the substance or mixture.

### 3. Composition/Information on Ingredients

#### Mixtures

##### Chemical nature

crop protection product, growth regulator, water dispersible granules

Contains: Prohexadione-Calcium (Content (W/W): 10%)

##### Hazardous ingredients (GHS)

according to Regulation (EC) No. 1272/2008

##### Ammonium sulphate

Content (W/W): < 60 %  
CAS Number: 7783-20-2  
EC-Number: 231-984-1  
REACH registration number: 01-2119455044-46

##### Silicic acid, calcium salt

Content (W/W): < 10 %  
CAS Number: 1344-95-2  
EC-Number: 215-710-8

##### Sucrose

Content (W/W): < 5 %  
CAS Number: 57-50-1  
EC-Number: 200-334-9

##### Kaolinite

Content (W/W): < 5 %  
CAS Number: 1318-74-7  
EC-Number: 215-286-4

##### Hazardous ingredients

according to Directive 1999/45/EC

##### Ammonium sulphate

Content (W/W): < 60 %  
CAS Number: 7783-20-2  
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Kaolinite  
Content (W/W): < 5 %  
CAS Number: 1318-74-7  
EC-Number: 215-286-4

#### 4. First-Aid Measures

##### **Description of first aid measures**

Show container, label and/or safety data sheet to physician.

If inhaled: Keep patient calm, remove to fresh air.

On skin contact: Wash thoroughly with soap and water.

On contact with eyes: Wash affected eyes for at least 15 minutes under running water with eyelids held open.

On ingestion: Rinse mouth and then drink plenty of water. Do not induce vomiting unless told to by a poison control center or doctor. Never induce vomiting or give anything by mouth if the victim is unconscious or having convulsions.

Rinse mouth and then drink plenty of water.

##### **Most important symptoms and effects, both acute and delayed**

Symptoms: No significant reaction of the human body to the product known.

##### **Indication of any immediate medical attention and special treatment needed**

Treatment: Symptomatic treatment (decontamination, vital functions).

## 5. Fire-Fighting Measures

### Extinguishing media

Suitable extinguishing media: dry powder, foam, water spray  
Unsuitable extinguishing media for safety reasons: carbon dioxide

### Special hazards arising from the substance or mixture

carbon monoxide, Carbon dioxide, nitrogen oxides

The substances/groups of substances mentioned can be released in case of fire.

### Advice for fire-fighters

Special protective equipment:

Wear self-contained breathing apparatus and chemical-protective clothing.

Further information: Collect contaminated extinguishing water separately, do not allow to reach sewage or effluent systems. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations. In case of fire and/or explosion do not breathe fumes. Keep containers cool by spraying with water if exposed to fire.

## 6. Accidental Release Measures

### Personal precautions, protective equipment and emergency procedures

Use personal protective clothing. Avoid contact with the skin, eyes and clothing. Avoid dust formation.

### Environmental precautions

UK

Do not allow contamination of public drains or surface or ground waters. Inform local water plc if spillage enters drains and the Environment Agency (England & Wales), the Scottish Environmental Protection Agency (Scotland), or the Environment and Heritage Service (Northern Ireland) if it enters surface or ground waters. Keep people and animals away.

Ireland

Do not discharge into the subsoil/soil. Do not allow contamination of public drains or surface or ground waters. Inform local water plc if spillage enters drains and the Environmental Protection Agency if it enters surface or ground waters. Keep people and animals away.

### Methods and material for containment and cleaning up

For small amounts: Sweep/shovel up. For large amounts: Sweep/shovel up.

Avoid raising dust. Collect waste in suitable containers, which can be labeled and sealed. Clean

contaminated floors and objects thoroughly with water and detergents, observing environmental regulations. Dispose of absorbed material in accordance with regulations.

#### **Reference to other sections**

Information regarding exposure controls/personal protection and disposal considerations can be found in section 8 and 13.

### **7. Handling and Storage**

#### **Precautions for safe handling**

No special measures necessary if stored and handled correctly. Ensure thorough ventilation of stores and work areas. When using do not eat, drink or smoke. Hands and/or face should be washed before breaks and at the end of the shift.

Protection against fire and explosion:

Avoid dust formation. Dust can form an explosive mixture with air. Prevent electrostatic charge – sources of ignition should be kept well clear - fire extinguishers should be kept handy.

#### **Conditions for safe storage, including any incompatibilities**

Segregate from foods and animal feeds.

Further information on storage conditions: Keep away from heat. Protect against moisture. Protect from direct sunlight.

Protect from temperatures above: 40 °C

Changes in the properties of the product may occur if substance/product is stored above indicated temperature for extended periods of time.

#### **Specific end use(s)**

For the relevant identified use(s) listed in Section 1 the advice mentioned in this section 7 is to be observed.

### **8. Exposure Controls/Personal Protection**

#### **Control parameters**

##### Components with workplace control parameters

1344-95-2: Silicic acid, calcium salt

TWA value 10 mg/m<sup>3</sup> (EH40 (UK)), Inhalable dust

TWA value 4 mg/m<sup>3</sup> (EH40 (UK)), Respirable dust

57-50-1: Sucrose

TWA value 10 mg/m<sup>3</sup> (EH40 (UK))

STEL value 20 mg/m<sup>3</sup> (EH40 (UK))

#### UK

Refer to the current edition of HSE Guidance Note EH40 Occupational Exposure Limits (United Kingdom). For normal use and handling refer to the product label/leaflet. In all other cases the following apply.

#### Ireland

Refer to the current schedule of occupational exposure standards published by the Irish HSA. For normal use and handling refer to the product label/leaflet. In all other cases the following apply.

### **Exposure controls**

#### Personal protective equipment

Respiratory protection: Respiratory protection not required.

Hand protection: Suitable chemical resistant safety gloves (EN 374) also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): E.g. nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), butyl rubber (0.7 mm) and other

Eye protection: Safety glasses with side-shields (frame goggles) (e.g. EN 166)

Body protection: Body protection must be chosen depending on activity and possible exposure, e.g. apron, protecting boots, chemical-protection suit (according to EN 14605 in case of splashes or EN ISO 13982 in case of dust).

#### General safety and hygiene measures

The statements on personal protective equipment in the instructions for use apply when handling crop-protection agents in final-consumer packing. Wearing of closed work clothing is recommended. Store work clothing separately. Keep away from food, drink and animal feeding stuffs.

## 9. Physical and Chemical Properties

### Information on basic physical and chemical properties

Form:	granules
Colour:	pale beige
Odour:	faint odour, smoky
Odour threshold:	not determined
pH value:	approx. 6 – 8 (1 g/l, 20 °C) (as suspension)
Melting point:	not applicable
Boiling point:	The product has not been tested.
Flash point:	not applicable
Evaporation rate:	not applicable
Flammability:	not highly flammable (Directive 92/69/EEC, A.10)
Lower explosion limit:	not determined
Upper explosion limit:	not determined
Vapour pressure:	The product has not been tested.
Density:	approx. 1.67 g/cm <sup>3</sup> (20 °C) (OECD Guideline 109)
Relative vapour density (air):	not determined
Solubility in water:	dispersible
Partitioning coefficient n-octanol/water (log Kow):	not applicable
Self ignition:	Test type: Self-ignition at high temperatures. (Method: Directive 92/69/EEC, A.16)
Temperature:	371 °C
Thermal decomposition:	not determined
Viscosity, dynamic:	not applicable
Explosion hazard:	Product is not explosive, however a dust explosion could result from an air / dust mixture.
Fire promoting properties:	not fire-propagating (Directive 84/449/EEC, A.17)

### Other information

Bulk density: approx. 754 – 819 kg/m<sup>3</sup> (20 °C)

Other Information:

If necessary, information on other physical and chemical parameters is indicated in this section.

## 10. Stability and Reactivity

### Reactivity

No hazardous reactions if stored and handled as prescribed/indicated.

### Chemical stability

The product is stable if stored and handled as prescribed/indicated.

### Possibility of hazardous reactions

No hazardous reactions if stored and handled as prescribed/indicated.

### Conditions to avoid

See MSDS section 7 – Handling and storage.

### Incompatible materials

Substances to avoid: strong bases, strong acids, strong oxidizing agents

### Hazardous decomposition products

Hazardous decomposition products: No hazardous decomposition products if stored and handled as prescribed/indicated.

## 11. Toxicological Information

### Information on toxicological effects

#### Acute toxicity

Assessment of acute toxicity: Virtually nontoxic after a single skin contact. Virtually nontoxic by inhalation. Virtually nontoxic after a single ingestion.

Experimental/calculated data:

LD<sub>50</sub> rat (oral): > 2,000 mg/kg (OECD Guideline 423)

LC<sub>50</sub> rat (by inhalation): > 5.2 mg/l 4 h (OECD Guideline 403)

An aerosol was tested.

LD<sub>50</sub> rat (dermal): > 2,000 mg/kg (OECD Guideline 402)

#### Irritation

Assessment of irritating effects: Not irritating to the skin. Not irritating to the eyes.

Experimental/calculated data:

Skin corrosion/irritation rabbit: non-irritant (OECD Guideline 404)

Serious eye damage/irritation rabbit: non-irritant (OECD Guideline 405)

Respiratory/Skin sensitization

Assessment of sensitization: There is no evidence of a skin-sensitizing potential.

Experimental/calculated data: modified Buehler test guinea pig: Skin sensitizing effects were not observed in animal studies. (OECD Guideline 406)

Germ cell mutagenicity

Assessment of mutagenicity: Mutagenicity tests revealed no genotoxic potential. The product has not been tested. The statement has been derived from the properties of the individual components.

Carcinogenicity

Assessment of carcinogenicity: The product has not been tested. The statement has been derived from the properties of the individual components. The results of various animal studies gave no indication of a carcinogenic effect.

Reproductive toxicity

Assessment of reproduction toxicity: The results of animal studies gave no indication of a fertility impairing effect. The product has not been tested. The statement has been derived from the properties of the individual components.

Developmental toxicity

Assessment of teratogenicity: The product has not been tested. The statement has been derived from the properties of the individual components. Animal studies gave no indication of a developmental toxic effect at doses that were not toxic to the parental animals.

Repeated dose toxicity and Specific target organ toxicity (repeated exposure)

Assessment of repeated dose toxicity: The product has not been tested. The statement has been derived from the properties of the individual components. No substance-specific organotoxicity was observed after repeated administration to animals.

Other relevant toxicity information

Misuse can be harmful to health.

## 12. Ecological Information

### Toxicity

Assessment of aquatic toxicity: Acutely harmful for aquatic organisms.

Toxicity to fish:

LC<sub>50</sub> (96 h) 119.5 mg/l, *Oncorhynchus mykiss* (OECD 203; ISO 7346; 92/69/EEC, C.1, static)

Aquatic invertebrates:

EC<sub>50</sub> (48 h) > 100 mg/l, *Daphnia magna* (OECD Guideline 202, part 1, static)

Aquatic plants:

EC<sub>50</sub> (72 h) > 100 mg/l (growth rate), *Pseudokirchneriella subcapitata* (OECD Guideline 201, static)

EC<sub>50</sub> (7 d) 37.3 mg/l, *Lemna gibba* (OECD guideline 221)

*Information on: Prohexadione-Ca*

*Microorganisms/Effect on activated sludge:*

EC50 (0.5 h) > 10,000 mg/l, *Pseudomonas putida*

### Persistence and degradability

Assessment biodegradation and elimination (H<sub>2</sub>O):

The product has not been tested. The statement has been derived from the properties of the individual components.

*Information on: Prohexadione-Ca*

*Assessment biodegradation and elimination (H<sub>2</sub>O):*

Not readily biodegradable (by OECD criteria).

*Information on: Ammonium sulphate*

*Assessment biodegradation and elimination (H<sub>2</sub>O):*

*Inorganic product which cannot be eliminated from water by biological purification processes. Can be oxidized to nitrate, or be reduced to nitrogen, by microorganisms.*

### Bioaccumulative potential

Assessment bioaccumulation potential:

The product has not been tested. The statement has been derived from the properties of the individual components.



*Information on: Ammonium sulphate*  
*Assessment bioaccumulation potential:*  
*Accumulation in organisms is not to be expected.*

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**Mobility in soil (and other compartments if available)**

Assessment transport between environmental compartments:  
The product has not been tested. The statement has been derived from the properties of the individual components.

*Information on: prohexadione calcium*  
*Assessment transport between environmental compartments:*  
*Following exposure to soil, the product trickles away and can – dependant on degradation - be transported to deeper soil areas with larger water loads.*

*Information on: Ammonium sulphate*  
*Assessment transport between environmental compartments:*  
*Adsorption to solid soil phase is not expected.*

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**Results of PBT and vPvB assessment**

The product does not contain a substance fulfilling the PBT (persistent/bioaccumulative/toxic) criteria or the vPvB (very persistent/very bioaccumulative) criteria.

**Other adverse effects**

The product does not contain substances that are listed in Annex I of Regulation (EC) 2037/2000 on substances that deplete the ozone layer.

**Additional information**

Other ecotoxicological advice:  
Do not discharge product into the environment without control.

**13. Disposal Considerations**

**Waste treatment methods**

Must be sent to a suitable incineration plant, observing local regulations.

UK only

The UK Environmental Protection (Duty of Care) Regulations (EP) and amendments should be noted (United Kingdom).

This product and any uncleaned containers must be disposed of as hazardous waste in accordance with the 2005 Hazardous Waste Regulations and amendments (United Kingdom)

Contaminated packaging:

Contaminated packaging should be emptied as far as possible and disposed of in the same manner as the substance/product.

**14. Transport Information**

**Land transport**

ADR

Not classified as a dangerous good under transport regulations

UN number:

Not applicable

UN proper shipping name:

Not applicable

Transport hazard class(es):

Not applicable

Packing group:

Not applicable

Environmental hazards:

Not applicable

Special precautions for user

None known

RID

Not classified as a dangerous good under transport regulations

UN number:

Not applicable

UN proper shipping name:

Not applicable

Transport hazard class(es):

Not applicable

Packing group:

Not applicable

Environmental hazards:

Not applicable

Special precautions for user

None known

**Inland waterway transport**

ADN

Not classified as a dangerous good under transport regulations

UN number:

Not applicable

UN proper shipping name:

Not applicable

Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user	None known
Transport in inland waterway vessel:	Not evaluated

**Sea transport**

IMDG	Not classified as a dangerous good under transport regulations
UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user	None known

**Air transport**

IATA/ICAO	Not classified as a dangerous good under transport regulations
UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user	None known

**Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Regulation:	Not evaluated
Shipment approved:	Not evaluated
Pollution name:	Not evaluated
Pollution category:	Not evaluated
Ship Type:	Not evaluated

## 15. Regulatory Information

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

To avoid risks to man and the environment, comply with the instructions for use.

#### UK

The data should be considered when making any assessment under the Control of Substances Hazardous to Health Regulations (COSHH), and related guidance, for example, 'COSHH Essentials' (United Kingdom).

This product is classified under the Chemicals (Hazard Information and Packaging) Regulations, (CHIP) (United Kingdom).

#### Ireland

This product may be subject to the Seveso II Directive and amendments if specific threshold tonnages are exceeded.

For further medical advice Doctors should contact the National Poison Information Centre at Beaumont Hospital, Dublin.

### **Chemical Safety Assessment**

Advice on product handling can be found in sections 7 and 8 of this safety data sheet.

## 16. Other Information

For proper and safe use of this product, please refer to the approval conditions laid down on the product label.

If you have any queries relating to this MSDS, its contents or any other product safety related questions, please write to the following e-mail address: [product-safety-north@basf.com](mailto:product-safety-north@basf.com)

The data contained in this safety data sheet are based on our current knowledge and experience and describe the product only with regard to safety requirements. The data do not describe the product's properties (product specification). Neither should any agreed property nor the suitability of the product for any specific purpose be deduced from the data contained in the safety data sheet. It is the responsibility of the recipient of the product to ensure any proprietary rights and existing laws and legislation are observed.

(Version: 3.0)